Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

LACTIC ACID BASED PRODUCTS

Product types 2 and 4

L-(+)-lactic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-YK050899-03

Evaluating Competent Authority: FR

Date: [07/02/2022]
Revised: 17/04/2024

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Note to the reader

This PAR has been updated with the post-authorisation data provided by the applicant and is based on the PAR of the first authorisation.

In this consolidated PAR, the assessments related to the post-authorisation data of the product family are at the end of the concerned section and are highlighted in grey.

The SPC (in the section 2.1 of the PAR) corresponds to the currently authorised uses in France.

History of the dossier

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	*FR*	*BC-YK050899-03*	09/02/2022	Initial assessment of the reference product
N.A	*FR*	*N.A*	17/04/2024	Post-authorisation data assessment

1 CONCLUSION

The biocidal products of LACTIC ACID BASED PRODUCTS family, based on 2.4 to 24 % of L-(+)-lactic acid, are product types 2, 3 and 4 intended for disinfection. The products of this biocidal family are in the form of a liquid intended to be used without dilution, a soluble concentrate or a microemulsion, to be applied for the disinfection of hard surfaces by industrials, professional and non-professional users.
The family is composed by 12 Meta-SPC (n° 1 to 13, without n°5).

The application methods claimed were revised by the applicant during the evaluation of the dossier. These updated claims correspond to deletion of some application methods in various meta SPCs. These modification are included and materialized as strikethrough text in the Intented uses part (see 2.2.1).

These changes were considered in the efficacy section but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions which consider only the updated claims.

Conclusion of the physico-chemical and technical properties

The physico-chemical properties of the biocidal product family LACTIC ACID BASED PRODUCTS have been described and considered acceptable in the conditions of use detailed in the SPC.

For all products within the family, the stability data indicate a shelf life of at least 2 years (extrapolated) at ambient temperature when stored in commercial packaging material. Long-term storage stability studies (24 months) are on-going and results after 2 years storage are required in post-authorisation for all tested products.

For Meta SPC 6, 7 and 8, products should be used within 30 minutes after dilution.

Products of Meta SPC 1, 2, 3, 4, 6, 7, 9 and 11 are classified as Corrosive to Metals (H290). However, products of Meta SPC 8, 10, 12 and 13 are not classified with regard to physical and chemical properties.
For self-reactive properties, DSC tests of representative products of all Meta SPCs should be provided in post-authorisation within 6 months to confirm the non-classification in this hazard class.

The analytical methods provided are fully validated for the determination of the active substance, lactic acid.

➢ **Post-authorisation data : 2022**

- Meta SPC 1, 2, 3, 4, 6, 7, 8 and 10 are demonstrated stable for 2 years.
- Meta SPC 11: the storage stability study is not acceptable.The applicant decided to discontinue this meta SPC. Meta SPC 11 is thus removed from BPF.
- Meta SPC 9: no shelf life study was submitted but as it is not authorized, no more data is required.
- Meta SPC 12: no shelf life study was provided, but a read across to Meta SPC 8 is proposed. This read across is acceptable.
- Meta SPC 13: no shelf life study was provided, but a read across to Meta SPC 10 is proposed. This read across is acceptable.

- For self-reactive properties, DSC tests of representative products of all Meta SPCs were provided and a waiver based on an analysis of the composition is proposed. The Meta SPC 1, 2, 3, 4, 6, 7, 8, 13 are not classified.
  For Meta SPC 10, the DSC test is not acceptable. As Meta SPC 10 is not authorised, the point was not assessed further.

Efficacy

LACTIC ACID BASED PRODUCTS family with 12 META SPC has shown a sufficient efficacy, in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for the following uses:

Meta-SPC 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces, with mechanical or non mechanical action – PT2:

- Bacteria (including *Bartonella henselae)*: 100 % v/v, 5 minutes, 20°C.

Meta-SPC 2:
Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces, with mechanical or non mechanical action – PT2:

- Bacteria: 100 % v/v, 5 minutes, 20°C.

Use 2: Disinfectants for hard surfaces including food contact surfaces of domestic area, with dirty conditions for non porous surfaces – PT 2 and 4.
With mechanical action:

- Bacteria and yeasts: 100 % v/v, 5 minutes, 20°C.

With non mechanical action:

- Bacteria and yeasts: 100 % v/v, 15 minutes, 20°C.

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT 2 and 4.
With mechanical action:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes*,) and yeasts: 100 %, 5 minutes, 20°C.

With non mechanical action:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes*,) and yeasts: 100 %, 15 minutes, 20°C.

Use 4: Disinfectants for hard surfaces for industry, institution and healthcare facilities areas, with dirty conditions for non porous surfaces – PT2.
With mechanical action:

- Bacteria and yeasts: 100 %, 5 minutes, 20°C.

With non mechanical action:

- Bacteria and yeasts: 100 %, 15 minutes, 20°C.

Meta-SPC 3:
Use 1: Disinfectants for hard surfaces for industry, institution, healthcare facilities, healthcare and food preparation and handling areas, with dirty conditions for non porous surfaces, with mechanical or non mechanical action – PT 2 and 4:

- Bacteria, yeasts: 100%, 5 minutes, 20°C.

Use 2: Disinfectants for hard surfaces for industry, institution, healthcare facilities and health care, with dirty conditions for non porous surfaces, with mechanical or non mechanical action – PT 2:

- Bacteria, yeasts: 100%, 5 minutes, 20°C.

Meta-SPC 4: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas, with dirty conditons for non porous surfaces.
With mechanical action – PT 2 and 4:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes)*, yeasts: 100%, 5 minutes, 20°C.

With non mechanical action:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes)*, yeasts: 100%, 15 minutes, 20°C.

Meta-SPC 6:
Use 1: Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2 and 4
In healthcare, with non mechanical action:

- Bacteria, yeasts: 8% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:

- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 5% v/v, 15 minutes, 20°C et 3% v/v, 30 minutes, 40°C.

All areas, with mechanical action:

- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2 and 4
With non mechanical action:

- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 5% v/v, 15 minutes, 20°C et 3% v/v, 30 minutes, 40°C.

With mechanical action:

- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare, with dirty conditions for non porous surfaces - PT2
In healthcare, with non mechanical action:

- Bacteria, yeasts: 8% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:

- Bacteria, yeasts: 5% v/v, 15 minutes, 20°C

All areas, with mechanical action:

- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C.

Use 4: Disinfectants for hard surfaces of industry, institution and healthcare facilities areas, with dirty conditions for non porous surfaces – PT2
With non mechanical action:

- Bacteria, yeasts: 5% v/v, 15 minutes, 20°C

With mechanical action:

- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Meta-SPC 7:
Use 1: Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, with dirty conditions for non porous surfaces - PT2 and 4:
In healthcare area, with non mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C and 6% v/v, 30 minutes, 40°C.

All areas, with mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces - PT2 and 4
With non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C and 6% v/v, 30 minutes, 40°C.

With mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare, with dirty conditions for non porous surfaces – PT2
In healthcare area, with non mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C.

All areas, with mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 4: Disinfectants for hard surfaces of industry, institution and healthcare facilities, with dirty conditions for non porous surfaces – PT2
With non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C

With mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Meta-SPC 8:
Use 1: Disinfectants for hard surfaces of domestic area with dirty conditions for non porous surfaces - PT2
With mechanical action:
- Bacteria (including additional strains: *Bartonella henselae*): 6% v/v, 5 minutes, 20°C

Meta-SPC 9:
Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces – PT2
With no mechanical action:
- Bacteria (including additional strains: *Bartonella henselae*): 100%, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of domestic area and in companion animals' environment for private homes and pets shelters, with clean conditions, for non porous surfaces –PT2 and 3

With no mechanical action:

- Bacteria and yeasts: 100%, 120 minutes, 20°C

Meta-SPC 10:
Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria (including additional strains *Bartonella henselae*): 6% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of domestic area and in companion animals' environment for private homes and pets shelters, with clean conditions for non porous surfaces – PT2 and 3:
With no mechanical action:

- Bacteria and yeasts: 10% v/v, 120 minutes, 20°C.

Meta-SPC 11:
Use 1: Disinfectants for hard surfaces of industry, institution and healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2 and 4:
With no mechanical action:

- Bacteria (including PT4 additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*) and yeasts: 1.5% v/v, 15 minutes, 20°C or 1% v/v, 30 minutes, 40°C.

Meta-SPC 12:
Use 1: Disinfectants for hard surfaces for industry, institution, healthcare facilities and healthcare with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria and yeasts: 100%, 5 minutes, 20°C.

Meta-SPC 13:
Use 1: Disinfectants for hard surfaces of industry, institution and healthcare facilities, with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria (including additional strain *Yersinia enterocolitica*) and yeasts: 8% v/v, 15 minutes, 20°C.

Conclusion for human health

Industrials/Professionals

The risk is considered acceptable considering systemic and local effects for all meta SPC.

The following PPE and RMM are needed:

*Meta SPC **2** (Uses #3-4) - **3** (Uses #1-2)*

PPE during loading of the trigger spray and application:

- ✓ Face shield
- ✓ Substance/task appropriate gloves
- ✓ Protection coverall

RMM:
- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with freshly treated surfaces (for bystanders).

*Meta SPC **4** (Use #1)*

PPE during loading of the trigger spray and application:
- Goggles

RMM:
- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.

*Meta SPC **6** (Uses #1-2-3-4) - **7** (Uses #1-2-3-4) - **11** (Use #1) -**13** (Use #1)*

During mixing and loading:

PPE:
- Face shield
- Substance/task appropriate gloves
- Protection coverall

RMM:
- Minimisation of splashes and spills
- Minimisation of manual phases

During application and cleaning of spray equipment:

PPE:
- Face shield
- Substance/task appropriate gloves
- Protection coverall

RMM:
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with freshly treated surfaces (for bystanders).

*Meta SPC **12** (Use #1)*

PPE during application:
- Substance/task appropriate gloves
- Protection coverall

Non-professionals

*Meta SPC **1** (Use #1)*

The risk is considered acceptable considering systemic and local effects.

*Meta SPC **2** (Uses #1-2)*

The risk is considered acceptable considering systemic and local effects.

The following RMM are needed:
- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with treated surfaces.
- Wash hands after application.

*Meta SPC **9** (Uses #1-2)*

The risk is considered acceptable considering systemic and local effects.

The following RMM are needed:
- Minimisation of splashes and spills during loading of the trigger spray or knapsack sprayer.
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with treated surfaces.
- Avoid touching the eyes with hands during application.
- Wash hands after application.
- Keep companion's animal away from fresly treated surfaces until dry (only for use #1).

*Meta SPC **8** (Use #1) – **10** (Uses #1-2)*

The risk is acceptable considering systemic effects but unacceptable considering local effects due to the potential dermal/ocular exposure to the concentrate and corrosive product.

General public (secondary exposure)

*Meta SPC **1** (Use #1)*

The risk is acceptable without RMM.

*Meta SPC **2**–**3**-**4**-**6**-**7**-**9**-**11**-**12**-**13**[1] (all uses)*

- The risk is acceptable considering the following RMM: Avoidance of contact with treated surfaces.

Indirect exposure via food

By definition, PT2 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs.
Regarding the intended uses on PT3 and 4, residues in food, feed, milk or drinking water might be expected.
Nevertheless, based on the low concentration of L(+) lactic acid, the endogenous production and the authorized uses of this active substance as food additive (E 270), significant indirect exposure via intended uses is not expected.

[1] Given the inacceptable risk for non-professionals regarding to the meta SPC 8 and 10, the risk for general public is therefore not considered.

Environment

The risk assessment for active substance L(+) Lactic acid, and substances of concern (SoC) for the environment Amines, coco alkyldimethyl, N-oxides (Meta-SPC 11; CAS 61788-90-7), and OTNE (Meta-SPC 9, 10, 13; EC:915-730-3) has been performed for each individual use with the following conclusions:

Acceptables risks are reached for the environment for:

Meta-SPC 1, 2, 3, 4, 6, 7, 8, 10, 11, 12 and 13 for the following uses:

- PT2/4 - Disinfection of **indoor** hard surfaces including food contact surfaces of domestic area
- PT2/4 - Disinfection of **indoor** hard surfaces of industry, institution, healthcare facilities and food and feed area

The levels of exposure for non-target species of aquatic and terrestrial compartments are lower than the reference values for the active substance L(+) Lactic acid and substances of concern Amines, coco alkyldimethyl, N-oxides and OTNE. Moreover, concentrations of L(+) Lactic acid and all the SoC in groundwater related to the use of the products LACTIC ACID BASED PRODUCTS are lower than the threshold value set by Directive 98/83/EC after refinement of the groundwater assessment with the FOCUS PEARL model.

Acceptables risks are reached for the environment for:

Meta-SPC 10 for the following use:

- PT2/3 - Disinfection for indoor and outdoor hard surfaces in companion animals' environment for private home.

The levels of exposure for non-target species of aquatic and terrestrial compartments are lower than the reference values for the active substance L(+) Lactic acid and substance of concern OTNE (the only SoC fo this Meta-SPC) when the following risk mitigation measure is applied:

Do not rinse the treated surfaces when the product is used outdoor.

Moreover, concentrations of L(+) Lactic acid and SoC in groundwater related to this use of the products LACTIC ACID BASED PRODUCTS are lower than the threshold value set by Directive 98/83/EC after refinement of the groundwater assessment with the FOCUS PEARL model.

Unacceptable risks are foreseen for:

Meta-SPC 9 for the following uses:

- PT2 - Disinfection of **indoor** hard surfaces of domestic area

- PT2/3 - Disinfection of **indoor and outdoor** hard surfaces in companion animals' environment for private home.

The levels of exposure for non-target species of aquatic and terrestrial compartments are above the reference values for the active substance L(+) Lactic acid and/or substance of concern OTNE in Scenario 1: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas and 6 : Outdoor - Animal housing direct emission to soil and indirect emission via STP.

All the uses of Meta-SPC 9 lead to unacceptable risks for the environment.

Unacceptable risks are foreseen for:

Meta-SPC 13 for the following uses:

- PT2 - Disinfectants for **outdoor** hard surfaces of industry, institution, healthcare facilities **including roadways (marketplaces, city events...) and waste containers and the floor around.**

The levels of exposure for non-target species of aquatic compartment are above the reference values for the substance of concern OTNE in Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP and in Scenario 5: Outdoor - Disinfection of road ways direct emission to surface water.

The outdoor use of Meta-SPC 13 product's leads to unacceptable risks for the environment.

The use of the products of meta-SPC 13 is restricted to indoor use.

The following risk mitigation measure must be applied:

The product is for an indoor use only

General conclusion

Overall conclusions for the claimed uses:

Meta SPC	**Uses**	**Target organism**	**Application rates**	**Use conditions**	**Acceptable /no acceptable**
Meta SPC 1	1 Disinfectants for hard surfaces of domestic area (PT2)	Bacteria (including additionnal strain *Bartonella henselae*)	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Non-professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe per 0.1m^2 (8 to 12 sprays)	Non-professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
Meta SPC 2	1 Disinfectants for hard surfaces of domestic area (PT2)	Bacteria	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Non-professional Spraying on hard surfaces.	Acceptable

			16 ml on wipe per 0.1m^2 (8 to 12 sprays)	Non-professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
	2 Disinfectants for hard surfaces including food contact surfaces of domestic area (PT2 and 4)	Bacteria (including *Salmonella* Typhimurium and *Listeria monocytogenes*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Non-professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe per 0.1m^2 (8 to 12 sprays)	Non-professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
	3 Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas (PT2 and 4)	Bacteria (including *Salmonella* Typhimurium and *Listeria monocytogenes*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by wiping).	Acceptable
	4 Disinfectants for hard surfaces for industry, institution and healthcare	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Industrial, Professional Spraying on hard surfaces.	Acceptable

	facilities areas (PT2)		16 ml on wipe/mop per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by wiping).	Acceptable
Meta SPC 3	1 Disinfectants for hard surfaces for industry, institution, healthcare facilities, healthcare and, food preparation and handling areas (PT2 and 4) And 2 Disinfectants for hard surfaces for industry, institution, healthcare facilities and healthcare (PT2)	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by wiping).	Acceptable
Meta SPC 4	1 Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling	Bacteria (including *Salmonella* Typhimurium and *Listeria monocytogenes*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable

	areas (PT2 and 4)			Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by wiping).	Acceptable
Meta SPC 6	1 Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas (PT2 and 4)	Bacteria (including *Salmonella* Typhimurium and *Listeria monocytogenes*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	Acceptable
				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable
	2 Disinfectants for hard surfaces of	Bacteria (including *Salmonella* Typhimurium	30 ml/m^2 (20 sprays on the surface per m^2)	Industrial, Professional Spraying on hard surfaces.	Acceptable

	industry, institution, healthcare facilities and food preparation and handling areas (PT2 and 4)	and *Listeria monocytogenes*) Yeasts	16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	Acceptable
				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable
	3 Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare (PT2)	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	Acceptable

				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable
	4 Disinfectants for hard surfaces of industry, institution and healthcare facilities areas (PT2)	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	Acceptable
				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable

Meta SPC 7	1 Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas (PT2 and 4) And 3 Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare (PT2)	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	Acceptable
				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable
	2 Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas (PT2 and 4) And 4	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Industrial, Professional Spraying on hard surfaces.	Acceptable
			16 ml on wipe/mop/brush/by machine per 0.1m^2 (8 to 12 sprays)	Industrial, Professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Acceptable
				Industrial, Professional Application by mopping on hard surfaces (applying product onto	Acceptable

	Disinfectants for hard surfaces of industry, institution and healthcare facilities areas (PT2)			mop followed by mopping).	
				Industrial, Professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	Acceptable
				Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable
Meta SPC 8	1 Disinfectants for hard surfaces of domestic area (PT2)	Bacteria (including additional strain *Bartonella henselae*)	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Non-professional Application by wiping on hard surfaces (applying product onto wipe followed by wiping).	Non acceptable for human health
				Non-professional Application by mopping on hard surfaces (applying product onto mop followed by mopping).	
				Non-professional Application by brushing on hard surfaces (applying product onto brush followed by brushing).	
Meta SPC 9	1 Disinfectants for hard surfaces of domestic area (PT2)	Bacteria (including additional strain *Bartonella henselae*)	30 ml/m^2 (20 sprays on the surface per m^2) For toilet bowls, 50 ml or 33 sprays per toilet	Non-professional Spraying on hard surfaces.	Non acceptable for environment
				Non-professional Application by pouring on hard surfaces.	
	2 Disinfectants for hard surfaces of	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Non-professional Spraying on hard surfaces.	

	domestic area and in companion animals' environment for private homes, … and pets shelters (PT2/3)			Non-professional Application by pouring on hard surfaces.	
Meta SPC 10	1 Disinfectants for hard surfaces of domestic area (PT2)	Bacteria (including additional strain *Bartonella henselae*)	30 ml/m^2 (20 sprays on the surface per m^2)	Non-professional Spraying on hard surfaces.	Non acceptable For human health
				Non-professional Application by brushing on hard surfaces.	
				Non-professional Application by pouring on hard surfaces.	
	2 Disinfectants for hard surfaces of domestic area and in companion animals' environment for private homes and pets shelters (PT2/3)	Bacteria Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Non-professional Spraying on hard surfaces.	
				Non-professional Application by brushing on hard surfaces.	
				Non-professional Application by pouring on hard surfaces.	
Meta SPC 11	1 Disinfectants for hard surfaces of industry, institution and healthcare facilities and, food preparation and handling areas (PT2 and 4)	Bacteria (including including additional PT4 strain *Salmonella* Typhimurium and *Listeria monocytogenes*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2)	Professional Spraying on hard surfaces.	~~Acceptable~~ Non acceptable for APCP-
				Professional Application by pouring on hard surfaces.	~~Acceptable~~ Non acceptable for APCP-
				Professional Application by scrubbing on hard surfaces (applying product by machine).	~~Acceptable~~ Non acceptable for APCP-

Meta SPC 12	1 Disinfectants for toilet bowls of industry, institution, healthcare facilities and health care (PT2)	Bacteria Yeasts	50 ml/m^2	Industrial, Professional Application by pouring on hard surfaces.	Acceptable
Meta SPC 13	1 Disinfectants for hard surfaces of industry, institution and healthcare facilities (PT2)	Bacteria (including the additional strain *Yersinia enterocolitica*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) for the outdoor disinfection of waste containers and around and roadways	Industrial, Professional Spraying on hard surfaces. Industrial, Professional Application by pouring on hard surfaces. Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Non acceptable for environment
	1 Disinfectants for hard surfaces of industry, institution and healthcare facilities (PT2)	Bacteria (including the additional strain *Yersinia enterocolitica*) Yeasts	30 ml/m^2 (20 sprays on the surface per m^2) for the indoor disinfection of waste containers and around	Industrial, Professional Spraying on hard surfaces. Industrial, Professional Application by pouring on hard surfaces. Industrial, Professional Application by scrubbing on hard surfaces (applying product by machine).	Acceptable

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
Lactic acid based products	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	**ACTION PIN**
	Address	**Z.I. de Cazalieu CS 60030 40260 CASTETS France**
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	ACTION PIN
Address of manufacturer	Z.I. de Cazalieu - CS 60030 40260 CASTETS France
Location of manufacturing sites	448 Route de l'Océan 40560 VIELLE-SAINT-GIRONS France

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	1322 - L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. et Portuaire B.P. 32 67390 MARCKOLSHEIM France
Location of manufacturing sites	Z.I. et Portuaire B.P. 32 67390 MARCKOLSHEIM France

Active substance	1322 - L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46 – NL 4206 AC Gorinchem Netherlands
Location of manufacturing sites 1	Arkelsedijk 46 – NL 4206 AC Gorinchem Netherlands
Location of manufacturing sites 2	Gran Vial 19-25 08160 MONTMELÓ Spain

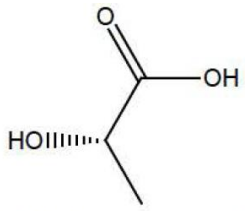
2.1.2 Product family composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	L(+) lactic acid
IUPAC or EC name	(2S)-2- Hydroxypropanoic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	
Minimum purity / content	≥ 955 g/kg (dry weight)
Structural formula	$C_3H_6O_3$ 

2.1.2.2 Candidate(s) for substitution

L(+) lactic acid is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Technical active substance*	79-33-4	201-196-2	2.40	24
		Pure active substance**			2.29	22.92
Content in the biocidal product of the mixture including the active substance					*3*	*30*
Reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	OTNE	Co-formulant	-	915-730-3	0	0.9
Diethylene glycol monobutyl ether	2-(2-Butoxyethoxy)ethan-1-ol	Co-formulant	112-34-5	203-961-6	0	5.5

*based on the content of active substance in the mixture used for the formulation of the biocidal product (80% w/w).
**based on the minimum purity of active substance: 95.5% w/w

2.1.2.4 Information on technical equivalence

The source of the active substance from Purac Biochem is the same as the one evaluated for inclusion in the Union list of approved active substance.

The source of the active substance from Jungbunzlauer S.A. is considered technically equivalent compared to the reference source (Decision number: TAP-D-1403137-31-00/F).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family

The biocidal product contains the active substance "Lactic Acid", which is not considered to have endocrine disrupting properties.

None of the co-formulants contained in the family are regulatory identified as endocrine disruptors or have significant ED properties.
However, that are indications that some co-formulants have ED properties and they should be further assessed in the frame of REACH Regulation.

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

AL - Any other liquid (META SPC 1 – 2 – 3 – 4 – 9 – 12) SL - Soluble concentrate (META SPC 6 – 7 – 8 – 11) ME - Micro-emulsion (META SPC 10 – 13)

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.1.3 Meta SPC 1 administrative information

2.1.3.1 Meta SPC identifier

Identification	META SPC 1

2.1.3.2 Suffix to the authorisation number

Number 1	

2.1.3.3 Product type(s)

Product type(s)	2

2.1.4 Meta SPC 1 composition

2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.29	2.29
		Technical active substance			2.4	2.4

2.1.4.2 Type(s) of formulation of the meta SPC 1

AL - Any other liquid

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1
Hazard statement	H290: May be corrosive to metals.
Labelling	
Signal words	
Hazard statements	H290: May be corrosive to metals.
Precautionary statements	P234: Keep only in original container. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner.
Note	

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1 – Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Products used for the disinfection of households surfaces including toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping)
Application rate(s) and frequency	Ready to use Non mechanical action (spraying) or mechanical action (wiping) Contact time: 5 min Dirty conditions Temperature: 20°C

	Application rates: Spraying : 30 ml/m^2 (20 sprays on the surface per m^2) Wiping : 16 ml onto wipe per 0.1 m^2 (8 to 12 sprays) For toilet bowls, 50 ml or 33 sprays per toilet
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 5 L, 1 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide):5 L

2.1.6.1.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surface. Allow to take effect for at least 5 minutes, then brush or scrub if required and wipe with a dry cloth.
- Ready-to-use liquid on hard surfaces by wiping: Spray on wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and then wipe the surface with a dry cloth if required or let to dry.
- Ready-to-use liquid for toilet bowls: Spray inside the toilet bowls by fully covering all surfaces to be treated. Allow to take effect for at least 5 minutes, then brush if required and flush the toilet.

2.1.6.1.2 Use-specific risk mitigation measures

-

2.1.6.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.6.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

2.1.6.1.5 -Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- Read carefully and follow all instructions.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- Product has been tested against bacteria, including *Bartonella henselae* (agent of cat scratch disease)

2.1.7.2 Risk mitigation measures

-

2.1.7.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.
- If medical advice is needed, have product container or label at hand.

2.1.7.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.7.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.
- Keep out of reach of children and pets.

2.1.8 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

2.1.9 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**DETERGENT DESINFECTANT**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.29
		Technical active substance			2.4

Trade name(s)	**ANTI CALCAIRE DESINFECTANT SALLE DE BAINS** **ANTI CALCAIRE DESINFECTANT**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.29
		Technical active substance			2.4

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.1.10 Meta SPC 2 administrative information

2.1.10.1 Meta SPC identifier

Identification	META SPC 2

2.1.10.2 Suffix to the authorisation number

Number 2	

2.1.10.3 Product type(s)

Product type(s)	2, 4

2.1.11 Meta SPC 2 composition

2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 2

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.87	2.87
		Technical active substance			3	3

2.1.11.2 Type(s) of formulation of the meta SPC 2

AL - Any other liquid

2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1 Skin Irrit. 2
Hazard statement	H290: May be corrosive to metals. H315: Causes skin irritation.
Labelling	
Signal words	Warning
Hazard statements	H290: May be corrosive to metals. H315: Causes skin irritation.

Classification	
Precautionary statements	P234: Keep only in original container. P264: Wash ... thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of water P321: Specific treatment (see ... on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner.
Note	

2.1.13 Authorised use(s) of the META SPC 2

2.1.13.1 Use description

Table 2. Use # 1 – Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of households surfaces, including toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping)
Application rate(s) and frequency	Ready to use Non mechanical action (spraying) or mechanical action (wiping) Contact time : 5 minutes Dirty conditions Temperature: 20°C Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2) For toilet bowls, 50 ml or 33 sprays per toilet
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L

	Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.13.1.1 Use-specific instructions for use

- Read carefully and follow all instructions.
- Ready-to-use liquid for spraying for hard surfaces: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 minutes, then brush or scrub if required and wipe with a dry cloth.
- Ready-to-use liquid for wipping on hard surfaces: Spray on wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.
- Ready-to-use liquid for toilet bowls: Spray inside the toilet bowls by fully covering all surfaces to be treated (approximately 50 ml or 33 sprays per toilet). Allow to take effect for at least 5 minutes, then brush if required and flush the toilet.

2.1.13.1.2 Use-specific risk mitigation measures

- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.
- Wash hands after application.

2.1.13.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- If medical advice is needed, have product container or label at hand.

2.1.13.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.13.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- Keep out of reach of children and pets.

2.1.13.2 Use description

Table 3. Use # 2 – Disinfectants for hard surfaces including food contact surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of households surfaces including food contact surfaces, toilets bowls and devices for baby care and other risk groups. Disinfection of all kind of non porous surfaces.

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping)
Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying): Contact time (bacteria and yeasts): 15 minutes Mechanical action (wiping): Contact time (bacteria, yeasts): 5 minutes Application rates: 30 ml/m^2 - 20 sprays on the surface per m^2 8 to 12 sprays or 16 ml on wipe per 0.1 m^2 For toilet bowls: 50 ml or 33 sprays per toilet
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.13.2.1 Use-specific instructions for use

- Read carefully and follow all instructions.
- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes, then brush or scrub if required and wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping: Spray on wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.
- Ready-to-use liquid for toilet bowls: Spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 15 minutes, then brush if required and flush the toilet.
- Product has been tested against bacteria, including *Salmonella* Typhimurium (agent of Salmonellosis disease) and *Listeria monocytogenes* (agent of Listeriosis disease)

2.1.13.2.2 Use-specific risk mitigation measures

- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.
- Wash hands after application.

2.1.13.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- If medical advice is needed, have product container or label at hand.

2.1.13.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.13.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- Keep out of reach of children and pets.

2.1.13.3 Use description

Table 4. Use # 3 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection for industry, institution and healthcare facilities, including external surfaces of toilets bowls and, food preparation and handling area. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying): Contact time (bacteria and yeasts): 15 minutes Mechanical action (wiping, mopping): Contact time (bacteria, yeasts): 5 minutes Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2
Category(ies) of users	Industrial, Professional

Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide):5 L

2.1.13.3.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes, then brush or scrub if required and wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping/mopping: Spray on wipe or soak the mop/wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.
- Product has been tested against bacteria, including *Salmonella* Typhimurium (agent of Salmonellosis disease) and *Listeria monocytogenes* (agent of Listeriosis disease)

2.1.13.3.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.
- During loading of the trigger spray and application, wear:
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6),
  - ✓ face shield.
- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.

2.1.13.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.13.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.13.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.13.4 Use description

Table 5. Use # 4 – Disinfectants for hard surfaces for industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution and healthcare facilities including external surfaces of toilets bowls. Use for cleaning and disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying): Contact time (bacteria and yeasts): 15 minutes Mechanical action (wiping and mopping): Contact time (bacteria and yeasts): 5 minutes Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2)
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.13.4.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surface intended to be treated and cover the entire surface. Allow to take effect for at least 15 minutes, then brush or scrub if required and rinse with water, wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping/mopping: Spray on wipe or soak the mop/wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and rinse with water, then wipe the surface with a dry cloth if required or let to dry.

2.1.13.4.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.
- During loading of the trigger spray and application, wear:
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6),
  - ✓ face shield.
- Minimisation of splashes and spills during loading of the trigger spray.

- The spray application must be downward in order to avoid any facial exposure.

2.1.13.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.13.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.13.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.14 General directions for use of the meta SPC 2

2.1.14.1 Instructions for use

- Comply with the instructions of uses. - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). - Inform the authorization holder if the treatment is ineffective. - For PT4 surfaces, application is only for general disinfection.

2.1.14.2 Risk mitigation measures

- Avoidance of contact with freshly treated surfaces.

2.1.14.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN: Wash with plenty of water - Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. - Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. - Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. - In case of impaired consciousness place in recovery position and seek medical advice immediately. - Keep the container or label available.

2.1.14.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. - Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.14.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shel life- : 2 years.

2.1.15 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

2.1.16 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**DÉGRAISSANT DÉSINFECTANT MULTI-SURFACES** **DEGRAISSANT DESINFECTANT CUISINE** **RESOLUTIONS Dégraissant Désinfectant Alimentaire P.A.E.** **DÉGRAISSANT DÉSINFECTANT SANS RINCAGE**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.87
		Technical active substance			3

Trade name(s)	**DÉTARTRANT DÉSINFECTANT SANITAIRES** **DÉTARTRANT DÉSINFECTANT SALLE DE BAINS** **RESOLUTIONS Détartrant Désinfectant Sanitaires P.A.E.**
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.87
		Technical active substance			3

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.17 Meta SPC 3 administrative information

2.1.17.1 Meta SPC identifier

Identification	META SPC 3

2.1.17.2 Suffix to the authorisation number

Number 3	

2.1.17.3 Product type(s)

Product type(s)	2, 4

2.1.18 Meta SPC 3 composition

2.1.18.1 Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.82	3.82
		Technical active substance			4	4

2.1.18.2 Type(s) of formulation of the meta SPC 3

AL - Any other liquid

2.1.19 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1 Eye Dam. 1 Skin Irrit. 2
Hazard statement	H290: May be corrosive to metals. H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P234: Keep only in original container. P264: Wash ... thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of water P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner.
Note	

2.1.20 Authorised use(s) of the META SPC 3

2.1.20.1 Use description

Table 6. Use # 1 – Disinfectants for hard surfaces for industry, institution, healthcare facilities, healthcare and, food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution, healthcare facilities and healthcare including toilets bowls and food preparation and handling area. Use for cleaning and disinfection of all kind of non porous surfaces.

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying) or mechanical action (wiping and mopping): Contact time (bacteria and yeasts): 5 minutes Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2 For toilet bowls: 50 ml or 33 sprays per toilet
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.20.1.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 minutes, then brush or scrub if required and wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping/mopping: Spray on wipe or soak the mop/wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and then rinse with water, wipe the surface with a dry cloth if required or let to dry.
- Ready-to-use liquid for toilet bowls: Spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 minutes, then brush if required and flush the toilet.

2.1.20.1.2 Use-specific risk mitigation measures

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2.1.20.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.20.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.20.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.20.2 Use description

Table 7. Use # 2 – Disinfectants for hard surfaces for industry, institution, healthcare facilities and healthcare

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution, healthcare facilities and health care including toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying) or mechanical action (wiping and mopping): Contact time (bacteria and yeasts): 5 minutes Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2 For toilet bowls: 50 ml or 33 sprays per toilet
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.20.2.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 minutes, then brush or scrub if required, rinse with water and wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping/mopping: Spray on wipe or soak the mop/wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and then rinse with water, wipe the surface with a dry cloth if required or let to dry.
- Ready-to-use liquid for toilet bowls: Spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 minutes, then brush if required and flush the toilet.

2.1.20.2.2 Use-specific risk mitigation measures

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2.1.20.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.20.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.20.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.21 General directions for use of the meta SPC 3

2.1.21.1 Instructions for use

- Comply with the instructions of uses.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the authorization holder if the treatment is ineffective.
- For PT4 surfaces, application is only for general disinfection.

2.1.21.2 Risk mitigation measures

- During loading of the trigger spray and application, wear:
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6),
  - ✓ face shield.
- Minimisation of splashes and spills during loading of the trigger spray

- The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces.

2.1.21.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. - IF ON SKIN: Wash with plenty of water - Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. - Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. - In case of impaired consciousness place in recovery position and seek medical advice immediately. - Keep the container or label available.

2.1.21.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. - Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.21.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.22 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

2.1.23 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**SANITAIRES DESINFECTANT EXTRA** **BACTOPIN VR**
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.82
		Technical active substance			4

PART II - SECOND INFORMATION LEVEL - META SPC 4

2.1.24 Meta SPC 4 administrative information

2.1.24.1 Meta SPC identifier

Identification	META SPC 4

2.1.24.2 Suffix to the authorisation number

Number 4	

2.1.24.3 Product type(s)

Product type(s)	2, 4

2.1.25 Meta SPC 4 composition

2.1.25.1 Qualitative and quantitative information on the composition of the meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.06	3.06
		Technical active substance			3.2	3.2

2.1.25.2 Type(s) of formulation of the meta SPC 4

AL - Any other liquid

2.1.26 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1 Eye Dam. 1
Hazard statement	H290: May be corrosive to metals. H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H318: Causes serious eye damage
Precautionary statements	P234: Keep only in original container. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner.
Note	

2.1.27 Authorised use(s) of the META SPC 4

2.1.27.1 Use description

Table 6. Use # 1 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution, healthcare facilities and, food preparation and handling area. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping)

Application rate(s) and frequency	Ready to use Dirty conditions Temperature: 20°C Non mechanical action (spraying): Contact time (bacteria and yeasts): 15 minutes Mechanical action (wiping and mopping): Contact time (bacteria and yeasts): 5 minutes Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 8 to 12 sprays or 16 ml on wipe per 0.1 m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 500 mL trigger spray, 750 mL trigger spray, 1 L, 5 L PET: 500 mL trigger spray, 750 mL trigger spray, 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L

2.1.27.1.1 Use-specific instructions for use

- Ready-to-use liquid for hard surfaces by spraying: Spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes, then brush or scrub if required rinse with water and wipe with a dry cloth.
- Ready-to-use liquid for hard surfaces by wipping/mopping: Spray on wipe or soak the mop/wipe and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and then rinse with water wipe the surface with a dry cloth if required or let to dry.

2.1.27.1.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated

2.1.27.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.27.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.27.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.28 General directions for use of the meta SPC 4

2.1.28.1 Instructions for use

- Comply with the instructions of uses.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the authorization holder if the treatment is ineffective.
- For PT4 surfaces, application is only for general disinfection.
- Product has been tested against bacteria, including *Salmonella* Typhimurium (agent of Salmonellosis disease) and *Listeria monocytogenes* (agent of Listeriosis disease)

2.1.28.2 Risk mitigation measures

- Wear goggles during loading of the trigger spray and application.
- Minimisation of splashes and spills during loading of the trigger spray.
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with freshly treated surfaces.

2.1.28.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting.
- Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

2.1.28.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.28.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.29 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

2.1.30 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**VSD** **VITRES ET SURFACES DESINFECTANT** **VITRES & SURFACES DESINFECTANT**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.06
		Technical active substance			3.2

PART II - SECOND INFORMATION LEVEL - META SPC 6

2.1.31 Meta SPC 6 administrative information

2.1.31.1 Meta SPC identifier

Identification	META SPC 6

2.1.31.2 Suffix to the authorisation number

Number 5	

2.1.31.3 Product type(s)

Product type(s)	2, 4

2.1.32 Meta SPC 6 composition

2.1.32.1 Qualitative and quantitative information on the composition of the meta SPC 6

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	22.92	22.92
		Technical active substance			24	24

2.1.32.2 Type(s) of formulation of the meta SPC 6

SL - Soluble concentrate

2.1.33 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1 Skin Corr. 1C Eye Dam. 1
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage

Classification	
Precautionary statements	P234: Keep only in original container. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash ... thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: If INHALED: Remove personto fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage. P405: Store locked up. P406: Store in a corrosive resistant/… container with a resistant inner liner. P501: Dispose of contents/container to…
Note	

2.1.34 Authorised use(s) of the META SPC 6

2.1.34.1 Use description

Table 7. Use # 1 – Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate to be diluted. Product used for the disinfection for industry, institution, healthcare facilities and healthcare, including toilets bowls and disinfection for areas of food preparation and handling. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)

Application rate(s) and frequency	Dirty conditions In healthcare area, without mechanical action (spraying): bacteria, yeasts: 8% (v/v), contact time 5 minutes, 20°C Other areas, without mechanical action (spraying): Bacteria, yeasts: 5% (v/v), contact time 15 min, 20°C 3% (v/v), contact time 30 min, 40°C All areas, with mechanical action (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min, 20°C Application rates: 30 ml/m2 - 20 sprays on the surface per m2 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 For toilet bowls: 50 ml or 33 sprays per toilet Daily frequency
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g LDPE/HDPE: 20 mL

2.1.34.1.1 Use-specific instructions for use

1. Manual disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 until 30 minutes depending on the temperature and the use area, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 and then let to dry. Rinse the tank after applying the product.

- Toilet bowls: Dilute in water and spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 minutes, then brush if required and flush the toilet.
- The product must be used directly after dilution.

- Products have been tested against bacteria, including *Salmonella* Typhimurium (agent of Salmonellosis disease) and *Listeria monocytogenes* (agent of Listeriosis disease)

2.1.34.1.2 Use-specific risk mitigation measures

-

2.1.34.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.34.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.34.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.34.2 Use description

Table 8. Use # 2 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas.

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate to be diluted. Product used for the disinfection of industry, institution and healthcare facilities, including external surfaces of toilets bowls and disinfection for area of food preparation and handling. Disinfection of all kind of non porous surfaces
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions Without mechanical action (spraying): Bacteria, yeasts: 5% (v/v), contact time 15 min, 20°C 3% (v/v), contact time 30 min, 40°C

	With mechanical action (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min, 20°C Daily frequency Application rates: 30ml/m2 - 20 sprays directly on the surface per m2 8 to 12 sprays or 16 ml onto wipe per 0.1 m2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g LDPE/HDPE: 20 mL

2.1.34.2.1 Use-specific instructions for use

1. Manual disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surface intended to be treated and cover the entire surface. Allow to take effect for at least 15 until 30 minutes depending on the temperature, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all the surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes depending on the temperature and then let to dry. Rinse the tank after applying the product.

- The product must be used directly after dilution.

- Products have been tested against bacteria, including *Salmonella* Typhimurium (agent of Salmonellosis disease) and *Listeria monocytogenes* (agent of Listeriosis disease)

2.1.34.2.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.

2.1.34.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.34.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.34.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.34.3 Use description

Table 9. Use # 3 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare

Product Type	PT02- Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection for industry, institution, healthcare facilities and healthcare including toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	In healthcare, without mechanical action (spraying): Bacteria, yeasts: 8% (v/v), contact time : 5 minutes, 20°C Other areas, without mechanical action (spraying): Bacteria, yeasts: 5% (v/v), contact time : 15 minutes, 20°C With mechanical action (wiping/mopping/brushing/scrubbing): Bacteria, yeasts: 10% (v/v) contact time 5 minutes, 20°C Application rates: 30ml/m^2 - 20 sprays on the surface per m^2 8 to 12 sprays - 16 ml onto wipe per 0.1 m^2 For toilet bowls, 50 ml or 33 sprays per toilet
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg

	Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g LDPE/HDPE: 20 mL

2.1.34.3.1 Use-specific instructions for use

1. Manual disinfection:
- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces intended to be treated and cover the entire surfaces Allow to take effect for at least 5 until 15 minutes, depending on the use area, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.

2. Machine:
- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes and then let to dry. Rinse the tank after applying the product.

- Toilet bowls: Dilute in water and spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 until 15 minutes, depending on the use area, then brush if required and flush the toilet.
- The product must be used directly after dilution.

2.1.34.3.2 Use-specific risk mitigation measures

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2.1.34.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.34.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.34.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.34.4 Use description

Table 10. Use # 4 – Disinfectants for hard surfaces of industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution and healthcare facilities, including external surfaces of toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Without mechanical action (spraying): Bacteria, yeasts: 5% (v/v), contact time 15 min, 20°C With mechanical action (wiping/mopping/brushing/scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min, 20°C Application rates: 30 ml/m^2 - 20 sprays on the surface per m^2 8 to 12 sprays - 16 ml onto wipe per 0.1 m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g LDPE/HDPE: 20 mL

2.1.34.4.1 Use-specific instructions for use

1. Manual disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes and then let to dry. Rinse the tank after applying the product.

- The product must be used directly after dilution.

2.1.34.4.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.

2.1.34.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.34.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.34.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.35 General directions for use of the meta SPC 6

2.1.35.1 Instructions for use

- Comply with the instructions of uses.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the authorization holder if the treatment is ineffective.
- For PT4 areas, application is only for general disinfection.

2.1.35.2 Risk mitigation measures

- Avoidance of contact with freshly treated surfaces.
- During mixing and loading, wear:
  - ✓ face shield,
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6).
- Minimisation of splashes and spills.
- Minimisation of manual phases.
- During application and cleaning of spray equipment, wear:
  - ✓ face shield,
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6).
- The spray application must be downward in order to avoid any facial exposure.

2.1.35.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- If INHALED: Remove personto fresh air and keep comfortable for breathing.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

2.1.35.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.35.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.36 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

2.1.37 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**DÉGRAISSANT DÉSINFECTANT CONCENTRÉ** **RESOLUTIONS Dégraissant Désinfectant Alimentaire Concentré**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	22.92
		Technical active substance			24

Trade name(s)	**DÉTARTRANT DÉSINFECTANT SANITAIRES CONCENTRÉ** **RESOLUTIONS Détartrant Désinfectant Sanitaires Concentré**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	22.92
		Technical active substance			24

Trade name(s)	**DETERGENT DESINFECTANT SOLS & SURFACES CONCENTRE**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	22.92

		Technical active substance			24

Trade name(s)	**DNAL**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	22.92
		Technical active substance			24

PART II - SECOND INFORMATION LEVEL - META SPC 7

2.1.38 Meta SPC 7 administrative information

2.1.38.1 Meta SPC identifier

Identification	META SPC 7

2.1.38.2 Suffix to the authorisation number

Number 6	

2.1.38.3 Product type(s)

Product type(s)	PT02, 04

2.1.39 Meta SPC 7 composition

2.1.39.1 Qualitative and quantitative information on the composition of the meta SPC 7

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	11.46	11.46
		Technical active substance			12	12

2.1.39.2 Type(s) of formulation of the meta SPC 7

SL - Soluble concentrate

2.1.40 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Met. Corr. 1 Skin Corr. 1C Eye Dam. 1
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage
Precautionary statements	P234: Keep only in original container. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash ... thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: If INHALED: Remove personto fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage. P405: Store locked up. P406: Store in a corrosive resistant/… container with a resistant inner liner. P501: Dispose of contents/container to…
Note	

2.1.41 Authorised use(s) of the META SPC 7

2.1.41.1 Use description

Table 11. Use # 1 – Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution, healthcare facilities and healthcare, including toilets bowls and disinfection for areas of food preparation and handling. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions In healthcare areas, without mechanical application (spraying): bacteria, yeasts: 10% (v/v), contact time 5 minutes, 20°C Other areas, without mechanical application (spraying): Bacteria, yeasts: 8% (v/v), contact time 15 min, 20°C 6% (v/v), contact time 30 min, 40°C All areas, with mechanical application (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min, 20°C Application rates: 30 ml/m^2 - 20 sprays directly on the surface per m^2 8 to 12 sprays or 16 ml onto wipe per 0.1 m^2 For toilet bowls: 50 ml or 33 sprays per toilet
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g

2.1.41.1.1 Use-specific instructions for use

1. Manual disinfection:
- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces

intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 until 30 minutes, depending on the area and temperature, and then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and wipe the surface with a dry cloth if required or let to dry.

2. Machine:
- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes and then let to dry. Rinse the tank after applying the product.
- Toilet bowls: Dilute in water and spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 until 15 minutes depending on the area, then brush if required and flush the toilet.
- The product must be used directly after dilution.

2.1.41.1.2 Use-specific risk mitigation measures

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2.1.41.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.41.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.41.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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2.1.41.2 Use description

Table 12. Use # 2 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution and healthcare facilities, including external surfaces of toilets bowls and disinfection for areas of food preparation and handling.

	Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions without mechanical application (spraying): Bacteria, yeasts: 8% (v/v), contact time 15 min, 20°C 6% (v/v), contact time 30 min, 40°C with mechanical application (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min, 20°C Application rates: 30 ml/m^2 - 20 sprays directly on the surface per m^2 8 to 12 sprays or 16 ml onto wipe per 0.1 m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g

2.1.41.2.1 Use-specific instructions for use

1. Manual disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surface intended to be treated and cover the entire surface. Allow to take effect for at least 15 until 30 minutes depending on the temperature, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes, then wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes depending on the temperature and then let to dry. Rinse the tank after applying the product.
- The product must be used directly after dilution.

2.1.41.2.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.

2.1.41.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.41.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.41.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.41.3 Use description

Table 13. Use # 3 – Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection for industry, institution, healthcare facilities and healthcare, including toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping) Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions Temperature: 20°C In healthcare areas, without mechanical application (spraying): bacteria, yeasts: 10% (v/v), contact time 5 minutes Other areas, without mechanical application (spraying): Bacteria, yeasts: 8% (v/v), contact time 15 min

	All areas, with mechanical application (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% v/v, contact time 5 min Application rates: 30 ml/m^2 (20 sprays on the surface per m^2) 16 ml on wipe per 0.1m^2 (8 to 12 sprays) For toilet bowls: 50 ml or 33 sprays per toilet
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g

2.1.41.3.1 Use-specific instructions for use

1. Manuel disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 5 until 15 minutes depending on the area, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes and then let to dry. Rinse the tank after applying the product.
- Toilet bowls: Dilute in water and spray inside the toilet bowls by fully covering all surface to be treated. Allow to take effect for at least 5 until 15 minutes depending on the area, then brush if required and flush the toilet.
- The product must be used directly after dilution.

2.1.41.3.2 Use-specific risk mitigation measures

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2.1.41.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.41.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.41.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.41.4 Use description

Table 14. Use # 4 – Disinfectants for hard surfaces of industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of industry, institution and healthcare facilities, including external surfaces of toilets bowls. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping), Mopping (applying product onto mop followed by mopping) Brushing (applying product onto brush followed by brushing) Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions 20°C Without mechanical application (spraying): Bacteria and yeasts: 8% (v/v), contact time 15 min With mechanical application (wiping /mopping /brushing /scrubbing): Bacteria, yeasts: 10% (v/v), contact time 5 min Application rates: 30 ml/m^2 - 20 sprays directly on the surface per m^2 8 to 12 sprays or 16 ml on wipe per 0.1 m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L / 1 kg, 5 L / 5 kg, 10 L / 10 kg, 20 L / 20 kg, 120 L / 120 kg, 200 L / 200 kg, 220 L / 220 kg PET: 1 L / 1 kg Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L / 5 kg

	Coextrude (HDPE/Adhesive resin/EVAL): 250 mL / 250 g

2.1.41.4.1 Use-specific instructions for use

1. Manual disinfection:

- For hard surfaces by spraying: Dilute in water and spray directly on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes, then brush or scrub if required and wipe with a dry cloth.
- For hard surfaces by wipping/mopping/brushing: Dilute in water, spray on wipe or soak the mop/wipe/brush and apply by fully wetting all surfaces intended to be treated. Allow to take effect for at least 5 minutes and wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 5 minutes and then let to dry. Rinse the tank after applying the product.

2.1.41.4.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.

2.1.41.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.41.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.41.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.42 General directions for use of the meta SPC 7

2.1.42.1 Instructions for use

- Comply with the instructions of uses.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the authorization holder if the treatment is ineffective.
- For PT4 areas, application is only for general disinfection.
- Use immediately the product after dilution.

2.1.42.2 Risk mitigation measures

- Avoidance of contact with freshly treated surfaces.
- During mixing and loading, wear:
  - ✓ face shield,
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6),
- Minimisation of splashes and spills.
- Minimisation of manual phases.
- During application and cleaning of spray equipment, wear:
  - ✓ face shield,
  - ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - ✓ coated coverall (at least category III type 6).
- The spray application must be downward in order to avoid any facial exposure.

2.1.42.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- If INHALED: Remove personto fresh air and keep comfortable for breathing.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

2.1.42.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.42.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.43 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

2.1.44 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**DEGRAISSANT DESINFECTANT +**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	11.46
		Technical active substance			12

Trade name(s)	**DETARTRANT DESINFECTANT SANITAIRES +** **DETERGENT DESINFECTANT SOLS & SURFACES +**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	11.46
		Technical active substance			12

PART II - SECOND INFORMATION LEVEL - META SPC 12

2.1.45 Meta SPC 12 administrative information

2.1.45.1 Meta SPC identifier

Identification	META SPC 12

2.1.45.2 Suffix to the authorisation number

Number 8	

2.1.45.3 Product type(s)

Product type(s)	2

2.1.46 Meta SPC 12 composition

2.1.46.1 Qualitative and quantitative information on the composition of the meta SPC 12

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	15.28	15.28
		Technical active substance			16	16

2.1.46.2 Type(s) of formulation of the meta SPC 12

AL - Any other liquid

2.1.47 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 12

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corr. 1C Eye Dam. 1
Hazard statement	H314: Causes severe skin burns and eye damage H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H314: Causes severe skin burns and eye damage

Classification	
Precautionary statements	P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash ... thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: If INHALED: Remove personto fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse. P501: Dispose of contents/container to…
Note	

2.1.48 Authorised use(s) of the META SPC 12

2.1.48.1 Use description

Table 15. Use # 1 – Disinfectants for hard surfaces for industry, institution, healthcare facilities and healthcare

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of toilet bowls of industry, institution, healthcare facilities and healthcare. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Pouring
Application rate(s) and frequency	Ready to use Dirty conditions Bacteria, yeasts: Contact time: 5 minutes, 20°C Application rate: 50 mL/m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1L bottle

2.1.48.1.1 Use-specific instructions for use

- Ready-to-use liquid for toilet bowls: Cover the entire toilet bowl with the product. Allow to take effect for at least 5 minutes, then brush or scrub if required and flush the toilet.

2.1.48.1.2 Use-specific risk mitigation measures

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2.1.48.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.48.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.48.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.49 General directions for use of the meta SPC 12

2.1.49.1 Instructions for use

- Comply with the instructions of uses. - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). - Inform the authorization holder if the treatment is ineffective.

2.1.49.2 Risk mitigation measures

- Avoidance of contact with freshly treated surfaces. - During application, wear: ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), ✓ coated coverall (at least category III type 6).

2.1.49.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

- If INHALED: Remove personto fresh air and keep comfortable for breathing.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

2.1.49.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.49.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.50 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 12

2.1.51 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**GEL WC DESINFECTANT**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	15.28
		Technical active substance			16

PART II - SECOND INFORMATION LEVEL - META SPC 13

2.1.52 Meta SPC 13 administrative information

2.1.52.1 Meta SPC identifier

Identification	META SPC 13

2.1.52.2 Suffix to the authorisation number

Number 9	

2.1.52.3 Product type(s)

Product type(s)	2

2.1.53 Meta SPC 13 composition

2.1.53.1 Qualitative and quantitative information on the composition of the meta SPC 13

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	7.64	7.64
		Technical active substance			8	8
Diethylene glycol monobutyl ether	2-(2-Butoxyethoxy)ethan-1-ol	Co-formulant	112-34-5	203-961-6	5.5	5.5
Reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	OTNE	Co-formulant		915-730-3	0.9	0.9

2.1.53.2 Type(s) of formulation of the meta SPC 13

ME - Micro-emulsion

2.1.54 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 13

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corr. 1C Eye Dam. 1 Aquatic chronic 3
Hazard statement	H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H412: Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H412: Harmful to aquatic life with long lasting effects H314: Causes severe skin burns and eye damage
Precautionary statements	P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash ... thoroughly after handling. P273: Avoid release to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: If INHALED: Remove personto fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse. P501: Dispose of contents/container in accordance with local regulation
Note	EUH208: Contains d-limonene, eucalyptol, menthone, l-carvone, alpha-pinene, isomenthone, cinnamaldehyde, dipentene, (αS,1R)-α-3,3-trimethyl-cyclohexanemethanol, (αR,1S)-α-3,3-trimethyl-cyclohexanemethanol, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one. May produce an allergic reaction.

2.1.55 Authorised use(s) of the META SPC 13

2.1.55.1 Use description

Table 16. Use # 1 – Disinfectants for hard surfaces of industry, institution and healthcare facilities

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Product used for the disinfection of hard surfaces of industry, institution and healthcare facilities. Disinfection of all kind of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying Pouring Scrubbing (machine)
Application rate(s) and frequency	Dirty conditions Bacteria and yeasts : 8% (v/v), contact time: 15 minutes, 20°C Application rate: 30 ml/m^2 for the indoor disinfection of waste containers and around
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	HDPE: 1 L, 5 L, 10 L, 20 L, 120 L, 200 L, 220 L, 1000 L PET: 1 L Coextrude (HDPE/Adhesive/Nylon polyamide): 5 L Coextrude (HDPE/Adhesive resin/EVAL): 250 mL

2.1.55.1.1 Use-specific instructions for use

1. Manual disinfection:

- Dilute in water, apply on the surfaces intended to be treated and cover the entire surfaces. Allow to take effect for at least 15 minutes and then wipe the surface with a dry cloth if required or let to dry.

2. Machine:

- Dilute in water in scrubber-dryers, single-disk scrubbers, high or low pressure sprayers... and apply on surface and/or floor intended to be treated. Allow to take effect for at least 15 minutes and then let to dry.

2.1.55.1.2 Use-specific risk mitigation measures

- For heathcare facilities, apply the product only in areas where disinfection is not medically indicated.

2.1.55.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

2.1.55.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

-

2.1.55.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

-

2.1.56 General directions for use of the meta SPC 13

2.1.56.1 Instructions for use

- Comply with the instructions of uses - Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.) - Inform the authorization holder if the treatment is ineffective. - The product must be used directly after dilution. - The product has been tested against bacteria, including *Yersinia enterocolitica* (agent of yersiniosis)

2.1.56.2 Risk mitigation measures

- The product is for an indoor use only. - Avoidance of contact with freshly treated surfaces. - During mixing and loading, wear: ✓ face shield, ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), ✓ coated coverall (at least category III type 6). - Minimisation of splashes and spills. - Minimisation of manual phases. - During application and cleaning of spray equipment, wear: ✓ face shield, ✓ protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), ✓ coated coverall (at least category III type 6). - The spray application must be downward in order to avoid any facial exposure.

2.1.56.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- If INHALED: Remove personto fresh air and keep comfortable for breathing.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

2.1.56.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

2.1.56.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf life: 2 years.

2.1.57 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 13

2.1.58 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**DESINFECTANT ODORISANT CONCENTRE** **DESINFECTANT ODORISANT PUISSANT** **OD OM +**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) Lactic acid	(S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	7.64

		Technical active substance			8
Diethylene glycol monobutyl ether	2-(2-Butoxyethoxy)ethan-1-ol	Co-formulant	112-34-5	203-961-6	5.5
Reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	OTNE	Co-formulant		915-730-3	0.9

2.1.59 Packaging of the biocidal product

Meta-SPC	Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
1, 2, 3, 4	Bottle with a hand-operated foam trigger	750 ml	Plastic: HDPE	Trigger cap in plastic: PE, PP	Professional / non-professional / Industrial	Yes
4	Bottle with a hand-operated spray trigger	750 ml	Plastic: PET	Trigger cap in plastic: PE, PP	Professional / Industrial	Yes
1, 2, 3, 4	Bottle with a hand-operated foam trigger	750 ml	Plastic: PET	Trigger cap in plastic: PE, PP	Professional / non-professional / Industrial	Yes

1, 2, 3, 4	Bottle with a hand-operated foam trigger	500 ml	Plastic: HDPE	Trigger cap in plastic: PE, PP	Professional / non-professional / Industrial	Yes
1, 2, 3, 4	Bottle with a hand-operated foam trigger	500 ml	Plastic: PET	Trigger cap in plastic: PP, POM, PE, HDPE, EVA, TPE, LDPE	Professional / non-professional / Industrial	Yes
2	Bottle with a hand-operated foam trigger	1 L	Plastic: HDPE	Trigger cap in plastic: PP, POM, PE, HDPE, EVA, TPE, LDPE	Professional / non-professional / Industrial	Yes
1, 2, 3, 4, 6, 7, 13	Drum	5 L	Plastic: HDPE	Cap in plastic: HDPE, PP	Professional / non-professional / Industrial	Yes
1, 2, 3, 4, 6, 7, 13	Bottle	1 L	Plastic: HDPE	Cap in plastic: PP	Professional / non-professional / Industrial	Yes
1, 2, 3, 4, 6, 7, 12, 13	Bottle	1 L	Plastic: HDPE	Cap with directional nozzle in plastic: PP	Professional / non-professional / Industrial	Yes
1, 2, 3, 4, 6, 7, 13	Bottle	1 L	Plastic: PET	Cap in plastic: PET, PP, PE	Professional / non-professional / Industrial	Yes
6, 7, 13	Drum	10 L	Plastic: HDPE	Cap in plastic: PE	Professional / non-professional / Industrial	Yes
6	Caps	20 ml	Plastic: HDPE, LDPE	/	Professional / Industrial	Yes
1, 2, 3, 4, 6, 7, 13	Drum	5 L	Plastic: HDPE, Adhesive, Nylon polyamide	Cap in plastic: LDPE, PP, HDPE	Professional / non-professional / Industrial	Yes
6, 7, 13	Barrel	20 L	Plastic: HDPE	Cap in plastic: PE	Professional / Industrial	Yes

6, 7, 13	Barrel	120 L	Plastic: HDPE	Cap in plastic: HDPE	Professional / Industrial	Yes
6, 7, 13	Barrel	220 L	Plastic: HDPE	Cap in plastic: HDPE	Professional / Industrial	Yes
6, 7, 13	Barrel	200 L	Plastic: HDPE	Cap in plastic: HDPE	Professional / Industrial	Yes
13	IBC	1 000 L	Plastic: HDPE	Cap in plastic: PP	Professional / Industrial	Yes
6, 7, 13	Bottle	250 ml	Plastic: HDPE / Adhesive resin / EVAL	Cap in plastic: PE, HDPE, PTFE, PP	Professional / Industrial	Yes

2.1.60 Documentation

2.1.60.1 Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product family were submitted by Action Pin.

All products studies efficacy were provided by the applicant Action PIN. Please refer to the reference list in Annex 3.1 for the complete list of products-related studies submitted in the context of this application.

2.1.60.2 Access to documentation

ACTION PIN could refer to the dossiers of the active substance L(+)-lactic acid with a Letter of Access of PURAC Biochem BV, approved substance supplier and Review Program Participant fot the active substance L(+)-lactic acid.
Source: PURAC Biochem BV.
Manufacturer Adress: Arkelsedijk 46 – NL 4206 AC Gorinchem Netherlands
Location site: Arkelsedijk 46 – NL 4206 AC Gorinchem Netherlands and Gran Vial 19-25 08160 MONTMELÓ Spain

ACTION PIN is allowed to use and make reference to the biodegradability data generated on behalf of Jungbunzlauer SA (OECD 301 D: closed bottle test by Ibacon, project number 80031161; QSAR study: In silico prediction of ready biodegradability by Kreatis, study no. OTS/JUN/DEG/18001) in their dossier for biocidal product authorisation.
Source: Jungbunzlauer S.A.
Manufacturer Adress: Z.I. et Portuaire B.P. 32 67390 MARCKOLSHEIM France
Location site: Z.I. et Portuaire B.P. 32 67390 MARCKOLSHEIM France

2.2 Assessment of the biocidal product family

2.2.1 Intended use(s) as applied for by the applicant

The application methods claimed were revised by the applicant during the evaluation of the dossier. These updated claims correspond to deletion of some application methods in various meta SPCs. These modification are included and materialized as strikethrough text below.

These changes were considered in the efficacy section but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions which consider only the updated claims.

Meta SPC 1:

Table 1. Use # 1 – META SPC 1: Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Products used for the disinfection of households surfaces including toilets bowls. Detergent, disinfectant (bactericidal activity) Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor, Domestic area
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing~~
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 2:

Table 2. Use # 1 – META SPC 2: Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of households surfaces including toilets bowls. Detergent, disinfectant (bactericidal activity). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor, Domestic area

Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing~~
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use # 2 – META SPC 2: Disinfectants for hard surfaces including food contact surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of households surfaces including food contact surfaces, toilets bowls and devices for baby care and other risk groups. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Domestic area
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing~~
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Table 4. Use # 3 – META SPC 2: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection for industry, institution and healthcare facilities including toilets bowls (outside) and food preparation and handling area. Detergent, disinfectant (bactericidal and yeasticidal activities) Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas.

Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 5. Use # 4 – META SPC 2: Disinfectants for hard surfaces for industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside). Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution and healthcare facilities areas
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

<u>Meta SPC 3:</u>

Table 6. Use # 1 – META SPC 3: Disinfectants for hard surfaces for industry, institution, healthcare facilities, health care and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of industry, institution, healthcare facilities and health care including toilets bowls and food preparation and handling area. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts

Field of use	Indoor, healthcare facilities, health care, institution, industry and food preparation and handling areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping), Brushing, scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 7. Use # 2 – META SPC 3: Disinfectants for hard surfaces for industry, institution, healthcare facilities and health care areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of industry, institution, healthcare facilities and health care including toilets bowls. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, healthcare facilities, health care, institution and industry areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping), Brushing, scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

<u>Meta SPC 4:</u>

Table 8. Use # 1 – META SPC 4: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of industry, institution, healthcare facilities and food preparation and handling area. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ ~~Brushing, scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	100 % - 30 ml/m2 - 20 sprays per m2 - 8 to 12 sprays or 16ml onto wipe per 0.1 m2 – RTU - Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 6:

Table 9. Use # 1 – META SPC 6: Disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection for industry, institution, healthcare facilities and health care including toilets bowls and disinfection for area of food preparation and handling. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ Brushing (applying product onto brush followed by brushing) , scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	30ml/m2 - 20 sprays directly on the surface per m2 / Wiping application for hard surfaces: 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 For spraying, scrubbing, mopping, brushing on hard surfaces: 8% (v/v) in medical area 5% (v/v), contact time of 15 min at 20°C and 3% (v/v), contact time of 30 min at 40°C in institutional, healthcare facilities and industrial areas In food preparation and handling areas: dilution at 3% (v/v), contact time of 5 min at 20°C and 2% (v/v), contact time of 15 min at 40°C for Bactericidal including Salmonella typhimurium and Listeria monocytogenes and 5% (v/v), contact time of 15 min at 20°C and 3% (v/v), contact time of

	30 min at 40°C for yeasticidal activity. 10% (v/v) for wiping application. Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 10. Use # 2 – META SPC 6: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside) and disinfection for area of food preparation and handling. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	30ml/m2 - 20 sprays directly on the surface per m2 / Wiping application for hard surfaces: 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 For spraying, scrubbing, mopping, brushing on hard surfaces: 8% (v/v) in medical area 5% (v/v), contact time of 15 min at 20°C and 3% (v/v), contact time of 30 min at 40°C in institutional, healthcare facilities and industrial areas In food preparation and handling areas: dilution at 3% (v/v), contact time of 5 min at 20°C and 2% (v/v), contact time of 15 min at 40°C for Bactericidal including Salmonella typhimurium and Listeria monocytogenes and 5% (v/v), contact time of 15 min at 20°C and 3% (v/v), contact time of 30 min at 40°C for yeasticidal activity. 10% (v/v) for wiping application. Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 11. Use # 3 – META SPC 6: Disinfectants for hard surfaces of industry, institution, healthcare facilities and health care areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection for industry, institution, healthcare facilities and health care including toilets bowls. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and health care areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Dilution at 8% (v/v) for spraying, scrubbing, mopping, brushing on hard surfaces: 30ml/m2 - 20 sprays directly on the surface per m2 Dilution at 10% (v/v): wiping application for hard surfaces: 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 12. Use # 4 – META SPC 6: Disinfectants for hard surfaces of industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside). Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution and healthcare facilities.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping),~~ Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Dilution at 5% (v/v) for spraying, scrubbing, mopping, brushing on hard surfaces: 30ml/m2 - 20 sprays per m2 Dilution at 10% (v/v): wiping application for hard surfaces: 8 to 12 sprays - 16 ml onto wipe per 0.1 m2

	Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 7:

Table 13. Use # 1 – META SPC 7: Disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of industry, institution, healthcare facilities and health care including toilets bowls and disinfection for area of food preparation and handling. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities, health care and food preparation and handling areas
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping~~), Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	30ml/m2 - 20 sprays directly on the surface per m2 / Wiping application for hard surfaces: 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 For spraying, scrubbing, mopping, brushing on hard surfaces: 10% (v/v) in medical area 8% (v/v), contact time of 15 min at 20°C and 6% (v/v), contact time of 30 min at 40°C in institutional, healthcare facilities and industrial areas In food preparation and handling areas: dilution at 5% (v/v), contact time of 5 min at 20°C and 4% (v/v), contact time of 15 min at 40°C for Bactericidal activity and 8% (v/v), contact time of 15 min at 20°C and 6% (v/v), contact time of 30 min at 40°C for yeasticidal activity. Dilution at 10% (v/v) for wiping application. Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 14. Use # 2 – META SPC 7: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside) and disinfection for area of food preparation and handling. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping~~), Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	30ml/m2 - 20 sprays directly on the surface per m2 / Wiping application for hard surfaces: 8 to 12 sprays or 16 ml onto wipe per 0.1 m2 For spraying, scrubbing, mopping, brushing on hard surfaces: 10% (v/v) in medical area 8% (v/v), contact time of 15 min at 20°C and 6% (v/v), contact time of 30 min at 40°C in institutional, healthcare facilities and industrial areas In food preparation and handling areas: dilution at 5% (v/v), contact time of 5 min at 20°C and 4% (v/v), contact time of 15 min at 40°C for Bactericidal activity and 8% (v/v), contact time of 15 min at 20°C and 6% (v/v), contact time of 30 min at 40°C for yeasticidal activity. Dilution at 10% (v/v) for wiping application. Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 15. Use # 3 – META SPC 7: Disinfectants for hard surfaces of industry, institution, healthcare facilities and health care areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection for industry, institution, healthcare facilities and health care including toilets bowls. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and health care areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping~~), Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Dilution at 10% (v/v): 30ml/m2 - 20 sprays directly on the surface per m2 for spraying, scrubbing, mopping, brushing on hard surfaces. Dilution at 10% (v/v): wiping application for hard surfaces: 8 to 12 sprays or 16 ml on wipe per 0.1 m2 Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Table 16. Use # 4 – META SPC 7: Disinfectants for hard surfaces of industry, institution and healthcare facilities areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside). Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution and healthcare facilities areas.
Application method(s)	Spraying, Wiping (applying product onto wipe followed by wiping ~~and applying product onto surface followed by wiping~~), Brushing (applying product onto brush followed by brushing), scrubbing (machine), Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Dilution at 8% (v/v): 30ml/m2 - 20 sprays directly on the surface per m2 for spraying, scrubbing, mopping, brushing on hard surfaces. Dilution at 10% (v/v): wiping application for hard surfaces: 8 to 12 sprays or 16 ml on wipe per 0.1 m2 Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 8:

Table 17. Use # 1 – META SPC 8: Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of households surfaces including toilets bowls. Detergent, disinfectant (bactericidal activity). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor, domestic area
Application method(s)	Wiping (applying product onto wipe followed by wiping), Brushing, ~~scrubbing,~~ Mopping (applying product onto mop followed by mopping)
Application rate(s) and frequency	Dilution at 6% (v/v): 30ml/m2 - Dilution at 6% (v/v) for wiping, scrubbing, mopping and brushing on hard surfaces. Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 9:

Table 18. Use # 1 – META SPC 9: Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of households surfaces including toilet bowls. Detergent, disinfectant (bactericidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor, domestic area
Application method(s)	Spraying, Pouring ~~Wiping (applying product onto surface followed by wiping), Brushing, scrubbing, Mopping (applying product onto surface followed by mopping)~~
Application rate(s) and frequency	100% - 30 ml/m2 - 20 sprays directly on the surface per m2 - RTU Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Table 19. Use # 2 – META SPC 9: Disinfectants for hard surfaces in companion animals' environment for private homes and pets shelters

Product Type	PT03 - Veterinary hygiene (Disinfectants) PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of households surfaces and in companion animals' environment including pets shelters and animal housing and associated equipment. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of non-porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, households and pets shelters
Application method(s)	Spraying, Pouring ~~Wiping (applying product onto surface followed by wiping), Brushing, scrubbing, Mopping (applying product onto surface followed by mopping)~~
Application rate(s) and frequency	100% - 30 ml/m2 - 20 sprays per m2 - RTU **Animal housings with hay (hutches, henhouses…):** Treat the floors and a height of 50cm of the walls. „Should not be applied directly to garden ground." One application per month **Animal housings without hay (dog kennel…):** Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 10:

Table 20. Use # 1 – META SPC 10: Disinfectants for hard surfaces of domestic area

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of households surfaces. Detergent, disinfectant (bactericidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria
Field of use	Indoor, domestic area
Application method(s)	Spraying, ~~Wiping (applying product onto surface followed by wiping),~~ Brushing, ~~scrubbing~~, ~~Mopping (applying product onto surface followed by mopping)~~, Pouring
Application rate(s) and frequency	Dilution at 6% (v/v): 30 ml/m2 for wiping, scrubbing, mopping, brushing on hard surfaces.

	Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Table 21. Use # 2 – META SPC 10: Disinfectants for hard surfaces in companion animals' environment for private homes and pets shelters

Product Type	PT03 - Veterinary hygiene (Disinfectants) PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of households surfaces and in companion animals' environment including pets shelters and animal housing and associated equipment. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of non porous surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, households and pets shelters
Application method(s)	Spraying~~, Wiping (applying product onto surface followed by wiping),~~ Brushing, ~~scrubbing,~~ ~~Mopping (applying product onto surface followed by mopping)~~, Pouring
Application rate(s) and frequency	Dilution at 10% (v/v): 30 ml/m2 for wiping, scrubbing, mopping, brushing on hard surfaces. **Animal housings with hay (hutches, henhouses…):** Treat the floors and a height of 50cm of the walls „Should not be applied directly to garden ground." One application per month **Animal housings without hay (dog kennel…):** Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 11:

Table 22. Use # 1 – META SPC 11: Disinfectants for hard surfaces of industry, institution and healthcare facilities and food preparation and handling areas

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate.

	Product used for the disinfection of industry, institution and healthcare facilities including toilets bowls (outside) and disinfection for area of food preparation and handling. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor, Industry, institution, healthcare facilities and food preparation and handling areas.
Application method(s)	Pouring, Spraying, ~~Brushing~~, scrubbing, ~~Mopping (applying product onto surface followed by mopping)~~
Application rate(s) and frequency	30 ml/m2 - For spraying, scrubbing, mopping, brushing on hard surfaces: 1.5% (v/v), contact time of 15 min at 20°C and 1% (v/v), contact time of 30 min at 40°C in institutional, healthcare facilities and industrial areas. In food preparation and handling areas : dilution at 1.5% (v/v), contact time of 5 min at 20°C and 0.5% (v/v), contact time of 15 min at 40°C for Bactericidal activity including *Salmonella typhimurium* and *Listeria monocytogenes* and 1.5% (v/v), contact time of 15 min at 20°C and 1% (v/v), contact time of 30 min at 40°C for yeasticidal activity. Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 12:

Table 23. Use # 1 – META SPC 12: Disinfectants for hard surfaces for industry, institution, healthcare facilities and health care

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-To-Use (RTU). Product used for the disinfection of industry, institution, healthcare facilities and health care for the inside of toilets bowls. Detergent, disinfectant (bactericidal and yeasticidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts

Field of use	Indoor, healthcare facilities, health care, institution and industry areas
Application method(s)	Pouring, ~~Brushing, scrubbing~~
Application rate(s) and frequency	100% - 30 ml/m2 - RTU Daily
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 13:

Table 24. Use # 1 – META SPC 13: Disinfectants for hard surfaces of industry, institution and healthcare facilities

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Concentrate. Product used for the disinfection of households surfaces. Detergent, disinfectant (bactericidal activities). Use for cleaning and disinfection of all kind of surfaces.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor and outdoor, Industry, institution, healthcare facilities
Application method(s)	Pouring, Spraying, ~~Wiping (applying product onto surface followed by wiping), Brushing,~~ scrubbing, ~~Mopping (applying product onto surface followed by mopping)~~
Application rate(s) and frequency	Dilution at 8% (v/v): 30ml/m2 for the disinfection of waste containers and around and roadways for spraying, scrubbing, wiping, mopping, brushing on hard surfaces. Disinfection of waste containers and around: Daily Disinfection of roadways: One application per day Surface treatment: 15 000 m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Information on physicochemical data for the biocidal product family were submitted in accordance with the technical document CA-Nov14-Doc.5.8 – Final.rev3 (2). The assessment and testing strategy are based on the realistic parameters for each Meta-SPC, that means that testing formula is one of the marketing formula of the Meta-SPC or the testing formula is very close in terms of composition of the marketing formula. So studies have been realized for each Meta-SPC and in some cases bridging justification between Meta-SPC is used.

Meta SPC	Tested formula	
	Product of the Meta SPC	Very close in terms of composition
Meta SPC 1 (2 products)		X (218087-P1)
Meta SPC 2 (2 products)		X (218221-P2)
Meta SPC 3 (1 product)		X (218242-P1)
Meta SPC 4 (1 product)	218114-B3	
Meta SPC 6 (4 products)		X (218228-P1)
Meta SPC 7 (2 products)		X (218291-P3)
Meta SPC 8 (1 product)		X (218282-P1)
Meta SPC 9 (1 product)	218284-V1	
Meta SPC 10 (1 product)	218291-V1	
Meta SPC 11 (1 product)		X (218255-P1)
Meta SPC 12 (1 product)		X (218282-P1)
Meta SPC 13 (1 product)	218285-V1	

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item: 218087-P1	The appearance of the test item was homogeneous colourless limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-009	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item: 218087-P1	Before the accelerated storage procedure, the mean value of the test item acidity was 1.25% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 1.31% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-009	Acceptable
pH value	CIPAC MT 75.3	Batch 5118225 Test item: 218087-P1	Before accelerated storage: pH=2.38 at 19,6°C After accelerated storage: pH=2,43 at 21,1°C	Demangel B. and Ricau H., 2019, Report No 18-901011-009	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD Guideline No. 109 (2012)	Batch 5118225 Test item: 218087-P1	The mean relative density of the test item was D^{20}_4 = 1.013 ± 0.001 at 20.4 °C.	Demangel B., 2019, Report No 18-901011-008	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR Evaluation</th></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-012</td><td>Batch 5118225
Test item: 218087-P1</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous colourless limpid liquid with a characteristic odour.
Packaging: Transparent HDPE sprayer with foam nozzle (no sign of degradation or leak was observed).

The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.1%).
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><th colspan="2">Active substance</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>2.37</td><td>2.37</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value -1.3</td><td>From the T = 0 value 0.0</td></tr>
</table>
</td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-009</td><td>Acceptable The product is stable after 14 days at 54°C.</td></tr>
</table>

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
	pH : CIPAC Handbook J - MT 75.3 method (2000) SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME : in-house method SPRAY		**DETERMINATION OF pH VALUES** Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.38 at 19.6 °C after 1 min and 2.37 at 19.7 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.43 at 21.1 °C after 1 min and 2.42 at 21.3 °C after 2 min. **SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME** Before the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.43 mL. The foam nozzles of the sprays were checked and no blocking was observed. After the accelerated storage procedure, the volume of a pulverisation of the sprayer was 1.19 mL. The foam nozzle of the sprayer was checked and no blocking was observed. **SPRAY DIAMETER AND PATTERN** Before the accelerated storage procedure, the mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. After the accelerated storage procedure, the spray diameter of the sprayer was 12 cm. The shape of the spray on the wetted patch was circular.		

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
	DIAMETER AND PATTERN : In-house method (FEA 644 adapted)		Products of META SPC 1 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218087-P1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-010	Study required in post-authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5118225 Test item: 218087-P1	At the start of the test, the test item was a homogeneous colourless limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-008	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (500 ml, 750 ml, 1 l, 5 l) and transparent packaging (500 ml, 750 ml, 1 l, 5 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable The active substance, lactic acid, is not light sensitive.

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its hand-operated trigger sprayer and caps, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Wettability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Disintegration time	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Persistent foaming	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
Flowability/Pourability/Dustability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Burning completeness — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Composition of smoke — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Sprayability	In house method	Batch 5118225 Test item: 218087-P1	The mean volume of a pulverisation of the sprayer was 1.43 mL. The foam nozzles of the sprays were checked and no blocking was observed. The mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 1 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required.	Demangel B. and Ricau H., 2019, Report No 18-901011-009	Acceptable
Physical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable

Meta-SPC 1 (AL – ready to use) Packaging: trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR Evaluation**
Chemical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not required as the product is a ready-to-use liquid.	-	Acceptable
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5118225 Test item: 218087-P1	The mean surface tension of the pure test item at 19.9 °C was 25.5 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-008	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218087-P1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 1.41 mPa.s at 20.0 °C ± 0.2 °C and 1.01 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-008	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 1
The Meta-SPC 1 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable. The appearance of the product is an homogeneous colourless limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, COEXTRUDE (HDPE/PA). The long term storage stability study is on-going and should be provided in post-authorisation. Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item: 218221-P2	The appearance of the test item was homogeneous colourless opalescent liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-014	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item: 218221-P2	Before the accelerated storage procedure, the mean value of the test item acidity was 1.62% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 1.73% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-014	Acceptable
pH value	CIPAC MT 75.3	Batch 5118225	Before accelerated storage: pH=2.07 at 19°C After accelerated storage: pH=2,13 at 21°C	Demangel B. and Ricau H.,	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td></td><td>Test item: 218221-P2</td><td></td><td>2019, Report No 18-901011-014</td><td></td></tr>
<tr><td>Relative density / bulk density</td><td>EC A.3. method (2008) and OECD Guideline No. 109 (2012)</td><td>Batch 5118225
Test item: 218221-P2</td><td>The mean relative density of the test item was D^{20}_4 = 1.015 ± 0.001 at 20.3 °C.</td><td>Demangel B., 2019, Report No 18-901011-013</td><td>Acceptable</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-016

pH : CIPAC Handbook J - MT 75.3</td><td>Batch 5118225
Test item: 218221-P2</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous colourless opalescent liquid with a characteristic odour.
Packaging: Transparent HDPE sprayer with foam nozzle (no sign of degradation or leak was observed).

The appearance of the test item and the packaging material was considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0,1%).
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><th>Active substance</th><th>Before the accelerate</th><th>After the accelerate</th></tr>
</table></td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-014</td><td>Acceptable
The product is stable after 14 days at 54°C.

However, a decrease in the mean volume of a pulverisation of the sprayer is noted.
Results after long-term storage are</td></tr>
</table>

<table>
<tr><th colspan="5">Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>method (2000)

SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME : in-house method

SPRAY DIAMETER AND PATTERN : In-house method (FEA 644 adapted)</td><td></td><td>
<table>
<tr><td colspan="2"></td><td>d storage procedure</td><td>d storage procedure</td></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>3.00</td><td>3.01</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value 0.0</td><td>From the T = 0 value +0.3</td></tr>
</table>

DETERMINATION OF pH VALUES
Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.07 at 19.0 °C after 1 min and 2.05 at 19.2 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.13 at 21.0 °C after 1 min and 2.12 at 21.2 °C after 2 min.
SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME
Before the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.38 mL. The foam nozzles of the sprays were checked and no blocking was observed. After the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.05 mL. The nozzles of the sprays were checked and no blocking was observed.</td><td></td><td>required to conclude on the satisfactory operation of the sprayer device.</td></tr>
</table>

Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			SPRAY DIAMETER AND PATTERN Before the accelerated storage procedure, the mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. After the accelerated storage procedure, the spray diameter of the sprayer was 14 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 2 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218221-P2	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-015	Study required in post authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3	Batch 5118225 Test item:	At the start of the test, the test item was a homogeneous pale yellow limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7	Demangel B., 2019, Report No 18-	Acceptable The product is stable

Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	method (2000)	218221-P2	days at 0 ± 2 °C, no change was observed in the test item aspect.	901011-013	after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (500 ml, 750 ml, 1 l, 5 l) and transparent packaging (500 ml, 750 ml, 1 l, 5 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable The active substance, lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its hand-operated trigger sprayer and caps, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Wettability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation

Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Disintegration time	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Persistent foaming	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant
Flowability/Pourability/Dustability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Burning completeness — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Composition of smoke — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Sprayability	In house method	Batch 5118225 Test item: 218221-P2	The mean volume of a pulverisation of the sprayer was 1.38 mL. The foam nozzles of the sprays were checked and no blocking was observed.	Demangel B. and Ricau H., 2019, Report No 18-	Acceptable

Meta-SPC 2 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			The mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 2 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required.	901011-014	
Physical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Chemical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not required as the product is a ready-to-use liquid.	-	Acceptable
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5118225 Test item: 218221-P2	The mean surface tension of the pure test item at 20.1 °C was 24.7 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-013	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218221-P2	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 6.24 mPa.s at 20.0 °C ± 0.2 °C and 2.60 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-013	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 2
The Meta-SPC 2 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable. The appearance of the product is an homogeneous colourless opalescent liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, COEXTRUDE (HDPE/PA). The long term storage stability study is on-going and should be provided in post-authorisation. Its technical characteristics are acceptable for an AL formulation. ➢ **Post-authorisation data : 2022** See specific post-authorisation data paragraph below.

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item:218242-P1	The appearance of the test item was homogeneous colourless opalescent liquid with a characteristic odour.	Demangel B., 2019, Report No 18-901011-018	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item:218242-P1	Before the accelerated storage procedure, the mean value of the test item acidity was 2.92% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 3.03% w/w.	Demangel B., 2019, Report No 18-901011-018	Acceptable
pH value	CIPAC MT 75.3	Batch 5118225	Before accelerated storage: pH=2.12 at 19.3°C	Demangel B., 2019, Report No	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td></td><td>Test item:218242-P1</td><td>After accelerated storage: pH=2,20 at 19.4°C</td><td>18-901011-018</td><td></td></tr>
<tr><td>Relative density / bulk density</td><td>EC A.3. method (2008) and OECD Guideline No. 109 (2012)</td><td>Batch 5118225 Test item:218242-P1</td><td>The mean relative density of the test item was D^{20}_4 = 1.023 ± 0.001 at 20.0 °C.</td><td>Demangel B., 2019, Report No 18-901011-017</td><td>Acceptable</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-020

Content of citric acid: Validated method in study No. 18-901011-021</td><td>Batch 5118225 Test item:218242-P1</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous colourless opalescent liquid with a characteristic odour.
Packaging: Transparent HDPE sprayer with foam nozzle (no sign of degradation or leak was observed).

The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0,1%).
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS and SoC
<table>
<tr><th>Active substances</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
</table></td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-018</td><td>Acceptable The product is stable after 14 days at 54°C.

However, a decrease in the mean volume of a pulverisation of the sprayer is noted. Results after long-term storage are required to conclude on the satisfactory</td></tr>
</table>

<table>
<tr><th colspan="5">Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>pH : CIPAC Handbook J - MT 75.3 method (2000)

SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME : in-house method

SPRAY DIAMETER AND PATTERN : In-house method (FEA 644 adapted)</td><td></td><td>
<table>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>3.93</td><td>3.94</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value -1.8</td><td>From the T = 0 value +0.3</td></tr>
<tr><td rowspan="2">Citric acid (SOC)</td><td>Content (% w/w)</td><td>1.01</td><td>1.00</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value +1.0</td><td>From the T = 0 value -1.0</td></tr>
</table>

DETERMINATION OF pH VALUES
Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.12 at 19.3 °C after 1 min and 2.11 at 19.5 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.20 at 19.4 °C after 1 min and 2.23 at 19.5 °C after 2 min.
SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME
Before the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.37 mL. The foam nozzles of the sprays were checked and no blocking</td><td></td><td>operation of the sprayer device.</td></tr>
</table>

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			was observed. After the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.11 mL. The nozzles of the sprays were checked and no blocking was observed. **SPRAY DIAMETER AND PATTERN** Before the accelerated storage procedure, the mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. After the accelerated storage procedure, the mean spray diameter of the sprayer was 14 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 3 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218242-P1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-019	Study requied in post authorisation

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5118225 Test item: 218242-P1	At the start of the test, the test item was a homogeneous opalescent liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-017	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (500 ml, 750 ml, 1 l, 5 l) and transparent packaging (500 ml, 750 ml, 1 l, 5 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable The active substance, lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its hand-operated trigger sprayer and caps, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Disintegration time	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Persistent foaming	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant
Flowability/Pourability/Dustability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Burning completeness — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Composition of smoke — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Sprayability	In house method	Batch 5118225 Test item: 218242-P1	The mean volume of a pulverisation of the sprayer was 1.37 mL. The foam nozzles of the sprays were checked and no blocking was observed. The mean spray diameter of the sprayer was 15 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 3 will be sold together with a srayer device with foam nozzle, therefore determination of the MMAD is not required.	Demangel B. and Ricau H., 2019, Report No 18-901011-018	Acceptable
Physical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Chemical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not required as the product is a ready-to-use liquid.	-	Acceptable
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5118225 Test item: 218242-P1	The mean surface tension of the pure test item at 20.0 °C was 25.4 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-017	Acceptable

Meta-SPC 3 (AL – ready to use) Packaging : trigger sprays with foam nozzle / bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218242-P1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 3.33 mPa.s at 20.0 °C ± 0.2 °C and 1.67 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-017	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 3

The Meta-SPC 3 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is an homogeneous colourless opalescent liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance and the SoC content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, COEXTRUDE (HDPE/PA). The long term storage stability study is on-going and should be provided in post-authorisation.

Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 1805000317 Test item: 218114-B3	The appearance of the test item was Homogeneous colourless limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-023	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5180500031 7 Test item: 218114-B3	Before the accelerated storage procedure, the mean value of the test item acidity was 1.74% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 1.76% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-023	Acceptable
pH value	CIPAC MT 75.3	Batch 5180500031 7 Test item: 218114-B3	Before accelerated storage: pH=2.12 at 20.1°C After accelerated storage: pH=2,13 at 20.5°C	Demangel B. and Ricau H., 2019, Report No 18-901011-023	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD Guideline No. 109 (2012)	Batch 1805000317 Test item: 218114-B3	The mean relative density of the test item was D^{20}_4 = 1.004 ± 0.001 at 20.0 °C.	Demangel B., 2019, Report No 18-901011-022	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-026

pH : CIPAC Handbook J - MT 75.3 method (2000)

SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME : in-house method

SPRAY</td><td>Batch 1805000317
Test item: 218114-B3</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous colourless limpid liquid with a characteristic odour.
Packaging: Transparent PET sprayer with classic nozzle and Transparent PET sprayer with foam nozzle. (no sign of degradation or leak was observed)

The appearance of the test item and the packaging materials were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant changes of weight were observed (-0.5%).
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><th colspan="2">Active substance</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>3.17</td><td>3.21</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value -0.9</td><td>From the T = 0 value +1.3</td></tr>
</table></td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-023</td><td>Acceptable The product is stable after 14 days at 54°C with both sprayers (classic nozzle / foam nozzle).

However, a decrease in the mean volume of a pulverisation of the sprayer is noted with the classic nozzle. Results after long-term storage are required to conclude on the satisfactory operation of</td></tr>
</table>

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	DIAMETER AND PATTERN : In-house method (FEA 644 adapted)		**DETERMINATION OF pH VALUES** Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.12 at 20.1 °C after 1 min and 2.12 at 20.3 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.13 at 20.5 °C after 1 min and 2.12 at 20.7 °C after 2 min. **SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME** Before the accelerated storage procedure, the mean volume of a pulverisation of the sprayer with a classic nozzle was 1.43 mL. The mean volume of a pulverisation of the sprayer with a foam nozzle was 1.44 mL. Both nozzles of the sprayers were checked and no blocking was observed. After the accelerated storage procedure, the mean volume of a pulverisation of the sprayer with a classic nozzle was 1.22 mL. The mean volume of a pulverisation of the sprayer with a foam nozzle was 1.41 mL. Both nozzles of the sprayers were checked and no blocking was observed. **SPRAY DIAMETER AND PATTERN** Before the accelerated storage procedure, the mean spray diameter of the sprayer with a classic nozzle was 24 cm. The mean spray diameter of the sprayer with a foam nozzle was 17 cm. The shape of the sprays on the wetted patch for both nozzles was		the sprayer device.

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			circular. After the accelerated storage procedure, the mean spray diameter of the sprayer with a classic nozzle was 23 cm. The mean spray diameter of the sprayer with a foam nozzle was 18 cm. The shape of the sprays on the wetted patch for both nozzles was circular. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218114-B3	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-024	study required in poste authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 1805000317 Test item: 218114-B3	At the start of the test, the test item was a homogeneous colourless limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-022	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (500 ml, 750 ml, 1 l, 5 l) and transparent packaging (500 ml, 750 ml, 1 l, 5 l).	-	Acceptable The active substance,

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).		lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its hand-operated trigger sprayer and caps, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Disintegration time	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
					an AL formulation
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Persistent foaming	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant
Flowability/Pourability/Dustability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Burning completeness — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Composition of smoke — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Sprayability	In house method	Batch 1805000317 Test item: 218114-B3	The mean volume of a pulverisation of the sprayer with a classic nozzle was 1.43 mL. The mean volume of a pulverisation of the sprayer with a foam nozzle was 1.44 mL. Both nozzles of the sprayers were checked and no blocking was observed.	Demangel B. and Ricau H., 2019, Report No 18-	Acceptable

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	CIPAC Handbook K - MT 187 method (2003) and ISO 13320:2009		The mean spray diameter of the sprayer with a classic nozzle was 24 cm. The mean spray diameter of the sprayer with a foam nozzle was 17 cm. The shape of the sprays on the wetted patch for both nozzles was circular. Sray droplet size distribution: The following values were obtained for the test item: - The mean diameter in volume dv was 117.2 µm. - The mean diameter in surface dsv was 83.3 µm. - The particule size D(0.1) was 49.33 µm. - The particule size D(0.5) was 102.75 µm. - The particule size D(0.9) was 203.13 µm. The particule size distribution of the test item was found to range approximately 6.31 µm to 464.16 µm.	901011-023 And Demangel B., 2020, Report No 18-901011-024	
Physical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Chemical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not required as the product is a ready-to-use liquid.	-	Acceptable
Surface tension	EC A.5. method	Batch 1805000317	The mean surface tension of the pure test item at 20.0 °C was 27.9 mN/m. The test	Demangel B., 2019,	Acceptable

Meta-SPC 4 (AL – ready to use) packaging : triggers sprays with both foam and classic nozzle / Bottles					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	(2008) and OECD Guideline No. 115 (1995)	Test item: 218114-B3	item was considered as surface-active in the experimental conditions used.	Report No 18-901011-022	
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 1805000317 Test item: 218114-B3	Taking into account the results obtained at 20.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 1.43 mPa.s at 20.0 °C ± 0.2 °C. It was not possible to obtain results at 40.0 °C ± 0.2 °C with our mobiles and viscosimeter as the results were lower 1.0 mPa.s (limit of reliability of the values). Moreover, the ratio (rotation speed/viscosity) was higher than 70.6, the flow was turbulent.	Demangel B., 2019, Report No 18-901011-022	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 4

The Meta-SPC 4 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is an homogeneous colourless limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, COEXTRUDE (HDPE/PA). The long term storage stability study is on-going and should be provided in post-authorisation.

Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 6 (SL- dilution concentrations: 3% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5125352 Test item: 218228-P1	The appearance of the test item was homogeneous slightly yellow limpid liquid with a characteristic odour.	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5125352 Test item: 218228-P1	Before the accelerated storage procedure, the mean value of the test item acidity was 13.0% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 12.1% w/w.	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	Acceptable
pH value	CIPAC MT 75.3	Batch 5125352 Test item: 218228-P1	Before accelerated storage: pH=2.01 at 19.8°C After accelerated storage: pH=1.99 at 21.2°C	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD Guideline	Batch 5125352 Test item: 218228-P1	The mean relative density of the test item was D204 = 1.077 ± 0.001 at 20.0 °C.	Halbwachs P., 2020, Report No 19-	Acceptable

<table>
<tr><td></td><td>No. 109 (2012)</td><td></td><td></td><td>901011-015</td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-034

pH : CIPAC Handbook J - MT 75.3 method (2000)</td><td>Batch 5125352 Test item: 218228-P1</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous slightly yellow limpid liquid with a characteristic odour.
Packaging: Transparent HDPE flask.
The appearance of the test item was considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. The packaging material was considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed.

ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><td colspan="2">Active substance</td><td>Before the accelerated storage procedure</td><td>After the accelerated storage procedure</td></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>24.1</td><td>24.1</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value +0.4</td><td>From the T = 0 value 0.0</td></tr>
</table>
No change was observed in the content of the active substance after the accelerated storage procedure at 54 °C ± 2 °C for 14 days. The test item was considered to be stable.</td><td>Halbwachs P. and Ricau H., 2020, Report No 19-901011-016</td><td>Acceptable except for the dilution stability.

The solution formed after dilution is not stable.
The label of products of META SPC 6 should mention: The product should be used within 30 minutes after dilution.</td></tr>
</table>

			DETERMINATION OF pH VALUES Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.01 at 19.8 °C after 1 min and 2.00 at 20 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 1.99 at 21.2 °C after 1 min and 1.98 at 21.3 °C after 2 min. DILUTION STABILITY OF AQUEOUS SOLUTIONS Before and after the accelerated storage procedure, The test item solution did not remain stable. 60 mL of whitish precipitate (before storage) and two different phases (after storage) were observed on the test item solution at 10% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. WET SIEVE TEST AFTER DILUTION STABILITY Before and after accelerated storage, no residue of the test item was heal on a 75 µm sieve. PERSISTENT FOAM (not required after accelerated storage for a SL formulation) Before the accelerated storage procedure, the mean volume of foam produced after several inversions of the test item diluted at 2% w/w and 10% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 2% w/w		

			in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D at 20 °C ± 2 °C was higher than 65 mL after 1 min of standing. Please see below (persistent foam row): One video has been provided to demonstrate that the presence of the foam will not affect the use of the product. These results can be extrapolated to the other packagings in HDPE, LDPE/HDPE, PET and COEXTRUDE according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218228-P1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-033	Study required in post authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5125352 Test item: 218228-P1	At the start of the test, the test item was a homogeneous slightly yellow limpid liquid. The appearance of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Halbwachs P., 2020, Report No 19-901011-015	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (20 ml, 250 ml, 1 l, 5 l, 120 l, 200 l, 220 l) and transparent packaging (1 l, 5 l, 10 l, 20 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable The active substance, lactic acid, is not light sensitive.

Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its cap, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above)	-	Acceptable
Wettability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Wet sieve analysis and dry sieve test	CIPAC Handbook K - MT 185 method (2003) adapted	Batch 5125352 Test item: 218228-P1	Before the accelerated storage procedure, no residue of the test item was held on a 75-µm sieve. After the accelerated storage procedure, no residue of the test item was held on a 75-µm sieve.	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	Acceptable, although not required for a SL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Disintegration time	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Persistent foaming	CIPAC Handbook O - MT 47.3 method (2017)	Batch 5125352 Test item: 218228-P1	Before the accelerated storage procedure, the mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	At both low and high dilution concentrations, the results are outside acceptable limits. However, it has been demonstrated

			at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D at 20 °C ± 2 °C was higher than 65 mL after 1 min of standing. One video of manual activity under real conditions of use at the maximum dilution concentration efficacy (10% v/v) of the product shows that the quantity of foam formed is not problematic. There is no overflow. The video is saved in IUCLID section 13.		that the presence of the foam will not affect the use of the product. No additional data are required.
Flowability/Pourability/Dustability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	not relevant
Burning completeness — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Composition of smoke — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Spraying pattern — aerosols	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied by spray with propellant gas under pressure.	-	not relevant

Physical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	not relevant
Chemical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	not relevant
Degree of dissolution and dilution stability	CIPAC Handbook O - MT 41.1 method (2017)	Batch 5125352 Test item: 218228-P1	Before the accelerated storage procedure, about 60 mL of white precipitate was observed at the bottom of the measuring cylinder after standing for 24 hours at 30 °C ± 2 °C. The test item solution did not remain stable.. After the accelerated storage procedure, two phases were observed after standing for 24 hours at 30 °C ± 2 °C. The test item solution did not remain stable. After 30 min test, the product was found to be homogenous whitish cloudy liquid (no separation observed).	Halbwachs P. and Ricau H., 2020, Report No 19-901011-016	Not acceptable The solution formed after dilution is not stable. The label of products of META SPC 6 should mention: The product should be used within 30 minutes after dilution.
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5125352 Test item: 218228-P1	The mean surface tension of the test item diluted at 10% w/w in distilled water at 20.2 °C was 25.5 mN/m. The test item was considered as surface-active in the experimental conditions used.	Halbwachs P., 2020, Report No 19-901011-015	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5125352 Test item: 218228-P1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 8.77 mPa.s at 20.0 °C ± 0.2 °C and 4.25 mPa.s at 40.0 °C ± 0.2 °C.	Halbwachs P., 2020, Report No 19-901011-015	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 6

The Meta-SPC 6 is a soluble concentrate (SL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable. The appearance of the product is an homogeneous slightly yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, LDPE/HDPE and COEXTRUDE (HDPE/PA and HDPE/EVAL). As the product is not stable after dilution, the labels should mention: The product should be used within 30 minutes after dilution. Results of the persistent foaming are outside acceptable limits, however it has been demonstrated that the presence of the foam will not affect the use of the product.
The long term storage stability study is on-going and should be provided in post-authorisation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item: 218291-P3	The appearance of the test item was homogeneous pale yellow limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item: 218291-P3	Before the accelerated storage procedure, the mean value of the test item acidity was 6.38% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 6.47% w/w.	Demangel B. and Ricau H., 2019, Report No	Acceptable

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
				18-901011-036	
pH value	CIPAC MT 75.3	Batch 5118225 Test item: 218291-P3	Before accelerated storage: pH=1.74 at 19.4°C After accelerated storage: pH=1.73 at 20°C	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD Guideline No. 109 (2012)	Batch 5118225 Test item: 218291-P3	The mean relative density of the test item was D^{20}_4 = 1.060 ± 0.001 at 20.0 °C.	Demangel B., 2019, Report No 18-901011-035	Acceptable
Storage stability test – **accelerated storage**	CIPAC Handbook J - MT 46.3 method (2000) Content of AS: Validated method in	Batch 5118225 Test item: 218291-P3	Test item characteristics before and after the accelerated storage procedure was: Homogeneous pale yellow limpid liquid with a characteristic odour. Packaging: Transparent HDPE flask. no sign of degradation or leak was observed) The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.1%).	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Acceptable except for the dilution stability. The solution formed after dilution is not stable. The label of products of META SPC 7

<table>
<tr><th colspan="5">Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr>
<td></td>
<td>studies No. 17-901011-001 and No. 18-901011-038

pH : CIPAC Handbook J - MT 75.3 method (2000)</td>
<td></td>
<td>
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><td colspan="2">Active substance</td><td>Before the accelerated storage procedure</td><td>After the accelerated storage procedure</td></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>12.0</td><td>12.0</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value 0.0</td><td>From the T = 0 value 0.0</td></tr>
</table>
DETERMINATION OF pH VALUES
Before the accelerated storage procedure, the mean pH value of the pure test item was: 1.74 at 19.1 °C after 1 min and 1.73 at 19.5 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 1.73 at 20.0 °C after 1 min and 1.72 at 20.0 °C after 2 min.

DILUTION STABILITY OF AQUEOUS SOLUTIONS
Before and after the accelerated storage procedure, two different phases were observed on the test item solution at 15%
</td>
<td></td>
<td>should mention: The product should be used within 30 minutes after dilution.</td>
</tr>
</table>

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA and HDPE/EVAL) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218291-P3	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2019, Report No 18-901011-037	study required in post authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5118225 Test item: 218291-P3	At the start of the test, the test item was a homogeneous pale yellow limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-035	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The biocidal product is packaged in opaque packaging (250 ml, 1 l, 5 l, 120 l, 200 l, 220 l) and transparent packaging (1 l, 5 l, 10 l, 20 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer to above)	-	Acceptable The active substance, lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal	-	-	With its cap, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
product – **temperature and humidity**					
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Wet sieve analysis and dry sieve test	CIPAC Handbook K - MT 185 method (2003) adapted	Batch 5118225 Test item: 218291-P3	Before the accelerated storage procedure, the mean percentage retention of the test item held on a 75-µm sieve was lower than 0.1% of the total sieved test item. After the accelerated storage procedure, no residue of the test item was held on a 75-µm sieve.	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Acceptable, although not required for a SL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Disintegration time	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Persistent foaming	CIPAC Handbook O - MT 47.3 method (2017)	Batch 5118225 Test item: 218291-P3	Before the accelerated storage procedure, the mean volume of foam produced after several inversions of the test item diluted at 3% w/w in standard water D at 20 °C ± 2 °C was 8 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 15% w/w in standard water D at 20 °C ± 2 °C was 4 mL after 1 min of standing. After the accelerated storage procedure. No foam was produced after several inversions of the test item diluted at 3% w/w in standard water D at 20 °C ± 2 °C after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 15% w/w in standard water D at 20 °C ± 2 °C was 4 mL after 1 min of standing.	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Acceptable
Flowability/Pourability/Dustability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Burning rate — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Burning completeness — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Composition of smoke — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Spraying pattern — aerosols	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied by spray with propellant gas under pressure.	-	Not relevant
Physical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Chemical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Degree of dissolution and dilution stability	CIPAC Handbook O - MT 41.1 method (2017)	Batch 5118225 Test item: 218291-P3	Before the accelerated storage procedure, two different phases were observed on the test item solution at 15% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. After the accelerated storage procedure, two different phases were observed on the test item solution at 15% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. After 30 min test, the product was found to be homogenous slightly yellow cloudy liquid (no separation observed).	Demangel B. and Ricau H., 2019, Report No 18-901011-036	Not acceptable The solution formed after dilution is not stable. The label of products of META SPC 7 should mention: The product should be used within 30 minutes

Meta-SPC 7 (SL - dilution concentrations: 6% v/v – 10% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
					after dilution.
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5118225 Test item: 218291-P3	The mean surface tension of the test item diluted at 15% w/w in distilled water at 19.9 °C was 25.2 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-035	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218291-P3	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 5.18 mPa.s at 20.0 °C ± 0.2 °C and 2.78 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-035	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 7

The Meta-SPC 7 is a soluble concentrate (SL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is an homogeneous pale yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET and COEXTRUDE (HDPE/PA and HDPE/EVAL). As the product is not stable after dilution, the labels should mention: The product should be used within 30 minutes after dilution. The long term storage stability study is on-going and should be provided in post-authorisation.

Its technical characteristics are acceptable for a SL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item: 218282-P1	The appearance of the test item was homogeneous slightly yellow limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-040	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item: 218282-P1	Before the accelerated storage procedure, the mean value of the test item acidity was 8.89% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 9.00% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-040	Acceptable
pH value	CIPAC MT 75.3	Batch 5118225 Test item: 218282-P1	Before accelerated storage: pH=1.79 at 20°C After accelerated storage: pH=1.75 at 20.4°C	Demangel B. and Ricau H., 2019, Report No 18-901011-040	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 8 (SL - dilution concentration: 6% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td>Relative density / bulk density</td><td>EC A.3. method (2008) and OECD Guideline No. 109 (2012)</td><td>Batch 5118225 Test item: 218282-P1</td><td>The mean relative density of the test item was D204 = 1.057 ± 0.001 at 20.0 °C.</td><td>Demangel B., 2019, Report No 18-901011-039</td><td>Acceptable</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-043

pH : CIPAC Handbook J - MT 75.3</td><td>Batch 5118225 Test item: 218282-P1</td><td>Test item characteristics before and after the accelerated storage procedure was: Homogeneous slightly yellow limpid liquid with a characteristic odour.
Packaging: White opaque HDPE flask. (no sign of degradation or leak was observed)
The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.2%).

ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><th colspan="2">Active substance</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
<tr><td></td><td>Content (% w/w)</td><td>16.2</td><td>16.1</td></tr>
</table></td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-040</td><td>Acceptable except for the dilution stability.

The solution formed after dilution is not stable.
The label of products of META SPC 8 should mention: The product should be used within 30 minutes after dilution.</td></tr>
</table>

<table>
<tr><th colspan="5">Meta-SPC 8 (SL - dilution concentration: 6% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>method (2000)</td><td></td><td>
<table>
<tr><td>Lactic acid</td><td>Deviation (%)</td><td>From the nominal value +1.3</td><td>From the T = 0 value -0.6</td></tr>
</table>

DETERMINATION OF pH VALUES
Before the accelerated storage procedure, the mean pH value of the pure test item was: 1.79 at 20.0 °C after 1 min and 1.78 at 20.2 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 1.75 at 20.4 °C after 1 min and 1.74 at 20.5 °C after 2 min.

DILUTION STABILITY OF AQUEOUS SOLUTIONS
Before and after the accelerated storage procedure, two different phases were observed on the test item solution at 10% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C.</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Technical Monograph No. 17</td><td>Test item: 218282-P1</td><td>Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).</td><td>Demangel B., 2018, Report No 18-901011-041</td><td>Study required in post-authorisation</td></tr>
</table>

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5118225 Test item: 218282-P1	At the start of the test, the test item was a homogeneous clear yellow limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-039	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not relevant as the biocidal product is packaged in opaque HDPE packaging (1 l).	-	Acceptable The active substance, lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its cap, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Wet sieve analysis and dry sieve test	CIPAC Handbook	Batch 5118225	Before the accelerated storage procedure, no residue of the test item was held on a	Demangel B. and	Acceptable , although not

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	K - MT 185 method (2003) adapted	Test item: 218282-P1	75-µm sieve. After the accelerated storage procedure, no residue of the test item was held on a 75-µm sieve.	Ricau H., 2019, Report No 18-901011-040	required for a SL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Disintegration time	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Persistent foaming	CIPAC Handbook O - MT 47.3 method (2017)	Batch 5118225 Test item: 218282-P1	Before the accelerated storage procedure, the mean volume of foam produced after several inversions of the test item diluted at 4.0% w/w in standard water D at 20 °C ± 2 °C was **higher than 70 mL** after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D at 20 °C ± 2 °C was **higher than 70 mL** after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 4.0% w/w in standard water D at 20 °C ±	Demangel B. and Ricau H., 2019, Report No 18-901011-040	At both low and high dilution concentrations, the results are outside acceptable limits. However, it has been demonstrated that the presence of the foam will

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			2 °C was between 60 mL and 70 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. One video of manual activity under real conditions of use at the maximum dilution concentration efficacy (6% v/v) of the product shows that the quantity of foam formed is not problematic. There is no overflow. The video is saved in IUCLID section 13.		not affect the use of the product. No additional data are required.
Flowability/Pourability/Dustability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Burning rate — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Burning completeness — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Composition of smoke — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Spraying pattern — aerosols	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied by spray with propellant gas under pressure.	-	Not relevant

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Chemical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Degree of dissolution and dilution stability	CIPAC Handbook O - MT 41.1 method (2017)	Batch 5118225 Test item: 218282-P1	Before the accelerated storage procedure, two different phases were observed on the test item solution at 10% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. After the accelerated storage procedure, two different phases were observed on the test item solution at 10% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. After 30 min test, the product was found to be homogenous white opaque liquid (no separation observed)	Demangel B. and Ricau H., 2019, Report No 18-901011-040	Not acceptable The solution formed after dilution is not stable. The label of products of META SPC 8 should mention: The product should be used within 30 minutes after dilution.
Surface tension	EC A.5. method (2008) and OECD Guideline	Batch 5118225 Test item: 218282-P1	The mean surface tension of the test item diluted at 10% w/w in distilled water at 20.0 °C was 24.4 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-	Acceptable

Meta-SPC 8 (SL - dilution concentration: 6% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	No. 115 (1995)			901011-039	
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218282-P1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have non-newtonian properties in the experimental conditions used. The dynamic viscosity varied as following: -At 20.0 °C ± 0.2 °C, from η (1.86 s-1) = 279 mPa.s to η(158.10 s-1) = 27 mPa.s. -At 40.0 °C ± 0.2 °C, from η (3.72 s-1) = 132 mPa.s to η(186.0 s-1) = 19 mPa.s.	Demangel B., 2019, Report No 18-901011-039	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 8

The Meta-SPC 8 is a soluble concentrate (SL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is an homogeneous slightly yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in this commercial packaging in HDPE. As the product is not stable after dilution, the labels should mention: The product should be used within 30 minutes after dilution. Results of the persistent foaming are outside acceptable limits, however it has been demonstrated that the presence of the foam will not affect the use of the product.

The long term storage stability study is on-going and should be provided in post-authorisation.

- **Post-authorisation data : 2022**

  See specific post-authorisation data paragraph below.

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 1805000317 Test item: 218284-V1	The appearance of the test item was homogeneous slightly yellow liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-045	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 1805000317 Test item: 218284-V1	Before the accelerated storage procedure, the mean value of the test item acidity was 1.20% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 1.24% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-045	Acceptable
pH value	CIPAC MT 75.3	Batch 1805000317 Test item: 218284-V1	Before accelerated storage: pH=2.67 at 21°C After accelerated storage: pH=2.70 at 19.3°C	Demangel B. and Ricau H., 2019, Report No 18-901011-045	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD	Batch 1805000317 Test item: 218284-V1	The mean relative density of the test item was D^{20}_4 = 1.021 ± 0.001 at 20.0 °C.	Demangel B., 2019, Report No 18-	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 9 (AL – ready to use)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>Guideline No. 109 (2012)</td><td></td><td></td><td>901011-044</td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-048

pH : CIPAC Handbook J - MT 75.3 method (2000)

SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME : in-house method</td><td>Batch 1805000317
Test item: 218284-V1</td><td>Test item characteristics before and after the accelerated storage procedure was: homogeneous slightly yellow liquid with a characteristic odour.
Packaging: White opaque PET sprayer (no sign of degradation or leak was observed).
The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.5%).
ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS:
<table>
<tr><th colspan="2">Active substance</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>2.37</td><td>2.38</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value -1.3</td><td>From the T = 0 value +0.9</td></tr>
</table>
DETERMINATION OF pH VALUES
Before the accelerated storage procedure,</td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-045</td><td>Acceptable The product is stable after 14 days at 54°C.</td></tr>
</table>

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
	SPRAY DIAMETER AND PATTERN : In-house method (FEA 644 adapted)		the mean pH value of the pure test item was: 2.67 at 21.0 °C after 1 min and 2.66 at 21.1 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.70 at 19.3 °C after 1 min and 2.69 at 19.6 °C after 2 min. **SATISFACTORY OPERATION OF THE SPRAYER AND SPRAY VOLUME** Before the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 1.44 mL. The nozzles of the sprays were checked and no blocking was observed. After the accelerated storage procedure, the mean volume of a pulverisation of the sprayer was 0.48 mL. The nozzles of the sprays were checked: A dysfunction and blocking were observed. **SPRAY DIAMETER AND PATTERN** Before the accelerated storage procedure, the mean spray diameter of the sprayer was 16 cm. The shape of the spray on the wetted patch was circular. After the accelerated storage procedure, the mean spray diameter of the sprayer was 13 cm. The shape of the spray on the wetted patch was circular. Products of META SPC 9 will not be sold together with a sraying device, therefore assessment of spray characteristics are not required.		

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218284-V1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-046	Study requied
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 1805000317 Test item: 218284-V1	At the start of the test, the test item was a homogeneous slightly yellow limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-044	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not relevant as the biocidal product is packaged in opaque packaging (1L and 5L).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its caps, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be	-	Acceptable

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
product - **reactivity towards container material**			stable after 14 days at 54 ± 2°C (please refer above).		
Wettability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Disintegration time	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a ready-to-use liquid. Besides, products of META SPC 9 will not be sold together with a sraying device.	-	Not relevant for an AL

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
					formulation
Persistent foaming	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant
Flowability/Pourability/Dustability	-	-	Not required as the product is a ready-to-use liquid.	-	Not relevant for an AL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Burning completeness — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Composition of smoke — smoke generators	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be applied as a smoke.	-	Not relevant for an AL formulation
Sprayability	In house method	Batch 1805000317 Test item: 218284-V1	The mean volume of a pulverisation of the sprayer was 1.44 mL. The nozzles of the sprays were checked and no blocking was observed. The mean spray diameter of the sprayer was 16 cm. The shape of the spray on the wetted patch was circular.	Demangel B. and Ricau H., 2019, Report No 18-	Acceptable

Meta-SPC 9 (AL – ready to use)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			Products of META SPC 9 will not be sold together with a sraying device, therefore assessment of spray characteristics are not required.	901011-045	
Physical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Chemical compatibility	-	-	Not applicable. The product is a ready-to-use liquid and is not intended to be added to any other product.	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not required as the product is a ready-to-use liquid.	-	Acceptable
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 1805000317 Test item: 218284-V1	The mean surface tension of the pure test item at 20.2 °C was 26.8 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-044	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 1805000317 Test item: 218284-V1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 2.28 mPa.s at 20.0 °C ± 0.2 °C and 1.48 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-044	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 9

The Meta-SPC 9 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.
The appearance of the product is an homogeneous slightly yellow liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET, COEXTRUDE (HDPE/PA). The long term storage stability study is on-going and should be provided in post-authorisation.
Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
Physical state/colour/odour at 20 °C and 101.3 kPa	-	Batch 1805000317 Test item: 218291-V1	The appearance of the test item was homogeneous yellow limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-051	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 1805000317 Test item: 218291-V1	Before the accelerated storage procedure, the mean value of the test item acidity was 3.98% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 4.24% w/w.	Demangel B. and Ricau H., 2019, Report No 18-	Acceptable

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
			After the low temperature stability, the mean value of the test item acidity was 4.03% w/w.	901011-051 Demangel B., 2019, Report No 18-901011-050	
pH value	CIPAC MT 75.3	Batch 18050003 17 Test item: 218291-V1	Before accelerated storage: pH=2.26 at 19.3°C After accelerated storage: pH=2.4 at 19.7°C	Demangel B. and Ricau H., 2019, Report No 18-901011-051	Acceptable
Relative density / bulk density	EC A.3. method (2008) and OECD Guideline No. 109 (2012)	Batch 18050003 17 Test item: 218291-V1	The mean relative density of the test item was D204 = 1.030 ± 0.001 at 20.0 °C.	Demangel B., 2019, Report No 18-901011-049	Acceptable
Storage stability test – **accelerated storage**	CIPAC Handbook J - MT 46.3 method (2000)	Batch 18050003 17 Test item: 218291-V1	Test item characteristics before and after the accelerated storage procedure was: homogeneous yellow limpid liquid with a characteristic odour. Packaging: White opaque HDPE flask. (no sign of degradation or leak was observed)	Demangel B. and Ricau H., 2019, Report No 18-	Acceptable The product is stable after 14 days at 54°C.

<table>
<tr><th colspan="5">Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evalutaion</th></tr>
<tr><td></td><td>Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-054.

Content of Butyldiglycol: Validated method in study No. 18-901011-055.

pH : CIPAC Handbook J - MT 75.3 method (2000)</td><td></td><td>The appearance of the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.2%).

ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCES
Content of AS and SoC:
<table>
<tr><td colspan="2">Active substances</td><td>Before the accelerated storage procedure</td><td>After the accelerated storage procedure</td></tr>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>8.04</td><td>8.11</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value +0.5</td><td>From the T = 0 value +0.9</td></tr>
<tr><td rowspan="2">Butyldiglycol (SOC)</td><td>Content (% w/w)</td><td>5.50</td><td>5.54</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value 0.0</td><td>From the T = 0 value +0.7</td></tr>
</table></td><td>901011-051</td><td></td></tr>
</table>

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
			DETERMINATION OF pH VALUES Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.26 at 19.3 °C after 1 min and 2.24 at 19.3 °C after 2 min. After the accelerated storage procedure, the mean pH value of the pure test item was: 2.40 at 19.7 °C after 1 min and 2.38 at 20.0 °C after 2 min. **DETERMINATION OF EMULSION CHARACTERISTICS** Before the accelerated storage procedure, the emulsions at 2% w/w and 10% w/w in standard waters A and D at 30 °C ± 2 °C were considered to be stable. After the accelerated storage procedure, the emulsions at 2% w/w and 10% w/w in standard waters A and D at 30 °C ± 2 °C were considered to be stable (only 3mL of white cream or oily yellow phase noticed at 10% after 24h in water A and D)		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218291-V1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-	Study required in post-authorisation

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
				901011-052	
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000) pH : CIPAC Handbook J - MT 75.3 method (2000)	Batch 1805000317 Test item: 218291-V1	At the start of the test, the test item was a homogeneous yellow limpid liquid. The appearance of the test item was considered to be stable after a low temperature stability at 0 ± 2 °C for 7 days, no change was observed in the test item aspect. **DETERMINATION OF pH VALUES** After the low temperature stability, the mean pH value of the pure test item was: 2.34 at 20.8 °C after 1 min and 2.33 at 20.9 °C after 2 min.	Demangel B., 2019, Report No 18-901011-05	Acceptable The product is stable after 7 days at 0°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not relevant as the biocidal product is packaged in opaque packaging (1L).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its cap, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
					a ME formulation.
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.
Wet sieve analysis and dry sieve test	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC Handbook K - MT 36.3 method (2003)	Batch 1805000317 Test item: 218291-V1	Before the accelerated storage procedure, the emulsions at 2% w/w and 10% w/w in standard waters A and D at 30 °C ± 2 °C were considered to be stable after 30 min, 2h, 24 h and also after remulsification 30s and 30 min. After the accelerated storage procedure, the emulsions at 2% w/w and 10% w/w in standard waters A and D at 30 °C ± 2 °C were considered to be stable after 30 min, 2h and also after remulsification 30s and 30 min. After 24h, 3mL of cream were detected on result at 10% in standard water A, other conditions at 24h are stable (trace or oil or cream detected). After the low temperature stability, the	Demangel B. and Ricau H., 2019, Report No 18-901011-051 Demangel B., 2019, Report No 18-901011-050	Acceptable

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
			emulsions at 2% w/w and 10% w/w in standard waters A and D at 30 °C ± 2 °C were considered to be stable after 30 min, 2h, 24 h and also after remulsification 30s and 30 min.		
Disintegration time	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.
Persistent foaming	CIPAC Handbook O - MT 47.3 method (2017).	Batch 18050003 17 Test item: 218291-V1	Before the accelerated storage procedure, the mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was **60 mL** after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w in standard water D at 20 °C ± 2 °C was **45 mL** after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was between 50 mL and 60 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 10% w/w	Demangel B. and Ricau H., 2019, Report No 18-901011-051	Acceptable

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
			in standard water D at 20 °C ± 2 °C was 50 mL and 60 mL after 1 min of standing.		
Flowability/Pourability/Dustability	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.
Burning rate — smoke generators	-	-	Not applicable. The product is a micro-emulsion liquid and is not intended to be applied as a smoke.	-	Not relevant
Burning completeness — smoke generators	-	-	Not applicable. The product is a micro-emulsion liquid and is not intended to be applied as a smoke.	-	Not relevant
Composition of smoke — smoke generators	-	-	Not applicable. The product is a micro-emulsion liquid and is not intended to be applied as a smoke.	-	Not relevant
Spraying pattern — aerosols	-	-	Not applicable. The product is a micro-emulsion liquid and is not intended to be applied by spray with propellant gas under pressure.	-	Not relevant
Physical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Chemical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Degree of dissolution and dilution stability	-	-	Not required as the product is a micro-emulsion (ME).	-	Not relevant for a ME formulation.

Meta-SPC 10 (ME - dilution concentrations: 6% v/v – 8% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evalutaion**
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 1805000317 Test item: 218291-V1	The mean surface tension of the test item diluted at 10% w/w in distilled water at 20.1 °C was 26 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-049	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 1805000317 Test item: 218291-V1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 6.65 mPa.s at 20.0 °C ± 0.2 °C and 3.71 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-049	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 10

The Meta-SPC 10 is a micro-emulsion (ME) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is an homogeneous yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance and the SoC content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in this commercial packaging in HDPE. The long term storage stability study is on-going and should be provided in post-authorisation.

Its technical characteristics are acceptable for a ME formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Physical state/odour/colour at 20 °C and 101.3 kPa	-	Batch 5118225 Test item: 218255-P1	The appearance of the test item was homogeneous slightly yellow limpid liquid with a characteristic odour.	Demangel B. and Ricau H., 2019, Report No 18-901011-057	Acceptable
Acidity / alkalinity	CIPAC Handbook L - MT 191 method (2006)	Batch 5118225 Test item: 218255-P1	Before the accelerated storage procedure, the mean value of the test item acidity was 12.8% w/w. After the accelerated storage procedure, the mean value of the test item acidity was 13.1% w/w.	Demangel B. and Ricau H., 2019, Report No 18-901011-057	Acceptable
pH value	CIPAC MT 75.3	Batch 5118225 Test item: 218255-P1	Before accelerated storage: pH=2.55 at 19°C After accelerated storage: pH=2.61 at 19.6°C	Demangel B. and Ricau H., 2019, Report No 18-901011-057	Acceptable
Relative density / bulk density	EC A.3. method (2008) and	Batch 5118225	The mean relative density of the test item was D204 = 1.057 ± 0.001 at 20.0 °C.	Demangel B., 2019,	Acceptable

<table>
<tr><th colspan="5">Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>OECD Guideline No. 109 (2012)</td><td>Test item: 218255-P1</td><td></td><td>Report No 18-901011-056</td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC Handbook J - MT 46.3 method (2000)

Content of AS: Validated method in studies No. 17-901011-001 and No. 18-901011-059

Content of Potassium sorbate and Amines, coco alkyldimethyl, N-oxides: Validated methods in studies No.</td><td>Batch 5118225 Test item: 218255-P1</td><td>Test item characteristics before the accelerated storage procedure was: homogeneous slightly yellow limpid liquid with a characteristic odour and after the accelerated storage procedure was: homogeneous yellow limpid liquid with a characteristic odour.
Packaging: Transparent HDPE flask.

The appearance of the test item has changed slightly (slightly yellow to yellow) however the test item and the packaging material were considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days. No significant change of weight was observed (-0.1%).

ANALYTICAL QUANTIFICATION OF THE ACTIVE SUBSTANCE
Content of AS and SoC:
<table>
<tr><th>Active substances</th><th>Before the accelerated storage procedure</th><th>After the accelerated storage procedure</th></tr>
</table></td><td>Demangel B. and Ricau H., 2019, Report No 18-901011-057</td><td>Acceptable The product is stable after 14 days at 54°C.</td></tr>
</table>

<table>
<tr><th colspan="5">Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)</th><th></th></tr>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td>18-901011-060 and No. 18-901011-066 respectively

pH : CIPAC Handbook J - MT 75.3 method (2000)</td><td></td><td>
<table>
<tr><td rowspan="2">Lactic acid</td><td>Content (% w/w)</td><td>24.0</td><td>23.9</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value 0.0</td><td>From the T = 0 value -0.4</td></tr>
<tr><td rowspan="2">Potassium sorbate (SOC)</td><td>Content (% w/w)</td><td>0.884</td><td>0.815</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value -11.6</td><td>From the T = 0 value -7.8</td></tr>
<tr><td rowspan="2">Amines, coco alkyldimethyl, N-oxides (SOC)</td><td>Content (% w/w)</td><td>5.36</td><td>5.68</td></tr>
<tr><td>Deviation (%)</td><td>From the nominal value +7.0</td><td>From the T = 0 value +6.0</td></tr>
</table>
.
DETERMINATION OF pH VALUES
Before the accelerated storage procedure, the mean pH value of the pure test item was: 2.55 at 19.0 °C after 1 min and 2.55 at 19.2 °C after 2 min. After the accelerated storage procedure,The mean pH value of the pure test item was: 2.61 at 19.6 °C after 1 min and 2.55 at 19.7 °C after 2 min.</td><td></td><td></td></tr>
</table>

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			DILUTION STABILITY OF AQUEOUS SOLUTIONS Before and after the accelerated storage procedure, no separated material was noted on the test item solution at 2% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. The test item solution remained stable. These results can be extrapolated to the other packagings in HDPE, PET and COEXTRUDE (HDPE/PA and HDPE/EVAL) according to ECHA Guidance Vol. I, Parts A+B+C (3), 3.6.4.2 Point 3.4.2 Table 7.		
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17	Test item: 218255-P1	Ongoing study - the results of this study will be submitted once this study will be finalised (November 2020).	Demangel B., 2018, Report No 18-901011-058	Study required in post authorisation
Storage stability test – **low temperature stability test for liquids**	CIPAC Handbook J - MT 39.3 method (2000)	Batch 5118225 Test item: 218255-P1	At the start of the test, the test item was a homogeneous yellow limpid liquid. The aspect of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item aspect.	Demangel B., 2019, Report No 18-901011-056	Acceptable
Effects on content of the active substance and	-	-	The biocidal product is packaged in opaque packaging (250 ml, 1 l, 5 l, 200 l, 220 l) and	-	Acceptable

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
technical characteristics of the biocidal product - **light**			transparent packaging (1 l, 5 l, 10 l, 20 l). The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).		The active substance, lactic acid, is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	With its cap, the packagings are leak-tight. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Experience on the product has proved that no reactivity is expected towards container materials. The test item is considered to be stable after 14 days at 54 ± 2°C (please refer above).	-	Acceptable
Wettability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Wet sieve analysis and dry sieve test	-	-	Not required.	-	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Disintegration time	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation.
Persistent foaming	CIPAC Handbook O - MT 47.3 method (2017)	Batch 5118225 Test item: 218255-P1	Before the accelerated storage procedure,The mean volume of foam produced after several inversions of the test item diluted at 1% w/w in standard water D at 20 °C ± 2 °C was **higher than 70 mL** after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was **higher than 70 mL** after 1 min of standing. After the accelerated storage procedure. The mean volume of foam produced after several inversions of the test item diluted at 1% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. The mean volume of foam produced after several inversions of the test item diluted at 2% w/w in standard water D at 20 °C ± 2 °C was higher than 70 mL after 1 min of standing. One video of manual activity under real conditions of use at the maximum dilution concentration efficacy (1.5% v/v) of the product shows that the quantity of foam formed is not problematic. There is no overflow. The video is saved in IUCLID section 13.	Demangel B. and Ricau H., 2019, Report No 18-901011-057	At both low and high dilution concentrations, the results are outside acceptable limits. However, it has been demonstrated that the presence of the foam will not affect the use of the product. No additional data are required.

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Flowability/Pourability/Dustability	-	-	Not required as the product is a soluble concentrate (SL).	-	Not relevant for a SL formulation
Burning rate — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Burning completeness — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Composition of smoke — smoke generators	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied as a smoke.	-	Not relevant
Spraying pattern — aerosols	-	-	Not applicable. The product is a soluble concentrate liquid and is not intended to be applied by spray with propellant gas under pressure.	-	Not relevant
Physical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Chemical compatibility	-	-	Not applicable. The product is a concentrated liquid to dilute with water and is not intended to be added to any other product.	-	Not relevant
Degree of dissolution and dilution stability	CIPAC Handbook O - MT 41.1 method (2017)	Batch 5118225 Test item: 218255-P1	Before the accelerated storage procedure, no separated material was noted on the test item solution at 2% w/w in standard water D after standing for 24 h at 30 °C ± 2 °C. The test item solution remained stable. After the accelerated storage procedure, no separated material was noted on the test item solution at 2% w/w in standard water D after	Demangel B. and Ricau H., 2019, Report No 18-901011-057	Acceptable

Meta-SPC 11 (SL - dilution concentration: 1% v/v – 1.5% v/v)					
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
			standing for 24 h at 30 °C ± 2 °C. The test item solution remained stable. After 30 min test, the product was found to be homogenous colorless limpid liquid (no separation observed).		
Surface tension	EC A.5. method (2008) and OECD Guideline No. 115 (1995)	Batch 5118225 Test item: 218255-P1	The mean surface tension of the test item diluted at 2% w/w in distilled water at 20.0 °C was 25.1 mN/m. The test item was considered as surface-active in the experimental conditions used.	Demangel B., 2019, Report No 18-901011-056	Acceptable
Viscosity	OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993)	Batch 5118225 Test item: 218255-P1	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 7.75 mPa.s at 20.0 °C ± 0.2 °C and 3.91 mPa.s at 40.0 °C ± 0.2 °C.	Demangel B., 2019, Report No 18-901011-056	Acceptable

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 11
The Meta-SPC 11 is a soluble concentrate (SL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable. The appearance of the product is an homogeneous slightly yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance and the SoC content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in these commercial packagings in HDPE, PET and COEXTRUDE (HDPE/PA and HDPE/EVAL). Results of the persistent foaming are outside acceptable limits, however it has been demonstrated that the presence of the foam will not affect the use of the product. The long term storage stability study is on-going and should be provided in post-authorisation. Its technical characteristics are acceptable for a SL formulation. ➢ **Post-authorisation data : 2022** See specific post-authorisation data paragraph below.

META SPC 12 (AL – ready to use)

Read across:

The comparison of the composition between the individual product of META SPC 12 and the product (218282-P1) assessed for the META SPC 8 demonstrates that all physico and chemical properties of META SPC 12 can be extrapolated from data obtained for META SPC 8. The justification of bridging is reported in the confidential annex.

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 12
The Meta-SPC 12 is an other liquid (AL) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The appearance of the product is a colourless limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in this commercial packaging in HDPE. Results of the persistent foaming are outside acceptable limits, however it has been demonstrated that the presence of the foam will not affect the use of the product.
The long term storage stability study is on-going and should be provided in post-authorisation.
Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

META SPC 13 (ME – dilution concentration : 8% v/v)

Read across:

The comparison of the composition between the individual product of META SPC 13 and the product (218291-V1) assessed for the META SPC 10 demonstrates that all physico and chemical properties of META SPC 13 can be extrapolated from data obtained for META SPC 10.
The dilution concentration of META SPC 13 (8% v/v) is covered by the dilution concentrations of META SPC 10 (6% v/v – 8% v/v).
The justification of bridging is reported in the confidential annex.

Conclusion on the physical, chemical and technical properties of the product: Meta-SPC 13

The Meta-SPC 13 is a micro-emulsion (ME) formulation. All studies above have been performed in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.
The appearance of the product is an homogeneous yellow limpid liquid with a characteristic odour. There is no effect of high temperature (14 days at 54°C) and low temperature (7 days at 0°C) on the stability of the formulation, neither the active substance and the SoC content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient

temperature when stored in these commercial packagings in HDPE, PET and COEXTRUDE (HDPE/PA and HDPE/EVAL). The long term storage stability study is on-going and should be provided in post-authorisation.
Its technical characteristics are acceptable for a ME formulation.

- **Post-authorisation data : 2022**
  See specific post-authorisation data paragraph below.

- **Post-authorisation data : 2022**

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Analytical method for active substance used is described in study 18-901011-001 assessed in analytical method part below</td><td>Meta SPC 1
Product : AL S1-2-0</td><td>Product AL S1-2-0 was stored for 2 years in commercial packaging material (HDPE spray bottle – trigger spray: OpUs[tm])
<table>
<tr><td></td><td>initial</td><td>After 2years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>2.37 %</td><td>2.38 %</td></tr>
<tr><td>packaging</td><td colspan="2">No change
No clogging of spray</td></tr>
<tr><td>pH pure item</td><td>2.38</td><td>2.46</td></tr>
<tr><td>Acidity (% w/w)</td><td>1.25%</td><td>1.28%</td></tr>
<tr><td>Spray volume per trigger</td><td>1.43 mL</td><td>1.44 mL</td></tr>
<tr><td>Spray diameter</td><td>14 cm</td><td>15 cm</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td><td>Coste E. 2020

18-901011-010
18-901011-011</td><td>Meta SPC 1 products are stable for 2 years at ambient temperature.</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Analytical method for</td><td>Meta SPC 2</td><td>Product AL S2-2-0 was stored for 2 years in commercial packaging material (HDPE spray bottle – trigger spray: OpUs[tm])</td><td>Coste E. 2020</td><td>Meta SPC 2 products are stable for 2</td></tr>
</table>

<table>
<tr>
<td></td>
<td>active substance used is described in study 18-901011-001 assessed in analytical method part below</td>
<td>Product : AL S2-2-0</td>
<td>
<table>
<tr><td></td><td>initial</td><td>After 2years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>3%</td><td>2.93%</td></tr>
<tr><td>packaging</td><td colspan="2">No change
No clogging of spray</td></tr>
<tr><td>pH pure item</td><td>2.07</td><td>2.24</td></tr>
<tr><td>Acidity (% w/w)</td><td>1.62%</td><td>1.67%</td></tr>
<tr><td>Spray volume per trigger</td><td>1.38 mL</td><td>1.37mL</td></tr>
<tr><td>Spray diameter</td><td>14 cm</td><td>15 cm</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td>
<td>18-901011-015
18-901011-069</td>
<td>years at ambient temperature.</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Analytical method for active substance used is described in study 18-901011-001 assessed in analytical method part below</td>
<td>Meta SPC 3
Product : AL S3-2-0</td>
<td>Product AL S3-2-0 was stored for 2 years in commercial packaging material (HDPE spray bottle – trigger spray: OpUs^{tm})
<table>
<tr><td></td><td>initial</td><td>After 2years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>3.93</td><td>3.97</td></tr>
<tr><td>packaging</td><td colspan="2">No change
No clogging of spray</td></tr>
<tr><td>pH pure item</td><td>2.12</td><td>2.11</td></tr>
<tr><td>Acidity (% w/w)</td><td>2.92%</td><td>3.0%</td></tr>
<tr><td>Spray volume per trigger</td><td>1.32 mL</td><td>1.39 mL</td></tr>
<tr><td>Spray diameter</td><td>16 cm</td><td>15 cm</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td>
<td>Coste E. 2020

18-901011-019</td>
<td>Meta SPC 3 products are stable for 2 years at ambient temperature.</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Analytical method for active substance</td>
<td>Meta SPC 4
Product : AL S4-2-0</td>
<td>Product AL S4-2-0 was stored for 2 years in commercial packaging material (HDPE spray bottle with foam and classic nozzle–trigger spray: OpUs^{tm})</td>
<td>Coste E. 2020</td>
<td>Meta SPC 4 products are stable for 2 years at</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>used is described in study 18-901011-001 assessed in analytical method part below</td>
<td></td>
<td>
<table>
<tr><td></td><td>initial</td><td>After 2years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>3.17</td><td>3.27</td></tr>
<tr><td>packaging</td><td colspan="2">No change</td></tr>
<tr><td>pH pure item</td><td>2.12</td><td>2.16</td></tr>
<tr><td>Acidity (% w/w)</td><td>1.74</td><td>1.82</td></tr>
<tr><td>Spray volume per trigger (classic nozzle)</td><td>1.38 mL</td><td>1.34 mL</td></tr>
<tr><td>Spray volume per trigger (foam nozzle)</td><td>1.45 mL</td><td>1.43 mL</td></tr>
<tr><td>Spray diameter (classic nozzle)</td><td>25 cm</td><td>25 cm</td></tr>
<tr><td>Spray diameter (foam nozzle)</td><td>17 cm</td><td>18 cm</td></tr>
<tr><td>Particle size distribution (µm)</td><td>D(0.1) : 49.3
D(0.5) 102.75
D(0.9) 203.13</td><td>D(0.1) 47.52
D(0.5) 90.69
D(0.9) 167.0</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td>
<td>18-901011-024</td>
<td>ambient temperature.</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Analytical method for active substance used is described in study 18-901011-001 assessed in analytical method part below</td>
<td>Meta SPC 6
Product : AL S6-2-0</td>
<td>Product AL S6-2-0 was stored for 2 years in commercial packaging material (HDPE flask)
<table>
<tr><td></td><td>initial</td><td>After 2years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>24.1%</td><td>23.7%</td></tr>
<tr><td>packaging</td><td colspan="2">No change</td></tr>
<tr><td>pH pure item</td><td>2.01</td><td>2.04</td></tr>
<tr><td>Acidity (% w/w)</td><td>13.0%</td><td>12.9%</td></tr>
<tr><td>Dilution stability after 24h</td><td>Not stable</td><td>Not stable</td></tr>
<tr><td>Wet sieve test</td><td>No residue on 75 µm seive</td><td>0.02% on 75 µm seive</td></tr>
</table>
</td>
<td>Coste E. 2020

18-901011-017</td>
<td>Meta SPC 6 products are foaming product, see persistant foaming section.

Meta SPC 6 products are stable for 2 years at ambient temperature.</td>
</tr>
</table>

			Persistent foaming after 1 min At 2% dilution At 10% dilution: > 70 mL / > 70 mL > 70 mL / 55 mL		
Storage stability test – **long term storage at ambient temperature**	Analytical method for active substance used is described in study 18-901011-001 assessed in analytical method part below	Meta SPC 7 Product : AL S7-2-0	Product AL S7-2-0 was stored for 2 years in commercial packaging material (HDPE flask) Lactic acid Content (% w/w): 12.0 % / 11.9% packaging: No change pH pure item: 1.74 / 1.77 Acidity (% w/w): 6/38 % / 6.46 % Dilution stability after 24h: Not stable / Not stable Wet sieve test: < 0/1% on 75 µm seive / < 0.1% on 75 µm seive Persistent foaming after 1 min At 3% dilution: 8 mL / 17 mL At 15% dilution: 4 mL / 12 mL	Coste E. 2020 18-901011-037	Meta SPC 7 products are stable for 2 years at ambient temperature.
Storage stability test – **long term storage at ambient temperature**	Analytical method for active substance used is described in study 18-901011-001 assessed in analytical	Met SPC 8 Product : AL S8-2-0	Product AL S8-2-0 was stored for 2 years in commercial packaging material (HDPE flask) Lactic acid Content (% w/w): 16.2% / 16.3% packaging: No change pH pure item: 1.79 / 1.80 Acidity (% w/w): 8.89% / 9.15%	Coste E. 2020 18-901011-037	Meta SPC 8 products are foaming products, see persistant foaming section. Meta SPC 8 products are stable for 2

<table>
<tr>
<td></td>
<td>method part below</td>
<td></td>
<td>
<table>
<tr><td>Dilution stability after 24h</td><td colspan="2">2 phases at 10% dilution in CIPAC water D</td></tr>
<tr><td>Wet sieve test</td><td>No residue on 75 µm seive</td><td>0.01% on 75 µm seive</td></tr>
<tr><td>Persistent foaming after 1 min
At 3% dilution
At 15% dilution</td><td>
> 70 mL
> 70 mL</td><td>
> 70 mL
> 70 mL</td></tr>
</table>
</td>
<td></td>
<td>years at ambient temperature.</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Analytical method for active substance used is described in study 18-901011-001 assessed in analytical method part below</td>
<td>Meta SPC 10
Product : AL S10-2-1</td>
<td>
Product AL S10-2-1 was stored for 2 years in commercial packaging material (HDPE flask)
<table>
<tr><td></td><td>initial</td><td>After 2 years rt</td></tr>
<tr><td>Lactic acid Content (% w/w)</td><td>8.04</td><td>7.99</td></tr>
<tr><td>packaging</td><td colspan="2">No change</td></tr>
<tr><td>pH pure item</td><td>2.26</td><td>2.41</td></tr>
<tr><td>Acidity (% w/w)</td><td>3.98%</td><td>4.24%</td></tr>
<tr><td>Emulsion characteristics</td><td colspan="2">emulsions at 2% w/w and 10% w/w in standard waters A and D at
30 °C ± 2 °C are stable</td></tr>
<tr><td>Persistent foaming after 1 min
At 2% dilution
At 10% dilution</td><td>
60 mL
45 mL</td><td>
43 mL
48 mL</td></tr>
</table>
</td>
<td>Coste E. 2020

18-901011-052</td>
<td>Meta SPC 10 products are stable for 2 years at ambient temperature.</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Analytical method for AS used is described in</td>
<td>Meta SPC 11
Product : AL S11-2-0</td>
<td>
Product AL S11-2-0 was stored for 2 years in commercial packaging material (HDPE flask)
<table>
<tr><td></td><td>Initial / declared</td><td>18 m rT</td><td>24m rt</td></tr>
</table>
</td>
<td>Coste E. 2020

18-901011-058</td>
<td>The measured content of SOC are quite different</td>
</tr>
</table>

	study 18-901011-001 For SOC, the methods are described in 18-901011-059, 18-901011-060 and 18-901011-066 These methods are assessed below in analytical method part below		Lactic acid Content (% w/w)	24.0% (ref 24%)	24.1%	23.8% (- 0.8% / ref)		from the content declared for this meta SPC. An explanation was requested to the applicant. The reply was: *"We can't explain these results, they are not compliant so we discontinue this meta-SPC 11."* Meta SPC is thus removed from BPF.
			Potassium sorbate	0.884 % (ref 1%)	0.688%	0.613 (-39% /ref)		
			Amines, coco alkyldimethyl, N-oxides	5.36% (ref 16.7%)	5.68%	18.29%		
			packaging	stable				
			pH pure item	2.55	/	2.58		
			Acidity (% w/w)	12.8%	/	13.3%		
			Dilution stability after 24h at 2%	stable	/	stable		
			Wet sieve test	No separate material	/			
			Persistent foaming after 1 min At 3% dilution At 15% dilution	> 70 mL > 70 mL	/	> 70 mL > 70 mL		

➢ **Post-authorisation data : 2022**

- Meta SPC 1, 2, 3, 4, 6, 7, 8 and 10 are demonstrated stable for 2 years.
- Meta SPC 11: the storage stability study is not acceptable.The applicant decided to discontinue this meta-SPC. Meta SPC 11 is thus removed from BPF.
- Meta SPC 9: no shelf life study was submitted but as it is not authorized, no more data is required.

- Meta SPC 12: no shelf life study was provided, but a read across to Meta SPC 8 is proposed. This read across is acceptable.
- Meta SPC 13: no shelf life study was provided, but a read across to Meta SPC 10 is proposed. This read across is acceptable.

2.2.3 Physical hazards and respective characteristics

Information on physical hazards and respective characteristics data for the biocidal product family were submitted in accordance with the technical document CA-Nov14-Doc.5.8 – Final.rev3 (2). The assessment and testing strategy are identicals to physicochemical part. They are based on the realistic parameters for each Meta-SPC, that means that testing formula is one of the marketing formula of the Meta-SPC or the testing formula is very close in terms of composition of the marketing formula. No studies have been realized for each Meta-SPC, except for the property: Corrosive to metals, the results are based on the knowledge of components and the products.

For Meta-SPC 1, 2, 3, 4, 9, 12: Liquid, Ready-To-Use AL
For Meta-SPC 6, 7, 8, 11: Liquid, Concentrate SL
For Meta-SPC 10, 13: Liquid, Concentrate ME

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
Explosives	statement	-	Not required as none of the major components of the product does contain chemical groups which are assiocated with explosive properties.	-	Acceptable In addition, a DSC test was submitted in the scope of self-reactive properties demonstrating no exothermic reaction for authorised meta SPC. In addition, a waiver based on

					the analysis of the composition (see confidential annex) was submitted to support the results of the DSC test.
Flammable gases	-	-	Not required as the product is a liquid.	-	Acceptable
Flammable aerosols	-	-	Not required as the product is a liquid.	-	Acceptable
Oxidising gases	-	-	Not required as the product is a liquid.	-	Acceptable
Gases under pressure	-	-	Not required as the product is a liquid.	-	Acceptable
Flammable liquids	statement	-	The products do not contain any flammable components in amounts that are significant enough to have any impact on the flammability of the final products	-	Acceptable
Flammable solids	-	-	Not required as the product is a liquid.	-	Acceptable
Self-reactive substances and mixtures	statement	-	According to the Guidance on the application of the CLP criteria, "substances and mixtures must be considered for classification in hazard class self-reactive property unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria". Based on the composition, we can expect that the products of the family do not have	-	DSC tests of representative products of all Meta SPCs should be provided in post authorisation to confirm the non-classification in this hazard class.

			self-reactive properties. However, this need to be confirmed. Therefore, DSC tests of representative products of all Meta SPCs should be provided to confirm the non-classification in this hazard class. Moreover, if their heat of decomposition is higher than 300 J/g, the self-accelerating decomposition temperature (SADT) of the products should also be determined.		
	DSC tests Condition used : nitrogen atmosphere Stainless steel crucibles with sealed lids resisting to high-pressure Crimped lid Heating ramp 5°C per minute From 30 to 550°C	Meta SPC 1 – 8 Products: AL-S1-2-0 AL-S2-2-0 AL-S3-2-0 AL-S4-2-0 AL-S6-2-0 AL-S7-2-0 AL-S8-2-0	Results from studies: No exothermic reactions observed for products: AL-S1-2-0, AL-S2-2-0, AL-S3-2-0, AL-S4-2-0, AL-S6-2-0, AL-S7-2-0 and AL-S8-2-0. Some phenomena are observed around 230-250°C without real exothermic peak.	Studies E. Coste 2022: 22-901011-003 22-901011-004 22-901011-005 22-901011-006 22-901011-007 22-901011-008 22-901011-009	Based on the DSC results and analysis of the composition, see confidential annex, eCA considers that products within biocidal family meta SPC 1-8 are not classified as self reactive.
	DSC tests Condition used : nitrogen atmosphere	Meta SPC 10 Products: AL-S10-2-1	Results from studies: two exothermic peaks (decomposition) were observed at	Study E. Coste 2022: 22-901011-010	The positive test found in meta SPC 10 is not consistent with the other DSC tests

	Stainless steel crucibles with sealed lids resisting to high-pressure Crimped lid Heating ramp 5°C per minute From 30 to 550°C		approximatively 100 °C and 200 °C. The total exothermic reaction energy is higher than 500 J/g.		performed on other Meta SPC. Indeed, the results for meta SPC 10 are very different from other DSC graph while the composition is not that different from the other meta SPC. No explanation was submitted by industry. As meta SPC 10 is refused for other reasons, no more data is required.
			meta SPC 9 was not tested, based on the fact meta SPC 9 was refused		Acceptable
			meta SPC 11 was not tested, no read across was proposed by industry.		As Meta SPC 11 is removed from the BPF no more data is required.
			Meta SPC 13 was not tested		Based on the composition, see confidential annex for more details, eCA considers the meta SPC 13 as not classified for self reactive properties.
Pyrophoric liquids	statement	-	Not required as experience in manufacture and handling shows that the product does not ignite	-	Acceptable

			spontaneously on coming into contact with air at normal temperature.		
Pyrophoric solids	-	-	Not required as the product is a liquid.	-	Acceptable
Self-heating substances and mixtures	-	-	Not required as the product is a liquid.	-	Acceptable
Substances and mixtures which in contact with water emit flammable gases	statement	-	Not required as experience in handling and use shows that the product does not react with water.	-	Acceptable
Oxidising liquids	statement	-	Not required as none of the major components of the product does contain chemical groups that act as an oxidising agent.	-	In the compositon of BPF, the only oxygen not bound to a C and H are with phosphate and sulphate functions. These functions are not known to be oxidizing. eCA agrees with applicant that no oxidising properties are expected for products in this BPF.
Oxidising solids	-	-	Not required as the product is a liquid.	-	Acceptable
Organic peroxides	statement	-	Not required as none of the major components of the product does contain organic peroxides.	-	Acceptable

Corrosive to metals	"Manual of tests and criteria" of the United Nations part 37 Condition tested: 7 days at 55°C -carbon steel: S235JR+CR -aluminum alloy: 7075-T6 Size of the specimens: 50x20x2 mm	Batch number of lactic acid: 5125352 Meta SPC 1	Following the 168 hours of testing the "AL-S1-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in depth was measured: the result is considered as positive. The product "AL-S1-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Bulidon N., 2020, Report No IC 860008-1	Acceptable The products of Meta SPC 1 are classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Batch number of lactic acid: 5125352 Meta SPC 2	Following the 168 hours of testing the "AL-S2-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in depth was measured: the result is considered as positive. The product "AL-S2-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Bulidon N., 2020, Report No IC 860008-2	Acceptable The products of Meta SPC 2 are classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Batch number of lactic acid: 5125352 Meta SPC 3	Following the 168 hours of testing the "AL-S3-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in depth was measured: the result is considered as positive. The product "AL-S3-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Fourny P., 2020, Report No IC 860008-3	Acceptable The product is classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Batch number of lactic acid: 5124643 Meta SPC 4	Following the 168 hours of testing the "AL-S4-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in	Fourny P., 2020, Report No IC 860008-4	Acceptable The product is classified as Met. Corr. 1 (H290:

			depth was measured: the result is considered as positive. The product "AL-S4-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.		May be corrosive to metals)
		Batch number of lactic acid: FR101127666 Meta SPC 6	The comparison between AL-S6-2-0 and "Enzypin détartrant désinfectant sanitaires concentré" demonstrated that the corrosive classification of AL-S6-2-0 can be extrapolated from the data obtained with "Enzypin détartrant désinfectant sanitaires concentré". The comparison between the two formulations is reported in the BPF file. Following the 168 hours of test of "Enzypin détartrant désinfectant sanitaires concentré" solution with carbon steel and aluminum alloy specimens, a maximum depth of attack higher than 120 µm was measured: the corrosiveness of the product " Enzypin détartrant désinfectant sanitaires concentré" is grade 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Fourny P., 2016, Report No PV/066/16/LC	Acceptable The products of Meta SPC 6 are classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Batch number of lactic acid: 1811000446 Meta SPC 7	Following the 168 hours of testing the "AL-S7-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in depth was measured: the result is	Fourny P., 2020, Report No IC 860008-5	Acceptable The products of Meta SPC 7 are classified as Met. Corr. 1 (H290:

			considered as positive. The product "AL-S7-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.		May be corrosive to metals)
		Batch number of lactic acid: 5125352 Meta SPC 8	Following the 168 hours of testing the "AL-S8-2-0" solution with carbon steel and aluminum alloy samples, the weight losses obtained were lower than 13.5%. The deepest intrusion measured was lower than 120 µm. The result is therefore not considered as positive. The product "AL-S8-2-0" is not classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Bulidon N., 2020, Report No IC 860008-6	Acceptable
		Batch number of lactic acid: 5123479 Meta SPC 9	Following the 168 hours of testing the "AL-S9-2-0" solution with carbon steel and aluminum alloy samples, an intrusion of more than 120 µm in depth was measured: the result is considered as positive. The product "AL-S9-2-0" is classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Bulidon N., 2020, Report No IC 860008-7	Acceptable The product is classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Batch number of lactic acid: 1805000317 % Meta SPC 10	Following the 168 hours of testing the "AL-S10-2-1" solution with carbon steel and aluminum alloy samples, the weight losses obtained were lower than 13.5%. The deepest intrusion measured was lower than 120 µm. The result is therefore not	Bulidon N., 2020, Report No IC 860008-8	Acceptable

			considered as positive. The product "AL-S10-2-1" is not classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.		
		Meta SPC 11 Batch number of lactic acid: FR101127666	The comparison between AL-S11-2-0 and "Enzypin détartrant désinfectant sanitaires concentré" demonstrated that the corrosive classification of AL-S11-2-0 can be extrapolated from the data obtained with "Enzypin détartrant désinfectant sanitaires concentré" based on the lactic acid content of the 2 formulations. Following the 168 hours of test of "Enzypin détartrant désinfectant sanitaires concentré" solution with carbon steel and aluminum alloy specimens, a maximum depth of attack higher than 120 µm was measured: the corrosiveness of the product " Enzypin détartrant désinfectant sanitaires concentré" is grade 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Fourny P., 2016, Report No PV/066/16/LC	Acceptable The product is classified as Met. Corr. 1 (H290: May be corrosive to metals)
		Meta SPC 12 Batch number of lactic acid: 5125352	The comparison between AL-S12-2-0 and AL-S8-2-0 demonstrated that the corrosive classification of AL-S12-2-0 can be extrapolated from the data obtained with AL-S8-2-0.	Bulidon N., 2020, Report No IC 860008-6	Acceptable

			Following the 168 hours of testing the "AL-S8-2-0" solution with carbon steel and aluminum alloy samples, the weight losses obtained were lower than 13.5%. The deepest intrusion measured was lower than 120 µm. The result is therefore not considered as positive. The product "AL-S8-2-0" is not classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.		
		Meta SPC 13 Batch number of lactic acid: 1805000317	The comparison between AL-S13-2-1 and AL-S10-2-1 demonstrated that the corrosive classification of AL-S13-2-1 can be extrapolated from the data obtained with AL-S10-2-1. Following the 168 hours of testing the "AL-S10-2-1" solution with carbon steel and aluminum alloy samples, the weight losses obtained were lower than 13.5%. The deepest intrusion measured was lower than 120 µm. The result is therefore not considered as positive. The product "AL-S10-2-1" is not classified as a corrosive substance of class 8 according to the specification « Manual of tests and criteria » of the United Nations part 37.	Bulidon N., 2020, Report No IC 860008-6	Acceptable
Auto-ignition temperatures of products (liquids and gases)	statement	-	Not required as none of the major components in the product is auto-flammable.	-	For liquids not flammable in air, determination of the autoignition temperature is not

					a requirement. Since the determination of the flash point is waived based on theoretical considerations, this argumentation can also be used for waiving of the determination of the autoignition temperature.
Relative self-ignition temperature for solids	-	-	Not required as the product is a liquid.	-	Acceptable
Dust explosion hazard	-	-	Not required as the product is a liquid.	-	Acceptable

Conclusion on the physical hazards and respective characteristics of the products: All Meta-SPC

All results above have been defined in accordance with the current requirements (Regulation (EU) No 528/2012 (1) and ECHA Guidance Vol. I, Parts A+B+C (3)) and the results are deemed to be acceptable.

The products are not flammable or explosive and does not possess oxidizing properties. Products of Meta SPC 1, 2, 3, 4, 6, 7, 9 and 11 are considered corrosive to metals.

For self-reactive properties, DSC tests of representative products of all Meta SPCs should be provided in post authorisation to confirm the non-classification in this hazard class.

- **Post-authorisation data : 2022**

For self-reactive properties, DSC tests of representative products of all Meta SPCs were provided in post authorisation. They confirm, in addition with the full analysis of composition present in confidential annex, the non-classification in this hazard class for products within meta SPC 1, 2, 3, 4, 6, 7, 8, 13.

For meta SPC 10, the DSC test is not considered acceptable. As meta SPC 10 is not authorised, the point was not assessed further.

2.2.4 Methods for detection and identification

Information on analytical method data for the biocidal product family were submitted in accordance with the technical document CA-Nov14-Doc.5.8 – Final.rev3 (2). The assessment and testing strategy are identicals to physicochemical part. They are based on the realistic parameters for each Meta-SPC, that means that testing formula is one of the marketing formula of the Meta-SPC or the testing formula is very close in terms of composition of the marketing formula. So studies have been realized for each Meta-SPC.

Meta-SPC	Analytical methods for the analysis of the product as such including the active substance, impurities and residues						
	Analyte (type of analyte e.g. active substance)	**Analytical method**	**Linearity**	**Accuracy**	**Specificity**	**Precision**	**Reference**
Transversal method for determination of Lactic acid in all Meta-SPC Test item: 214063-B1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C	To define the linearity of the detector answer of lactic acid, five concentrations of the reference items were analysed. **The response of the detector during the analysis of lactic acid was linear**	The accuracy was determined by comparison of the reference items and two reconstituted samplings. The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance.	To define the specificity of the analytical method, the following solutions were analyzed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank. In the formulation blank, the reference item	The precision was determined by analysing twice five test item solutions. The content of lactic acid for each analysis was calculated with the average value of the response factor of the two calibration solutions	Ricau H., 2019, Report No 17-901011-001

		and 90 °C during 1 hour then the solution was left to stand at room temperature. Lactic acid was analyzed by liquid chromatography using an UV detector.	**within the range of 1.128 g/L to 12.73 g/L (r = 1.0000).**	Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 100.3% and 100.8%. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 100.3% and 100.8%.**	and the test item, the peak at the retention time around 5.162 min represented lactic acid. No additional peak appeared in the reference item, the formulation blank and in the test item. As the peak area of lactic acid in the formulation blank was lower than 3% of the peak area of lactic acid in the test item, the specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**	bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. **The concentration of lactic acid in the test item was equal to 24.2% w/w or 242 g/kg. In the case of lactic acid, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.26 < 1.66 (C = 0.242).**	
1 Test item: 218087-P1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a		The accuracy was determined by comparison of the reference items and two reconstituted test	To define the specificity of the analytical method, the following solutions were		Ricau H., 2019, Report No 18-

		30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 99.8% and 100.2%.**	analysed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.229 min represented lactic acid. No additional peak appeared in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		901011-012
2 Test item: 218221-P2	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item.		Defitraces, Report No 18-901011-016

		solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		**the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 99.8% and 100.2%.**	No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.138 min represented lactic acid. No additional peak appeared in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		
3 Test item: 218242-P1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing between 1%**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference		Ricau H., 2019, Report No 18-901011-020

		between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. Lactic acid was analyzed by liquid chromatography using an UV detector.		**and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 98.8% and 99.2%.**	item and in the test item, the peak at the retention time at about 6.212 min represented lactic acid. No additional peak appeared in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		
3 Test item: 218242-P1	Citric acid	A quantity of about 1.0 g (to the nearest 0.01 mg) of the test item was weighed into a 20-mL volumetric flask and the volume was made up with the dilution phase solution. Citric acid was analysed by liquid chromatography using a reverse phase column and an UV detector.	To define the linearity of the detector answer of citric acid, five concentrations of the reference items were analysed. **The response of the detector during the analysis of citric acid was linear within the range of 250.14 mg/L to 755.92**	The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of citric acid were in conformity with the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank. In the formulation blank, an unknown peak appeared at the retention time around 5.370 min.	The precision was determined by analysing twice five test item solutions. The content of citric acid for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content,	Ricau H., 2019, Report No 18-901011-021

			mg/L (r = 0.9999).	**should be in the range 97% - 103% and they were experimentally equal to 101.0% and 101.3%.**	In the reference item and in the test item, the peak at the retention time at about 5.360 min represented citric acid. As the peak area of the unknown peak in the formulation blank was lower than 3% of the peak area of citric acid in the test item, the unknown peak was not considered to be interfering peak for the analysis. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of citric acid.**	the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. **The concentration of citric acid in the test item was equal to 1.02% w/w or 10.2 g/kg.** **In the case of citric acid, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.46 < 2.67 (C = 0.0102).**	
4 Test item: 218114-B3	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was		The accuracy was determined by comparison of the reference items and two	To define the specificity of the analytical method, the following		Ricau H., 2019, Report No 18-

		weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. Lactic acid was analyzed by liquid chromatography using an UV detector.		reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 98.3% and 99.1%.**	solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.232 min represented lactic acid. No additional peak appeared in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		901011-026
6 Test item: 218228-P1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation,		Ricau H., 2020, Report No 19-901011-018

		sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature and a vial was taken for analysis. Lactic acid was analyzed by liquid chromatography using an UV detector.		**acid were in conformity with the SANCO/3030/99 rev.5 requirements for formulations containing equal or more than 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 100.2% and 100.4%.**	reference item and test item. No peak appears in the solvent blank and in the formulation blank near the peak of lactic acid. In the reference item and in the test item, the peak at the retention time at about 5.645 min represents lactic acid. No additional peak appears in the reference item and in the test item near the peak of lactic acid. The specificity is therefore defined. **The analytical method showed a good specificity for the analysis of lactic acid in AL-S6-2-0.**		
7 Test item: 218291-P3	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass		The accuracy was determined by comparison of the reference items and two reconstituted test item.	To define the specificity of the analytical method, the following solutions were		Ricau H., 2018, Report No 18-901011-038

		flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		**The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.6% and 99.7%.**	analyzed: solvent blank, blank formulation, reference item and test item. In the solvent blank and in the formulation blank, no peak appeared and in the reference item and in the test item, the peak at the retention time at about 6.078 min represented lactic acid. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		
8 Test item: 218282-P1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic**	To define the specificity of the analytical method, the following solutions were analyzed: solvent blank, blank formulation,		Ricau H., 2018, Report No 18-901011-043

		adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		**acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.2% and 99.6%.**	reference item and test item. No peak appeared in the solvent blank. In the reference item and in the test item, the peak at the retention time at about 6.053 min represented lactic acid. An unknown peak appeared in the formulation blank near the peak of lactic acid at the retention time at about 5.947 min. As the area of the unknown peak was less than 3% of the area of the lactic acid peak, the unknown peak was not considered to be interfering for the calculation. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is therefore defined. **The analytical method showed**		

					a good specificity for analysis of lactic acid.		
9 Test item: 218284-V1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.0%.**	To define the specificity of the analytical method, the following solutions were analyzed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.070 min represented lactic acid. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for**		Ricau H., 2018, Report No 18-901011-048

					analysis of lactic acid.		
10 Test item: 218291-V1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.1 and 99.7%.**	To define the specificity of the analytical method, the following solutions were analyzed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.045 min represented lactic acid. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		Ricau H., 2018, Report No 18-901011-054

10 Test item: 218291-V1	Butyldiglycol (2-(2-butoxyethoxy)ethanol)	A quantity of about 500 mg of the test item was weighed (to the nearest 0.01 mg) into a 100-mL volumetric flask and the volume was made up with methanol. The solution was homogenised before analysis. Butyldiglycol was analysed by gas chromatography using a flame ionisation detector.	To define the linearity of the detector answer of butyldiglycol, five concentrations of the reference items were analysed. **The response of the detector during the analysis of butyldiglycol was linear within the range of 132.03 mg/L to 408.47 mg/L (r = 0.9996).**	The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of butyldiglycol were in conformity with the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 98.2% and 100.8%.**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appears in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time around 8.24 min represents butyldiglycol. No additional peak appears in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of butyldiglycol.**	The precision was determined by analysing twice five test item solutions. The content of butyldiglycol for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. **The concentration of butyldiglycol in the test item was equal to 5.40% w/w or 54.0 g/kg. In the case of butyldiglycol, the precision**	Ricau H., 2019, Report No 18-901011-055

						was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.49 < 2.08 (C = 0.0540).	
11 Test item: 218248-P1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.0%.**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.110 min represented lactic acid. No additional peak appeared in the reference item and in the test item. The specificity is therefore defined.		Ricau H., 2019, Report No 18-901011-059

		using an UV detector.			**The analytical method showed a good specificity for analysis of lactic acid.**		
11 Test item: 218248-P1	Potassium sorbate	A quantity of about 1.0 g of the test item was weighed (to the nearest 0.01 mg) into a 100-mL volumetric flask and the volume was slowly made up with water to avoid the bubbles. The solution was diluted 4 times with water before analysis. Potassium sorbate was analysed by liquid chromatography using a reverse phase column and an UV detector.	To define the linearity of the detector response of potassium sorbate, five concentrations taken between 50% and 150% of the reference items were analysed. **The response of the detector during the analysis of potassium sorbate was linear within the range of 12.75 mg/L to 38.51 mg/L (r = 0.9983).**	The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of potassium sorbate were in conformity with the SANCO/3030/99 rev. 4 requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 101.4% and 100.7%.**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appears in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 3.151 min represents potassium sorbate. No additional peak appears in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for**	The precision was determined by analysing twice five test item solutions. The content of potassium sorbate for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. **The concentration of potassium sorbate in the test item was equal to**	Ricau H., 2019, Report No 18-901011-060

					the analysis of potassium sorbate in AL-S11-2-0.	**0.890% w/w or 8.90 g/kg. In the case of potassium sorbate, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.59 < 2.73 (C = 0.00890).**	
11 Test item: 218248-P1	Amines, coco alkyldimethyl, N-oxides	A quantity of about 0.5 g of the test item was weighed (to the nearest 0.01 mg) into a 50-mL volumetric flask and the volume was made up with propan-2-ol. The solution was homogenised before analysis. Amines, coco alkyldimethyl, N-oxides was analysed by gas chromatography using a flame ionisation detector.	To define the linearity of the detector response of amines, coco alkyldimethyl, N-oxides, five concentrations taken between 50% and 150% of the reference items were analysed. **The response of the detector during the analysis of amines, coco alkyldimethyl, N-oxides was linear within the range of 242.11 mg/L**	The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of amines, coco alkyldimethyl, N-oxides were in conformity with the SANCO/3030/99 rev. 4 requirements for formulations containing between 1% and 10% of an active substance. Indeed, the**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appears in the solvent blank and in the formulation blank. In the reference item and in the test item, an unknown peak (A) appears near the peak of amines C12 at the retention time at about 18.18 min.	The precision was determined by analysing twice five test item solutions. The content of amines, coco alkyldimethyl, N-oxides for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard	Ricau H., 2019, Report No 18-901011-066

			to 755.55 mg/L (r = 0.9987).	**recovery results should be in the range 97% - 103% and they were experimentally equal to 101.3% and 101.9%.**	As the area of the unknown peak (A) was less than 3% of the area of the amines C12, this unknown peak (A) was not considered to be interfering peak for the analysis. In, the reference item and in the test item, the peaks at the retention times at about 17.68 min and 42.79 min represent respectively amine C12 and amine C14. No additional peak appears in the reference item and in the test item near the peaks of amines. The specificity is therefore defined. **The analytical method showed a good specificity for the analysis of amines, coco alkyldimethyl, N-oxides in AL-S11-2-0.**	deviation and the Relative Standard Deviation (R.S.D.) were calculated. **The concentration of amines, coco alkyldimethyl, N-oxides in the test item was equal to 5.30% w/w or 53.0 g/kg. In the case of amines, coco alkyldimethyl, N-oxides, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 1.39 < 2.09 (C = 0.0530).**	
12	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01		The accuracy was determined by comparison of the	To define the specificity of the analytical		Ricau H., 2018, Report No

Test item: 818292-P1		mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography using an UV detector.		reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 99.2% and 99.7%.**	method, the following solutions were analyzed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank. In the reference item and in the test item, the peak at the retention time at about 6.045 min represented lactic acid. An unknown peak appears in the formulation blank near the peak of lactic acid at the retention time at about 6.040 min. As the area of the unknown peak was less than 3% of the area of the lactic acid peak, the unknown peak was not considered to be interfering for the calculation. No additional peak appeared in the reference item, the formulation blank		18-901011-062

					and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		
13 Test item: 218285-V1	Lactic acid	A quantity of about 0.5 g (to the nearest 0.01 mg) of the test item was weighed into a 30-mL glass flask and the weight was adjusted with the sulphuric acid 1N solution until 10 g (to the nearest 0.01 mg). The flask was put in a water-bath between 85 °C and 90 °C during 1 hour then the solution was left to stand at room temperature. The solution was filtered on 0.45-µm filter. Lactic acid was analyzed by liquid chromatography		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of lactic acid were in conformity with the Guidelines requirements for formulations containing more than 10% of an active substance. Indeed, the recovery results should be in the range 98% - 102% and they were experimentally equal to 98.9 and 99.3%.**	To define the specificity of the analytical method, the following solutions were analyzed: solvent blank, blank formulation, reference item and test item. No peak appeared in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time at about 6.033 min represented lactic acid. No additional peak appeared in the reference item, the formulation blank and in the test item. The specificity is		Ricau H., 2018, Report No 18-901011-064

		using an UV detector.			therefore defined. **The analytical method showed a good specificity for analysis of lactic acid.**		
13 Test item: 218285-V1	Butyldiglycol (2-(2-butoxyethoxy)ethanol)	A quantity of about 50 mg of the test item was weighed (to the nearest 0.01 mg) into a 50-mL volumetric flask and the volume was made up with methanol (REF01 BDG). The solution was diluted 3.6 times (2.75 mL into 10 mL) with methanol (REF01 BDG dil). Butyldiglycol was analysed by gas chromatography using a flame ionisation detector.		The accuracy was determined by comparison of the reference items and two reconstituted test item. **The accuracy results of butyldiglycol were in conformity with the Guidelines requirements for formulations containing between 1% and 10% of an active substance. Indeed, the recovery results should be in the range 97% - 103% and they were experimentally equal to 100.0% and 101.1%.**	To define the specificity of the analytical method, the following solutions were analysed: solvent blank, blank formulation, reference item and test item. No peak appears in the solvent blank and in the formulation blank. In the reference item and in the test item, the peak at the retention time around 8.19 min represents butyldiglycol. No additional peak appears in the reference item and in the test item. The specificity is therefore defined. **The analytical method showed a good specificity for**		Ricau H., 2019, Report No 18-901011-065

					analysis of butyldiglycol.		

Conclusion on the methods for detection and identification of the products
Analytical methods for the determination of Lactic acid, 2-(2-butoxyethoxy)ethanol, citric acid, potassium sorbate and "Amines, coco alkyldimethyl, N-oxides" in all Meta-SPC of the biocidal product family have been performed and validated in accordance to the Regulation (EU) No 528/2012 (1).

ANALYTICAL METHODS FOR DETERMINATION RELEVANT COMPONENTS AND/OR RESIDUES IN DIFFERENT MATRICES

Relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+)lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

2.2.5 Efficacy against target organisms

The application methods claimed were revised by the applicant during the evaluation of the dossier. These updated claims correspond to deletion of some application methods in various meta SPCs. These modification are included and materialized as strikethrough text in the Intented uses part (see 2.2.1).

These changes were considered in the efficacy section but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions which consider only the updated claims.

2.2.5.1 Function and field of use

Main group 01: Disinfectants.
Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals.
Product type 03: Veterinary hygiene
Product type 04: Food and feed area.

The product LACTIC ACID BASED PRODUCTS family are ready-to-use products or products to be diluted, used for surface disinfection.

The family has 12 META-SPC (Meta SPC5 has been withdrawn by the applicant during the evaluation phase):

Meta-SPC 1: Disinfectant for hard surfaces in domestic area by spraying, wiping (applying product onto wipe followed by wiping). Ready-To-Use. General public, PT02, Indoor.
Meta-SPC 2: Disinfectant for hard surfaces in domestic area, industry, institution, healthcare facilities and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), and mopping (applying product onto mop followed by mopping). Ready-To-Use. General public, professional and industrial, PT02 and 04, Indoor.
Meta-SPC 3: Disinfectant for hard surfaces in industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping) and mopping (applying product onto mop followed by mopping). Ready-To-Use. Professional and industrial, PT02 and 04, Indoor.
Meta-SPC 4: Disinfectant for hard surfaces in industry, institution, healthcare facilities and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), and mopping (applying product onto mop followed by mopping). Ready-To-Use. Professional and industrial, PT02 and 04, Indoor.
Meta-SPC 6: Disinfectant for hard surfaces in industry, institution, healthcare facilities health care and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by

brushing), mopping (applying product onto mop followed by mopping) and scrubbing. Concentrate products to be diluted. Professional and industrial, PT02 and 04, Indoor.
Meta-SPC 7: Disinfectant for hard surfaces in industry, institution, healthcare facilities, healthcare, and food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by brushing), mopping (applying product onto mop followed by mopping) and scrubbing. Concentrate products to be diluted. Professional and industrial, PT02 and 04, Indoor.
Meta-SPC 8: Disinfectant for hard surfaces in domestic area by wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by brushing), and mopping (applying product onto mop followed by mopping). Concentrate products to be diluted. General public, PT02, Indoor.
Meta-SPC 9: Disinfectant for hard surfaces in domestic area and companion animal's environment, by spraying and pouring. Ready-To-Use. General public, PT02 and 03, Indoor.
Meta-SPC 10: Disinfectant for hard surfaces in domestic area and companion animal's environment, by spraying and pouring. Concentrate products to be diluted. General public, PT02 and 03, Indoor.
Meta-SPC 11: Disinfectant for hard surfaces in industry, institution, healthcare facilities, and, food preparation and handling areas, by spraying, pouring and scrubbing. Concentrate products to be diluted. Professional and industrial, PT02 and 04, Indoor.
Meta-SPC 12: Disinfectant for toilet bowls in industry, institution, healthcare facilities, and healthcare, by pouring. Ready-To-Use. Professional and industrial, PT02, Indoor.
Meta-SPC 13: Disinfectant for hard surfaces in industry, institution and healthcare facilities, by spraying, pouring and scrubbing. Concentrate products to be diluted. Professional and industrial, PT02, Indoor and outdoor.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The products of LACTIC ACID BASED PRODUCTS family are intended to be used for PT02, PT03 and PT04 hard surfaces disinfection. Products family irreversibly inactivates vegetative bacteria and yeasts.
Surfaces to be disinfected include those found in industrial, domestic, institutional, healthcare facilities, food preparation and handling areas.

The product is used for the purpose of the protection of human health (in order to prevent the transmission of disease causing microorganisms).

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products of LACTIC ACID BASED PRODUCTS family are able to produce a reduction in the number of viable bacterial cells (bactericidal activity) and yeast cells (yeasticidal activity) of relevant test organisms under defined conditions.

2.2.5.4 Mode of action, including time delay

According to the Assessment Report of L(+) lactic acid for PTs 2, 3 and 4:
"In solution, L (+) lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell

membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L (+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed."
Therefore the mode of action for this product family is inhibition of cells grows and biomass producing and finally cells are destroyed.

According to Sofwjournal of Corbion on L-Lactic Acid: "During short exposures that lead directly to inactivation of bacteria, some of these mechanisms are more relevant than others. In standardized testing of the antimicrobial quality of cleaning products, exposures can be as brief as 30 seconds. In this time frame, bacteria cannot respond by adapting their structure or their metabolism for survival. The sudden severe acid stress leads to an unmitigated shock of oxidative stress, while any survival mechanisms are suppressed by the low intracellular pH."

2.2.5.5 Efficacy data

Laboratory studies were conducted with the product LACTIC ACID BASED PRODUCTS family according to the Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

Following results have been obtained in the studies submitted:

- **Meta SPC 1: Disinfectant for hard surfaces in domestic area by spraying, wiping (applying product onto wipe followed by wiping) - PT2**

META-SPC1 contains ready-to-use products containing 2.4% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with representative product AL-S1-1-0 (2.4% w/w lactic acid). Taking into account the minor variations of the co-formulants presented in the META-SPC1, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S1-1-0 cover the whole META-SPC1 claims.

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.
An activity against the additional strain *Bartonella henselae* is also demonstrated in phase 2, step 2 test (EN 13697), at 20 °C, with a contact time of 5 minutes, in conditions simulating dirty conditions (2.7 g/L BSA + 8,5 g/L skimmed milk) at 50% v/v.

Bactericidal activity are demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity are shown at the in-use concentration of 100 % v/v.
The additional strain *Bartonella henselae* has been also tested according to EN 16615 but despite adaptations to limit the drying loss, efficacy criteria cannot not be achieved with this methodology. Nevertheless considering that efficacy is demonstrated in EN 13697, and methodology of EN 16615 is not adapted to this strain, eCA agree to consider that efficacy is demonstrated against *Bartonella henselae*, for wiping.

Justification of this additional strain (*Bartonella henselae)***:**
Bartonella henselae is a bacteria which is frequently carried by cats. Transmission between animals is most often done via fleas, more specifically their excrement deposited on the animal hair or in the cat's living environment. The disease is spread to humans by scratching or biting or through the eye by rubbing their eyes with contaminated hands.
In addition to the anti-flea treatment of the animal, the disinfection of soiled surfaces by flea droppings is an effective way to fight against this bacteria.

Experimental data on the efficacy of the biocidal product against target organism(s): META SPC 1							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic area	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations tested (v/v): 1%, 20%, 40%, 80%. Temperature: 20°C Contact time:5 minutes Dirty conditions: 3 g/L BSA Criteria: ≥5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-091 R.I=1
Disinfectant, bactericidal activity	Domestic area	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 1%, 20%, 50%, 100% Temperature: 20°C Contact time: 5 minutes Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 100 % v/v	Huguet N., 2019, Report No 18.CM.18-030 R.I=1
Disinfectant, bactericidal activity	Domestic area	AL-S1-1-0 2.4% lactic acid	*Bartonella henselae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 1%, 50%, 100% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 2.7 g/L BSA + 8,5 g/L skimmed milk (equivalent to 3 g/L BSA as 8,5 g/L skimmed milk simulates 0,3 g/L BSA for strains with drying loss) Criteria: ≥ 4 log unit reduction	Activity against *B.henselae* demonstrated at 50 % v/v	Pinon A., 2019, Report No 180228b R=2
Disinfectant, bactericidal activity	Domestic area	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 16615 (May 2015)	Phase 2 step 2 (surface test) Tested concentrations of 100% and 10% (v/v) of the product on the wipe required with an impregnation rate of 16 ml. Temperature: 20°C Contact time: 5 minutes Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 100 % v/v	Carre A., 2019, Report No RE-2191/0818 R=1

Experimental data on the efficacy of the biocidal product against target organism(s): META SPC 1							
Disinfectant, bactericidal activity	Domestic area	AL-S1-1-0 2.4% lactic acid	*Bartonella henselae*	NF EN 16615 (May 2015)	Phase 2 step 2 (surface test) Tested concentrations of 100% and 10% (v/v) of the product on the wipe required with an impregnation rate of 16 ml. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 2.7 g/L BSA and skimmed milk at 8.5 g/L (equivalent to 3 g/L BSA as 8,5 g/L skimmed milk simulates 0,3 g/L BSA for strains with drying loss). Criteria: ≥ 5 log unit reduction	Activity against *B.henselae* is not demonstrated at 10 % v/v and 100% v/v (red log > 3, 91). Not possible to observe 5 log of reduction as the method is not adapted to this strain: not sufficient recovery of bacteria on the test surface (natural drying loss)	Pinon A., 2020, Report No 190287 RI=2

- **Meta SPC 2: Disinfectant for hard surfaces in domestic area, industry, institution, healthcare facilities and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping) and mopping (applying product onto mop followed by mopping) – PT2/4**

META-SPC2 contains ready-to-use products containing 3% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with representative products AL-S2-1-0 (3% w/w lactic acid) and AL-S1-1-0 (2.4% w/w lactic acid) from META-SPC1. Taking into account that products from META-SPC 1 have a lower AS concentration, that the compositions of META SPC1 and META-SPC2 are relatively similar and the minor variations of the co-formulants presented in the META-SPC2, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S2-1-0 and AL-S1-1-0 cover the whole META-SPC2 claims.

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 50 % v/v.
An activity against additional strains *Salmonella* Typhimurium and *Listeria monocytogenes* is demonstrated in phase 2, step 2 test (EN 13697) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), at 50% v/v.

Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and 13697), at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 50% v/v.

Bactericidal and yeasticidal activities are also demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 100 % v/v.

Justification of additional strains (*Salmonella* Typhimurium and *Listeria monocytogenes)***:**
Salmonella Typhimurium causes generalized infections with fever, this bacteria is the cause of the majority of collective food poisoning, hence the importance of respecting good hygiene practices at all stages of the food chain.
In addition, this strain is cited in standard NF EN 14885 as an additional possible strain for the food industry, industrial and collectivity sectors in PT4.

Listeria monocytogenes is a bacteria which is very widespread in the environment and resistant in the outside environment. It causes in infected people a disease which can be very severe with a high fatality rate. The transmission takes place mainly through food and can affect all stages of the food preparation chain. It is therefore important to ensure effective cleaning-disinfection of surfaces and premises in this area of surfaces in contact with food (PT4).

Experimental data on the efficacy of the biocidal product against target organism(s) : META SPC 2							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 20%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-091 RI=1
Disinfectant, yeasticidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S2-1-0 3% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 20%, 40%, 80 % Contact time: 15 min Temperature: 20°C Dirty conditions:3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 40 % v/v	Huguet N., 2019, Report No 18.CM.18-015 RI=1
Disinfectant, bactericidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S2-1-0 3% lactic acid	*Salmonella* Typhimurium *Listeria monocytogenes*	NF EN 13697 (June 2015)	Phase 2 step 2 (suspension test) Concentrations of product tested (v/v): 1%, 50%, 100%. Contact time: 5 min Temperature:20°C Dirty conditions:3 g/L BSA Criteria: ≥ 4 log unit reduction	Activity demonstrated at 50 % v/v	Teulier M., 2018, Report No 5107-1 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s) : META SPC 2							
Disinfectant, bactericidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (suspension test) Concentrations of product tested (v/v): 1%, 20%, 50%, 100%. Contact time:5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 50 % v/v	Huguet N., 2019, Report No 18.CM.18-030 RI=1
Disinfectant, bactericidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 16615 (May 2015)	Phase 2 step 2 (suspension test) Tested concentrations of 100% and 10% (v/v) on the wipe required with an impregnation rate of 16 g Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 100 % v/v	Carre A., 2019, Report No RE-2191/0818 RI=1
Disinfectant, yeasticidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S2-1-0 3% lactic acid	*Candida albicans*	NF EN 16615 (May 2015)	Phase 2 step 2 (surface test) Tested concentrations of 100% and 10% (v/v) on the wipe required with an impregnation rate of 16 g Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3.0 g/l BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 10 % v/v and 100 % v/v	Carre A., 2019, Report No RE-2192/0818 RI=1
Disinfectant, yeasticidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S2-1-0 3% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (suspension test) Concentrations of product tested (v/v): 1%, 50%, 100% Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 50 % v/v	Huguet N., 2019, Report No 18.CM.18-024 RI=1

- **Meta SPC 3: Disinfectant for hard surfaces in industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping) and mopping (applying product onto mop followed by mopping) – PT2/4**

META-SPC3 contains ready-to-use products containing 4% w/w lactic acid, and minor variations of coformulants.
One of the coformulants (described as buffering/descaling agent) is also an active substance included in the review program of the BPR and test has been performed according to the requirements of the TAB in order to demonstrate that it has no biocidal activity in the formulations (see confidential part).

Efficacy studies have been performed with the representative product AL-S3-1-0 (4% w/w lactic acid). Taking into account the minor variations of the co-formulants presented in the META-SPC3, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S3-1-0_cover the whole META-SPC3 claims.

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13727 and EN 13697) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA + 3 ml/l sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 40 % v/v.

Yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA + 3 ml/l sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 40% v/v.

Bactericidal and yeasticidal activities are also demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA + 3 ml/l sheep erythrocytes). In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 10 % v/v.

The applicant has also submitted studies according to EN 1276 and EN 1650 from META-SPC1 and META-SPC2, assuming that representative products tested have a lower AS concentration and minor variations between the other ingredients.
Nevertheless, since dirty conditions from medical area are a worst case related to those of food, industry, domestic, institutional areas, results from medical areas conditions cover the efficacy of all the uses claimed for this META-SPC.

Experimental data on the efficacy of the biocidal product against target organism(s) : META SPC 3							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S1-1-0 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 20%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA. Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-091 R=1 Supportive data
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S3-1-0 4% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13727 (2012) + A2 (December 2015)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 20%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes. Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-120 R=1
Disinfectant, yeasticidal activity	Domestic, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S2-1-0 3% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 20%, 40%, 80% Contact time:15 min Temperature: 20°C Dirty conditions: 3 g/L BSA. Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 40 % v/v	Huguet N., 2019, Report No 18.CM.18-015 R=1 Supportive data

Experimental data on the efficacy of the biocidal product against target organism(s) : META SPC 3							
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S3-1-0 4% lactic acid	*Candida albicans*	NF EN 13624 (November 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L + 3 ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-137 R=1
Disinfectant, bactericidal and yeasticidal activities	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S3-1-0 4% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans*	NF EN 16615 (May 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 100%, 10% on the wipe required with an impregnation rate of 16 g. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 5 log unit reduction for bacteria and > 4log reduction for yeast	Bactericidal and yeasticidal activity demonstrated at 10 % v/v and 100% v/v	Carre A., 2018, Report No RE-2193/0818 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S3-1-0 4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 10% - 50% and 100% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 50 % v/v	Teulier M., 2018, Report No 5145-1 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s) : META SPC 3							
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S3-1-0 4% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 1% - 50% and 100%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 50 % v/v	Huguet N., 2018, Report No 18.CM.18-155 RI=1

- **Meta-SPC 4: Disinfectant for hard surfaces in industry, institution, healthcare facilities and, food preparation and handling areas by spraying, wiping (applying product onto wipe followed by wiping) and mopping (applying product onto mop followed by mopping) – PT2/4**

META-SPC4 contains ready-to-use products containing 3.2% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with the representative product AL-S4-1-0 (3.2% w/w lactic acid). Taking into account the minor variations of the co-formulants presented in the META-SPC4, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S4-1-0 cover the whole META-SPC4 claims.

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.
Activity against additional strains *Salmonella* Typhimurium and *Listeria monocytogenes* is demonstrated in phase 2, step 2 test (EN 13697) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), at 100% v/v.

Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 100% v/v.

Bactericidal and yeasticidal activities are also demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 100 % and 10% v/v, respectively.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 4							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 20%, 40%, 80% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2018, Report No 18.CM.18-081 RI=1
Disinfectant, yeasticidal activity	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 20%, 40%, 80%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 80 % v/v	Huguet N., 2018, Report No 18.CM.18-099 RI=1
Disinfectant, bactericidal activity	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Pseudomonas aeruginosa* CIP *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 1%, 20%, 50%, 100%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 100 % v/v	Huguet N., 2018, Report No 18.CM.18-073 RI=1
Disinfectant, bactericidal activity	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Salmonella* Typhimurium *Listeria monocytogenes*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 1%, 50% and 100% (V/V). Contact time: 5 min Temperature: 20°C Dirty conditions:3 g/l Criteria: ≥ 4 log unit reduction	Activity demonstrated at 100 % v/v	Teulier M., 2018, Report No 5108-1 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 4							
Disinfectant, bactericidal and yeasticidal activities	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans*	NF EN 16615 (May 2015)	Phase 2 step 2 (surface test) Tested concentrations: 100% and 10% (v/v) on the wipe required with an impregnation rate of 16 g Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3.0 g/l BSA. Criteria: ≥ 5 log unit reduction for bacteria and 4 lg unit for yeast.	Bactericidal and yeasticidal activities demonstrated at respectively 100 % v/v and 10% v/v.	Carre A., 2019, Report No RE-2194/0818 RI=1
Disinfectant, yeasticidal activity	Institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S4-1-0 3.2% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 20%, 50%, 100%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA. Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 100 % v/v	Huguet N., 2018, Report No 18.CM.18-087 RI=1

Note that META-SPC5 has been withdrawn by the applicant during the evaluation

- **Meta-SPC 6: Disinfectants for hard surfaces in industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by mopping), mopping (applying product onto mop followed by mopping) and scrubbing –PT2/4**

META-SPC6 contains products to be diluted in water, containing 24% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with representative product AL-S6-1-0 (24% w/w lactic acid). Taking into account the minor variations of the co-formulants presented in the META-SPC6, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S6-1-0 cover the whole META-SPC6 claims.

For institutional, industrial and, food preparation and handling areas:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 3 % (v/v).
Activity against additional strains *Salmonella* Typhimurium and *Listeria monocytogenes* is demonstrated in phase 2, step 2 test (EN 13697), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, activity on these strains is shown at the in-use concentration of 3 % (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN1650 and EN13697), at 20°C, with contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is demonstrated at the in-use concentration of 5% (v/v).

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 2% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 3% (v/v).

For healthcare area:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 13727 and EN 13697), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 4% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L + 3mL/L sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% (v/v).

For institutional, industrial, healthcare facilities, healthcare and, food preparation and handling areas, bactericidal and yeasticidal activities are also demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, at 20°C, in dirty conditions (3 g/L BSA + 3mL/L sheep erythrocytes) for wiping application. In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 10 % v/v.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 6							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 0.2%, 0.5%, 1%, 2%, 3%, 4%, 5%. Contact time : 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 3% v/v.	Huguet N., 2018, Report No 18.CM.18-106 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 2%, 1%, 0.25%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 1% v/v.	Feuillolay C., 2019, Report No 19-1354 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 1%, 2%, 3%. Contact time : 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 2% v/v.	Huguet N., 2018, Report No 18.CM.18-12410 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 13624 (November 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 2%, 6%, 8%. Contact time : 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 6% v/v.	Huguet N., 2019, Report No 19.CM.19-007 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 6							
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 1650 + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v): 2%, 1%, 0.25%. Contact time: 30 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 2% v/v.	Feuillolay C., 2019, Report No 19-1373 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 0.5%, 1%, 2%, 3%, 4%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 3% v/v.	Huguet N., 2019, Report No 18.CM.18-135 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13727 (2012) + A2 (December 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 0.5%, 1%, 2%, 3%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 3% v/v.	Huguet N., 2018, Report No 18.CM.18-140 RI=1
Disinfectant, bactericidal and yeasticidal activities	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans*	NF EN 16615 (2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 10% and 1% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 5 log unit reduction for bacteria and 4 log for yeast.	Bactericidal and yeasticidal activities demonstrated at 10% v/v.	Lemaitre P., 2018, Report No RE18-643-1 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 6							
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 2% - 4% and 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction.	Bactericidal activity demonstrated at 4% v/v.	Teulier M., 2018, Report No 5147-1 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Salmonella* Typhimurium *Listeria monocytogenes*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 0.5%, 1.0% and 3.0%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction.	Bactericidal activity demonstrated at 3% v/v.	Teulier M., 2018, Report No 5270-1 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (june 2015)	Phase 2 step 2 (surface test) Concentrations of product tested: 2% - 1% and 0.25%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction.	Bactericidal activity demonstrated at 2% v/v.	Feuillolay C., 2019, Report No 19-1368 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 3%, 4% and 5%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction.	Yeasticidal activity demonstrated at 5% v/v.	Huguet N., 2019, Report No 19.CM.19-014 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v): 4%, 8%, 10%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 8% v/v.	Huguet N., 2018, Report No 18.CM.18-150 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 6							
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S6-1-0 24% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (suspension test) Concentrations of product tested were: 3%, 2%, 1%. Contact time: 30 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 3% v/v.	Feuillolay C., 2019, Report No 19-1381 RI=1

- **Meta-SPC 7: Disinfectant for hard surfaces in industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, by spraying, wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by mopping), mopping (applying product onto mop followed by mopping) and scrubbing – PT2/4**

META-SPC7 contains products to be diluted in water containing 12% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with representative product AL-S7-1-0 (12% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC7, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S7-1-0 cover the whole META-SPC7 claims.

For institutional, industrial, healthcare facilities and food preparation and handling areas:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN1276 and EN13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 5% (v/v)
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN1650 and EN13697), at 20°C with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% (v/v).

Bactericidal activity, is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 4% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 6% (v/v).

For healthcare area:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 13727 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 6% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with contact time of 5 minutes, in dirty conditions (3.0 g/L + 3mL/L sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 10% (v/v).

For healthcare, institutional, industrial, healthcare facilities and, food preparation and handling areas, bactericidal and yeasticidal activities are demonstrated in phase 2 step 2 test (EN16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA + 3mL/L sheep erythrocytes) for wiping application. In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 10 % v/v.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 7							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 0.5%, 3%, 4%, 5%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 5% v/v.	Huguet N., 2018, Report No 18.CM.18-132 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 4%, 3%, 0.5%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 3% v/v.	Feuillolay C., 2019, Report No 19-1355 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13727 (2012) + A2 (December 2015)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 0.5%, 3%, 4%, 5%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 5% v/v.	Huguet N., 2019, Report No 19.CM.19-008 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 1%, 3%, 4%. Contact time : 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 3% v/v.	Huguet N., 2018, Report No 18.CM.18-125 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 7							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 13624 (November 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 4%, 8%, 10%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 10% v/v.	Huguet N., 2019, Report No 19.CM.19-006 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 1650 + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested were: 4%, 3%, 0.5%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 4% v/v.	Feuillolay C., 2019, Report No 19-1358 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 1% - 3% and 5%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 5% v/v.	Gabillet AF., 2018, Report No 5236-1 RI=1
Disinfectant, bactericidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 4% - 3% and 0.5%. Contact time : 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 4% v/v.	Feuillolay C., 2019, Report No 19-1369 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 7							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 2% - 6% and 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes. Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 6% v/v.	Gabillet AF., 2019, Report No 5264-1 RI=1
Disinfectant, bactericidal and yeasticidal activities	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans*	NF EN 16615 (2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 10% and 1% (v/v) Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes. Criteria: ≥ 5 log unit reduction	Bactericidal and yeasticidal activities demonstrated at 10% v/v.	Lemaitre P., 2018, Report No RE18-645-1 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 7%, 8%, 10%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 8% v/v.	Huguet N., 2019, Report No 19.CM.19-010 RI=1
Disinfectant, yeasticidal activity	Medical, institutional, industrial, healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 2%, 6%, 10%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 10% v/v.	Huguet N., 2019, Report No 18.CM.18-151 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 7							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, yeasticidal activity	Medical, institutional, industrial healthcare facilities and food preparation and handling areas	AL-S7-1-0 12% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested were: 6%, 4%, 2%. Contact time: 30 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 6% v/v.	Feuillolay C., 2019, Report No 19-1382 RI=1

- **Meta-SPC 8: Disinfectant for hard surfaces in domestic area by wiping (applying product onto wipe followed by wiping), brushing (applying product onto brush followed by mopping), and mopping (applying product onto mop followed by mopping) – PT2**

META-SPC8 contains products to be diluted in water containing 16% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with representative product AL-S8-1-0 (16% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC8, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S8-1-0 cover the whole META-SPC8 claims.

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 6% (v/v).
An activity against the additional strain *Bartonella henselae* is also demonstrated in phase 2, step 2 test (EN 13697), at 20 °C, with a contact time of 5 minutes, in conditions simulating dirty conditions (2.7 g/L BSA + 8,5 g/L skimmed milk) at 3% v/v.

Bactericidal and yeasticidal activities are also demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA + 3 ml/l sheep erythrocytes). In these conditions, bactericidal and yeasticidal activities are shown at the in-use concentration of 6 % v/v.

The additional strain *Bartonella henselae* has not been tested according to EN 16615, as for META SPC 1, indeed efficacy criteria cannot be achieved with this methodology. Nevertheless considering that efficacy is demonstrated both in EN 1276 and EN 13697, and methodology of EN 16615 is not adapted to this strain, eCA agree to consider that efficacy is demonstrated against *Bartonella henselae*, for wiping.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 8							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic area	AL-S8-1-0 16% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5%, 1%, 2%, 3%, 4%, 6%, 8% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 4 % v/v	Huguet N., 2018, Report No 18.CM.18-104 RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S8-1-0 16% lactic acid	*Bartonella henselae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5%, 2%, 4%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 0.5 % v/v	Pinon A., 2019, Report No 180228a RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S8-1-0 16% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 16615 (2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 1%, 6%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Lemaitre P., 2020, Report No RE20-175-1 RI=1

Disinfectant, bactericidal activity	Domestic area	AL-S8-1-0 16% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 0.5%, 2%, 4%, 5%, 6%, 8%, 10%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Huguet N., 2019, Report No 18.CM.18-136 RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S8-1-0 16% lactic acid	*Bartonella henselae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 0.5%, 3%, 6%, Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 8.5 g/L skimmed milk (equivalent to 3 g/L BSA as 8,5 g/L skimmed milk simulates 0,3 g/L BSA for strains with drying loss). Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 3 % v/v	Pinon A., 2019, Report No 180228c RI=1

- **Meta-SPC 9: Disinfectant for hard surfaces in domestic area and companion animal's environment, by spraying and pouring – PT2/3**

META-SPC9 contains ready-to-use products containing 2.4% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with the representative product AL-S9-1-1 (2.4% w/w lactic acid). Taking into account that products from META-SPC 10 have a higher AS concentration, that the compositions of META SPC9 and META-SPC10 are relatively similar and the minor variations of the co-formulants presented in the META-SPC9, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S9-1-0 and AL-S10-1-0 cover the whole META-SPC9 claims.

For domestic area:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 50% (v/v).
An activity against the additional strain *Bartonella henselae* is also demonstrated in phase 2, step 2 test (EN 13697), at 20 °C, with a contact time of 5 minutes, in conditions simulating dirty conditions (2.7 g/L BSA + 8,5 g/L skimmed milk) at 50% v/v.

For companion animal's environment:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1656 and EN14349), at 10°C, with a contact time of 30 minutes under low level soiling conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 80 % v/v for non porous surfaces.
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), respectively at 10°C and 20°C, with a contact time of 120 minutes, under low level soiling conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 80 % v/v for non porous surfaces.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 9							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcusaureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40 % v/v	Huguet N., 2019, Report No 18.CM.18-147 RI=1
Disinfectant, bactericidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa*	NF EN 1656 (march 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 40%, 80%. Contact time: 30 minutes Temperature: 10°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 80 % v/v	Gabillet AF., 2018, Report No 5268-1 RI=1
Disinfectant, yeasticidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Candida albicans*	NF EN 1657 (April 2006)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 40%, 80%. Contact time: 120 minutes Temperature: 10°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 80 % v/v	Huguet N., 2020, Report No 19.CM.19-035 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 9							
Disinfectant, bactericidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Eschrichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 5% - 50% and 100%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 50 % v/v	Gabillet AF., 2018, Report No 5235-1 RI=1
Disinfectant, bactericidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Enterococcus hirae* *Staphylococcus aureus* *Pseudomonas aeruginosa* *Proteus hauserii*	NF EN 14349 (December 2012)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 10% - 50% and 100%. Contact time: 30 minutes Temperature: 10°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 50 % v/v	Feuillolay C., 2018, Report No 18-1348 RI=1
Disinfectant, bactericidal activity	Domestic area and companion animals environment	AL-S9-1-1 2.4% lactic acid	*Bartonella hensela*	NF EN 13697+A1 (July 2019)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 10% - 50% and 100%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 2.7 g/L BSA + 8.5g/L skimmed milk (equivalent to 3 g/L BSA as 8,5 g/L skimmed milk simulates 0,3 g/L BSA for strains with drying loss) Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 10 % v/v	Pinon A., 2020, Report No 200290c RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 9							
Disinfectant, yeasticidal activity	Domestic area and companion animals environment	AL-S10-1-1 8% lactic acid	*Candida albicans*	NF EN 16438 (March 2014)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 6% - 8% and 10%. Contact time: 120 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction	Yeasticidal activity demonstrated at 10 % v/v Therefore the product AL S9 1-1 2.4% acid lactic ready to use is efficient	Gabillet AF., 2020, Report No 5870-1 RI=1

- **Meta-SPC 10: Disinfectant for hard surfaces in domestic area and companion animal's environment, by spraying and pouring – PT2/3**

META-SPC10 contains products to be diluted in water containing 8% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with the representative product AL-S10-1-0 (8% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC10, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S10-1-0 cover the whole META-SPC10 claims.

In domestic area:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 6% (v/v).
An activity against the additionnal strain *Bartonella henselae* is demonstrated in phase 2, step 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in conditions simulating dirty conditions (3.0 g/L BSA + 8.5 g/L skimmed milk), at 6 % (v/v).

In companion animal's environment:
Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 10°C with a contact time of 30 minutes, under low level soiling conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 6% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at respectively at 10°C and 20°C with a contact time of 120 minutes, in low level soiling conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 10% (v/v).

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 10							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Domestic area	AL-S10-1-0 8% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5%, 2%, 6%, 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Huguet N., 2019, Report No 18.CM.18-148 RI=1
Disinfectant, bactericidal activity	Companion animals environment	AL-S10-1-0 8% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa*	NF EN 1656 (march 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 2% - 6% and 8%. Contact time: 30 minutes Temperature: 10°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Teulier M., 2018, Report No 5267-1 RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S10-1-0 8% lactic acid	*Bartonella henselae*	NF EN 1276 (August 2019)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5% - 1% and 6%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction	Activity against *B.henselae* demonstrated at 6 % v/v	Pinon A., 2020, Report No 200290a RI=1
Disinfectant, yeasticidal activity	companion animals environment	AL-S10-1-0 8% lactic acid	*Candida albicans*	NF EN 1657 (April 2006)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 6%, 8%, 10%. Contact time: 120 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 8 % v/v	Huguet N., 2020, Report No 19.CM.19-036 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 10							
Disinfectant, bactericidal activity	Companion animals environment	AL-S10-1-0 8% lactic acid	*Enterococcus hirae* *Staphylococcus aureus* *Pseudomonas aeruginosa* *Proteus hauserii*	NF EN 14349 (December 2012)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 8% - 6% and 2%. Contact time: 30 minutes Temperature: 10°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Feuillolay C., 2018, Report No 18-1349 RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S10-1-0 8% lactic acid	*Bartonella henselae*	NF EN 13697+A1 (July 2019)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 1% - 3% and 6%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 2.7 g/L BSA + 8.5 g/L skimmed milk (Equivalent to 3 g/L BSA as 8.5 g/L skimmed milk simulates 0,3 g/L BSA for strains with drying loss). Criteria: ≥ 4log unit reduction	Activity against *B.henselae* demonstrated at 3 % v/v	Pinon A., 2020, Report No 200290b RI=1
Disinfectant, bactericidal activity	Domestic area	AL-S10-1-0 8% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 2% - 6% and 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA milk Criteria: ≥ 4log unit reduction	Bactericidal activity demonstrated at 6 % v/v	Gabillet AF., 2018, Report No 5237-1 RI=1
Disinfectant, yeasticidal activity	Companion animals environment	AL-S10-1-0 8% lactic acid	*Candida albicans*	NF EN 16438	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 6% - 8% and 10%. Contact time: 120 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3log unit reduction	Yeasticidal activity demonstrated at 10 % v/v	Gabillet AF., 2020, Report No 5871-1 RI=1

- **Meta-SPC 11: Disinfectant for hard surfaces in industry, institution, healthcare facilities, and food preparation and handling areas, by spraying, pouring and scrubbing – PT2/4**

META-SPC11 contains products to be diluted in water containing 24% w/w lactic acid, and minor variations of coformulants.
One of the coformulants (described as buffering/descaling agent) is also an active substance included in the review program of the BPR and test has been performed according to the requirements of the TAB in order to demonstrate that it has no biocidal activity in the formulations (see confidential part).

Efficacy studies have been performed with the representative product AL-S11-1-0 (24% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC11, it can be assumed that they have no impact on efficacy and the efficacy results of the representative product AL-S11-1-0 cover the whole META-SPC11 claims.

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1.5% (v/v).
An activity against additional strains (*Salmonella* Typhimurium and *Listeria monocytogenes)* is also demonstrated in phase 2, step 2 test (EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), at 1% v/v.
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1.5% v/v.

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 test (EN 1650 and EN13697) at 40°C with a contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1% (v/v).

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 11							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.1%, 0.5%, 1%, 1.5%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5log unit reduction	Bactericidal activity demonstrated at 1.5 % v/v	Huguet N., 2018, Report No 18.CM.18-133 RI=1
Disinfectant, bactericidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 0.5%, 0.1%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5log unit reduction	Bactericidal activity demonstrated at 1 % v/v	Feuillolay C., 2019, Report No 19-1356 RI=1
Disinfectant, yeasticidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5%, 1%, 2%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4log unit reduction	Yeasticidal activity demonstrated at 1% v/v	Huguet N., 2018, Report No 18.CM.18-126
Disinfectant, yeasticidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Candida albicans*	NF EN 1650 + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 0.5%, 0.1%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4log unit reduction	Yeasticidal activity demonstrated at 1% v/v	Feuillolay C., 2019, Report No 19-1359 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 11							
Disinfectant, bactericidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 0.1%, 0.5%, 1%, 1.5%, 2%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4log unit reduction	Bactericidal activity demonstrated at 1.5 % v/v	Huguet N., 2019, Report No 18.CM.18-115 RI=1
Disinfectant, bactericidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Salmonella* Typhimurium *Listeria monocytogenes*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 0.5%, 1.0% and 1.5% (V/V). Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4log unit reduction	Activity demonstrated at 1% v/v	Teulier M., 2018, Report No 5269-1 RI=1
Disinfectant, bactericidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 1%, 0.5%, 0.1%. Contact time: 15 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4log unit reduction	Bactericidal activity demonstrated at 0.5% v/v	Feuillolay C., 2019, Report No 19-1370 RI=1
Disinfectant, yeasticidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 1%, 1.5%, 2%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3log unit reduction	Yeasticidal activity demonstrated at 1.5 % v/v	Huguet N., 2019, Report No 19.CM.19-012 RI=1

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 11							
Disinfectant, yeasticidal activity	Institutional, healthcare facilities, industrial and food preparation and handling areas	AL-S11-1-0 24% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 1%, 0.5%, 0.1%. Contact time: 30 minutes Temperature: 40°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3log unit reduction	Yeasticidal activity demonstrated at 1% v/v	Feuillolay C., 2019, Report No 19-1383 RI=1

- **Meta-SPC 12: Disinfectant for toilet bowls in industry, institution, healthcare facilities and healthcare, by pouring – PT2:**

META-SPC12 contains ready-to-use products containing 16% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with the representative product AL-S12-1-0 (16% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC12, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products AL-S12-1-0 cover the whole META-SPC12 claims.

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 13727 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA + 3mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 40% (v/v).
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA + 3mL/L sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 20% v/v.

The applicant didn't submit studies according to the standards for institutional and industry areas. Nevertheless, since dirty conditions from medical area are a worst case related to those of food, industry, domestic, institutional areas, results from medical areas conditions cover the efficacy of all the uses claimed for this META-SPC.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 12							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Medical, healthcare facilities, institutional and industrial areas	AL-S12-1-0 16% lactic acid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 13727 (2012) + A2 (December 2015)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 10%, 20%, 40%, 80%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 5 log unit reduction	Bactericidal activity demonstrated at 40% v/v	Huguet N., 2018, Report No 18.CM.18-144 RI=1
Disinfectant, yeasticidal activity	Medical, healthcare facilities, institutional and industrial areas	AL-S12-1-0 16% lactic acid	*Candida albicans*	NF EN 13624 (November 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 1%, 20%, 40%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction	Yeasticidal activity demonstrated at 20% v/v	Huguet N., 2018, Report No 18.CM.18-146 RI=1
Disinfectant, bactericidal activity	Medical, healthcare facilities, institutional and industrial areas	AL-S12-1-0 16% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 5%, 50% and 100%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 4 log unit reduction.	Bactericidal activity demonstrated at 5% v/v	Gabillet AF., 2019, Report No 5262-1 RI=1
Disinfectant, yeasticidal activity	Medical, healthcare facilities, institutional and industrial areas	AL-S12-1-0 16% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 10%, 50%, 100%. Contact time: 5 minutes Temperature: 18-25°C Dirty conditions: 3 g/L BSA + 3ml/l sheep erythrocytes Criteria: ≥ 3 log unit reduction.	Yeasticidal activity demonstrated at 50% v/v.	Carre A., 2019, Report No RE-2317/1118 RI=1

- **Meta-SPC 13: Disinfectant for hard surfaces in industry, institution, healthcare facilities, by spraying, pouring and scrubbing – PT2**

META-SPC13 contains products to be diluted in water containing 8% w/w lactic acid, and minor variations of coformulants, in low concentrations without biocidal activity.
Efficacy studies have been performed with the representative product AL-S13-1-0 (8% w/w lactic acid). Taking into account the variations of the co-formulants presented in the META-SPC13, it can be assumed that they have no impact on efficacy and the efficacy results of the representative product AL-S13-1-0 cover the whole META-SPC13 claims.

Bactericidal activity is demonstrated in phase 2, steps 1 and 2 (EN 1276 and EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 6% (v/v).
An activity against the additional strain *Yersinia enterocolitica* is also demonstrated in phase 2, step 2 (EN 13697), at 20°C with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), at 2% v/v.
Yeasticidal activity is demonstrated in phase 2, steps 1 and 2 tests (EN1650 and EN13697), at 20°C with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% (v/v).

Justification of additional strain (*Yersinia enterocolitica):*
Yersinia enterocolitica is a bacteria that causes acute gastroenteritis. The main reservoir for this pathogenic strain is pork. Small rodents, rabbits, dogs and cats can carry the strain and contribute to its propagation between farms. Transmission occurs through direct contact with animals, infected people or contaminated surfaces.
Hence the interest in having effective disinfectant products on this strain in the field of collection and processing of food waste to prevent its spread.

Experimental data on the efficacy of the biocidal product against target organism(s): Meta-SPC 13							
Function	**Field of use envisaged**	**Test item**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant, bactericidal activity	Institutional, healthcare facilities and industrial areas	AL-S10-1-0 8% lactic acid	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	NF EN 1276 (March 2010)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 0.5%, 2%, 6%, 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 5 log unit reduction.	Bactericidal activity demonstrated at 2% v/v	Huguet N., 2019, Report No 18.CM.18-148 RI=1
Disinfectant, yeasticidal activity	Institutional, healthcare facilities and industrial areas	AL-S13-1-0 8% lactic acid	*Candida albicans*	NF EN 1650 (2008) + A1 (July 2013)	Phase 2 step 1 (suspension test) Concentrations of product tested (v/v) were: 4%, 6%, 8%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction.	Yeasticidal activity demonstrated at 8% v/v.	Huguet N., 2018, Report No 18.CM.18-153 RI=1
Disinfectant, bactericidal activity	Institutional, healthcare facilities and industrial areas	AL-S13-1-0 8% lactic acid	*Yersinia enterocolitica*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 2%, 6%, 8%. Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction.	Activity against *Y.enterocolitica* demonstrated at 2% v/v.	Pinon A., 2018, Report No 180235a RI=1
Disinfectant, bactericidal activity	Institutional, healthcare facilities and industrial areas	AL-S10-1-0 8% lactic acid	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	NF EN 13697 (June 2015)	Phase 2 step 2 (suspension test) Concentrations of product tested (v/v) were: 2%, 6%, 8%. Contact time : 5 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 4 log unit reduction.	Bactericidal activity demonstrated at 6% v/v.	Gabillet AF., 2018, Report No 5237-1
Disinfectant, yeasticidal activity	Institutional, healthcare facilities and industrial areas	AL-S13-1-0 8% lactic acid	*Candida albicans*	NF EN 13697 (June 2015)	Phase 2 step 2 (surface test) Concentrations of product tested (v/v) were: 6%, 8%, 10%. Contact time: 15 minutes Temperature: 20°C Dirty conditions: 3 g/L BSA Criteria: ≥ 3 log unit reduction.	Yeasticidal activity demonstrated at 8% v/v.	Huguet N., 2019, Report No 19.CM.19-013 RI=1

Conclusion on the efficacy of the product

Lactic acid based products family with 13 META SPC has shown a sufficient efficacy, in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for the following uses:

Meta-SPC 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces, with mechanical or non mechanical action:

- Bacteria (including *Bartonella henselae)*: 100 % v/v, 5 minutes, 20°C.

Meta-SPC 2:

Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces, with mechanical or non mechanical action:

- Bacteria: 100 % v/v, 5 minutes, 20°C.

Use 2: Disinfectants for hard surfaces including food contact surfaces of domestic area, with dirty conditions for non porous surfaces.
With mechanical action:

- Bacteria and yeasts: 100 % v/v, 5 minutes, 20°C.

With non mechanical action:

- Bacteria and yeasts: 100 % v/v, 15 minutes, 20°C.

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces.
With mechanical action:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes*,) and yeasts: 100 %, 5 minutes, 20°C.

With non mechanical action:

- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes*,) and yeasts: 100 %, 15 minutes, 20°C.

Use 4: Disinfectants for hard surfaces for industry, institution and healthcare facilities areas, with dirty conditions for non porous surfaces.
With mechanical action:

- Bacteria and yeasts: 100 %, 5 minutes, 20°C.

With non mechanical action:

- Bacteria and yeasts: 100 %, 15 minutes, 20°C.

Meta-SPC 3:
Use 1: Disinfectants for hard surfaces for industry, institution, healthcare facilities, healthcare and food preparation and handling areas, with dirty conditions for non porous surfaces, with mechanical or non mechanical action:

- Bacteria, yeasts: 100%, 5 minutes, 20°C.

Use 2: Disinfectants for hard surfaces for industry, institution, healthcare facilities and health care, with dirty conditions for non porous surfaces, with mechanical or non mechanical action:
Bacteria, yeasts: 100%, 5 minutes, 20°C.

Meta-SPC 4: Disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas, with dirty conditons for non porous surfaces.

With mechanical action:
- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes)*, yeasts: 100%, 5 minutes, 20°C.

With non mechanical action:
- Bacteria (including additional strains *Salmonella* Typhimurium and *Listeria monocytogenes)*, yeasts: 100%, 15 minutes, 20°C.

Meta-SPC 6:

Use 1: Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2/4

In healthcare, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 5% v/v, 15 minutes, 20°C et 3% v/v, 30 minutes, 40°C.

All areas, with mechanical action:
- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2/4

With non mechanical action:
- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 5% v/v, 15 minutes, 20°C et 3% v/v, 30 minutes, 40°C.

With mechanical action:
- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare, with dirty conditions for non porous surfaces - PT2

In healthcare, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria, yeasts: 5% v/v, 15 minutes, 20°C

All areas, with mechanical action:
- Bacteria (including additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*,), yeasts: 10% v/v, 5 minutes, 20°C.

Use 4: Disinfectants for hard surfaces of industry, institution and healthcare facilities areas, with dirty conditions for non porous surfaces – PT2

With non mechanical action:
- Bacteria, yeasts: 5% v/v, 15 minutes, 20°C

With mechanical action:

- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Meta-SPC 7:

Use 1: Disinfectants for hard surfaces of industry, institution, healthcare facilities, healthcare and, food preparation and handling areas, with dirty conditions for non porous surfaces - PT2/4:
In healthcare area, with non mechanical action
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C and 6% v/v, 30 minutes, 40°C.

All areas, with mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of industry, institution, healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces - PT2/4
With non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C and 6% v/v, 30 minutes, 40°C.

With mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 3: Disinfectants for hard surfaces of industry, institution, healthcare facilities and healthcare, with dirty conditions for non porous surfaces – PT2
In healthcare area, with non mechanical action
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Other areas, with non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C.

All areas, with mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Use 4: Disinfectants for hard surfaces of industry, institution and healthcare facilities, with dirty conditions for non porous surfaces – PT2
With non mechanical action:
- Bacteria, yeasts: 8% v/v, 15 minutes, 20°C

With mechanical action:
- Bacteria, yeasts: 10% v/v, 5 minutes, 20°C

Meta-SPC 8:
Use 1: Disinfectants for hard surfaces of domestic area with dirty conditions for non porous surfaces - PT2
With mechanical action:
- Bacteria (including additional strains: *Bartonella henselae*,): 6% v/v, 5 minutes, 20°C

Meta-SPC 9:
Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces – PT2
With no mechanical action:
- Bacteria (including additional strains: *Bartonella henselae*): 100%, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of domestic area and in companion animals' environment for private homes and pets shelters, with clean conditions, for non porous surfaces –PT2/3
With no mechanical action:

- Bacteria and yeasts: 100%, 120 minutes, 20°C

Meta-SPC 10:
Use 1: Disinfectants for hard surfaces of domestic area, with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria (including additional strains *Bartonella henselae*): 6% v/v, 5 minutes, 20°C

Use 2: Disinfectants for hard surfaces of domestic area and in companion animals' environment for private homes and pets shelters, with clean conditions for non porous surfaces – PT2/3:
With no mechanical action:

- Bacteria and yeasts: 10% v/v, 120 minutes, 20°C.

Meta-SPC 11:
Use 1: Disinfectants for hard surfaces of industry, institution and healthcare facilities and, food preparation and handling areas, with dirty conditions for non porous surfaces – PT2/4:
With no mechanical action:

- Bacteria (including PT4 additional strains: *Salmonella* Typhimurium and *Listeria monocytogenes*) and yeasts: 1.5% v/v, 15 minutes, 20°C or 1% v/v, 30 minutes, 40°C.

Meta-SPC 12:
Use 1: Disinfectants for hard surfaces for industry, institution, healthcare facilities and healthcare with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria and yeasts: 100%, 5 minutes, 20°C.

Meta-SPC 13:
Use 1: Disinfectants for hard surfaces of industry, institution and healthcare facilities, with dirty conditions for non porous surfaces – PT2:
With no mechanical action:

- Bacteria (including additional strain *Yersinia enterocolitica*) and yeasts: 8% v/v, 15 minutes, 20°C.

2.2.5.6 Occurrence of resistance and resistance management

According to the Assessment Report of L(+) lactic acid for PTs 02, 03 and 04 (4):
"No resistance to lactic acid has been observed in the course of the efficacy studies. Furthermore, development of resistance is considered unlikely due to the non-specific mode of action (Doc III B5.11)."

The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the

recommendations proposed in the SPC have to be implemented

2.2.5.7 Known limitations

none

2.2.5.8 Evaluation of the label claims

See Efficacy conclusion

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The products in the different Meta-SPC are not intended to be used simultaneously with other biocidal products.

2.2.6 Risk assessment for human health

The application methods claimed were revised by the applicant during the evaluation of the dossier. These updated claims correspond to deletion of some application methods in various meta SPCs. These modifications are included and materialized as strikethrough text in the Intented uses part (see 2.2.1).

These changes were considered in the efficacy section but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions which consider only the updated claims.

For each meta SPC, when no study was available, classification has been determined using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017).

For more details, please see confidential annex.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of *in vitro* studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
In vitro skin irritation (Reconstructed Human Epidermis Test Method) OECD 439 GLP 1	AL-S1-3-0 16 µL to 3 living Reconstructed Human epidermis (SkinEthic RHE model)	Positive control = Sodium Dodecyl Sulfate (5%) Negative control = distilled water Application time: 42 min Rinse with 25 mL of DPBS Post-treatment incubation period = 42 hours MTT incubation period = 3 hours Formazan extraction solvent = isopropanol	Mean viability: AL-S1-3-0 = **81.8%** Positive control = **1.7%** Negative control: **100%** **Conclusion:** Mean viability of treated tissues > 50%. According to the OECD 439 guideline, no classification required for the product AL-S1-3-0	No deviation	Barré T. (2018) Study Number: HSMI-PH-18/0259

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro Membrane Barrier Test Method for Skin Corrosion OECD 435 GLP 1	AL-S2-3-0 500 µL onto 4 membrane barriers	Positive control = sodium hydroxide Negative control = propionic acid 6%	Test performed following 3 steps: Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation Step 2 – Timescale Category test: First trial: not conclusive Second trial: liquid turned into a grey coloration → assignment to category 2 Step 3 - Measurement of membrane barrier penetrations: <u>AL-S2-3-0 and negative control:</u> no disruption of the membrane after 1 hour (4 replicates) <u>Positive control:</u> disruption of the membrane after 21 minutes and 24 seconds **Conclusion:** According to the OECD 435 guideline, AL-S2-3-0 is not corrosive to the skin.	No deviations	Barré T. (2018) Study Number: CTX-PH-18/0391

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro skin irritation (Reconstructed Human Epidermis Test Method) OECD 439 GLP 1	AL-S2-3-0 16 µL to 3 living Reconstructed Human epidermis (SkinEthic RHE model)	Positive control = Sodium Dodecyl Sulfate (5%) Negative control = distilled water Application time: 42 min Rinse with 25 mL of DPBS Post-treatment incubation period = 42 hours MTT incubation period = 3 hours Formazan extraction solvent = isopropanol	Mean viability: AL-S2-3-0 = **14.6%** Positive control = **1.9%** Negative control: **100%** **Conclusion:** Mean viability of treated tissues <50%. According to the OECD 439 guideline, no classification can be determined for the product AL-S2-3-0	No deviations	Barré T. (2018) Study Number: HSMI-PH-18/0391

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro Membrane Barrier Test Method for Skin Corrosion OECD 435 GLP 1	AL-S3-3-0 500 µL onto 4 membrane barriers	Positive control = sodium hydroxide Negative control = propionic acid 6%	Test performed following 3 steps: Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation Step 2 – Timescale Category test: First trial: not conclusive Second trial: liquid turned into a yellow coloration → assignment to category 2 Step 3 - Measurement of membrane barrier penetrations: <u>AL-S3-3-0 and negative control:</u> no disruption of the membrane after 1 hour (4 replicates) <u>Positive control:</u> disruption of the membrane after 21 minutes and 24 seconds **Conclusion:** According to the OECD 435 guideline, AL-S3-3-0 is not corrosive to the skin.	No deviations	Barré T. (2018) Study Number: CTX-PH-18/0392

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro Skin irritation (Reconstructed Human Epidermis Test Method) OECD 439 GLP 1	AL-S4-3-0 16 µL to 3 living Reconstructed Human epidermis (SkinEthic RHE model)	Positive control = Sodium Dodecyl Sulfate (5%) Negative control = distilled water Application time: 42 min Rinse with 25 mL of DPBS Post-treatment incubation period = 42 hours MTT incubation period = 3 hours Formazan extraction solvent = isopropanol	Mean viability: AL-S4-3-0 = **83%** Positive control = **1.9%** Negative control = **100%** **Conclusion:** Mean viability of treated tissues > 50%. According to the OECD 439 guideline, no classification required for the product AL-S4-3-0	No deviations	Barré T. (2018) Study Number: HSMI-PH-18/0393

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro Membrane Barrier Test Method for Skin Corrosion OECD 435 GLP 1	AL-S9-3-0 500 µL onto 4 membrane barriers	Positive control = sodium hydroxide Negative control = propionic acid 6%	Test performed following 3 steps: Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation Step 2 – Timescale Category test: First trial: not conclusive Second trial: liquid turned into a yellow coloration → assignment to category 2 Step 3 - Measurement of membrane barrier penetrations: <u>AL-S9-3-0 and negative control:</u> no disruption of the membrane after 1 hour in the four replicates <u>Positive control:</u> disruption of the membrane after 21 minutes and 24 seconds **Conclusion:** According to the OECD 435 guideline, AL-S9-3-0 is not corrosive to the skin.	No deviations	Barré T. (2018) Study Number: CTX-PH-18/0394

Summary table of *in vitro* studies on skin corrosion/irritation					
In vitro Skin irritation (Reconstructed Human Epidermis Test Method) OECD 439 GLP 1	AL-S9-3-0 16 µL to 3 living Reconstructed Human epidermis (SkinEthic RHE model)	Positive control = Sodium Dodecyl Sulfate (5%) Negative control = distilled water Application time: 42 min Rinse with 25 mL of DPBS Post-treatment incubation period = 42 hours MTT incubation period = 3 hours Formazan extraction solvent = isopropanol	Mean viability: AL-S9-3-0 = **2.6%** Positive control = **1.9%** **Conclusion:** Mean viability of treated tissues <50%. According to the OECD 439 guideline, no classification can be determined for the product AL-S9-3-0	No deviations	Barré T. (2018) Study Number: HSMI-PH-18/0394

Meta SPC 1

The composition of the test item AL-S1-3-0 has been considered to cover (in terms of skin corrosion/irritation ingredients) the composition of meta SPC 1 products (see justification in the confidential annex). Therefore, the results of the *in vitro* skin irritation study performed with AL-S1-3-0 can be extrapolated to meta SPC 1.

Since the product AL-S1-3-0 is not classified for skin corrosion/irritation, the meta SPC 1 products are also considered neither corrosive nor irritant for the skin.

Meta SPC 2

The composition of the test item AL-S2-3-0 has been considered to cover (in terms of skin corrosion/irritation ingredients) the composition of meta SPC 2 products (see justification in the confidential annex). Therefore, the results of the two *in vitro* skin corrosion/irritation studies performed with AL-S2-3-0 can be extrapolated to meta SPC 2.

Since the product AL-S2-3-0 is not classified for skin corrosion and in the absence of conclusive data for skin irritation potential, the product AL-S2-3-0 and thus the meta SPC 2 products are considered as skin irritant.

Meta SPC 3

The composition of the test item AL-S3-3-0 has been considered to cover (in terms of skin corrosion/irritation ingredients) the composition of meta SPC 3 products (see justification in the confidential annex). Therefore, the results of the *in vitro* skin corrosion study performed with AL-S3-3-0 can be extrapolated to meta SPC 3.

AL-S3-3-0 is not classified for skin corrosion and in the absence of data for skin irritation potential, it is considered as a skin irritant. Therefore, the meta SPC 3 products are also considered as irritant for the skin.

Meta SPC 4

The composition of the test item AL-S4-3-0 has been considered to cover (in terms of skin corrosion/irritation ingredients) the composition of meta SPC 4 (see justification in the confidential annex). Therefore, the results of the *in vitro* skin irritation study performed with AL-S4-3-0 can be extrapolated to meta SPC 4.

Since the product AL-S4-3-0 is not classified for skin corrosion/irritation, the meta SPC 4 products are also considered neither corrosive nor irritant for the skin.

Meta SPC 9

The composition of the test item AL-S9-3-0 has been considered to cover (in terms of skin corrosion/irritationingredients) the composition of meta SPC 9 products (see justification in the confidential annex). Therefore, the results of the two *in vitro* skin corrosion/irritation studies performed with AL-S9-3-0 can be extrapolated to meta SPC 9.

AL-S9-3-0 is not classified for skin corrosion and in the absence of conclusive data for skin irritation potential, it is considered as a skin irritant. Therefore, the meta SPC 9 products are also considered irritant for the skin.

Meta SPC 6-7-8-10-11-12-13

No *in vitro*, *in vivo* or human data on the skin corrosion and irritation potential of products pertaining to meta 6-7-8-10-11-12-13 are available.

Besides, none of the studies performed with test items AL-S1-3-0, AL-S2-3-0, AL-S3-3-0, AL-S4-3-0 and AL-S9-3-0 presented above can be used by read-across for the products of meta SPC 6-7-8-10-11-12-13.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The products of meta SPC 6-7-8-10-11-12-13 are considered corrosive to the skin.
Justification for the value/conclusion	No study on skin corrosion/irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance (lactic acid) in the meta SPC 6-7-8-10-11-12-13 (8 to 24%), a classification Skin Corr. 1C H314 (in accordance with Regulation EC/1272/2008) is needed.

Classification of the product according to CLP	Skin Corr. 1C (H314)

Aspiration hazard

Meta SPC 1-4-9-10-11-12

Conclusion used in Risk Assessment – Aspiration hazard	
Value/conclusion	Not classified
Justification for the value/conclusion	Some co-formulants are classified for aspiration hazard (H304). However, they are present at a concentration largely inferior to the aspiration hazard threshold of 10%. Therefore, no classification is required.
Classification of the product according to CLP	Not classified

Meta SPC 2-3-6-7-8-13

Conclusion used in Risk Assessment – Aspiration hazard	
Value/conclusion	Not classified
Justification for the value/conclusion	None co-formulants are classified for aspiration hazard (H304). Therefore, no classification is required.
Classification of the product according to CLP	Not classified

Eye irritation

Summary table of in vitro studies on eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Isolated Chicken Eye Test Method OECD 438 GLP 1	AL-S2-3-0 30 µL to 3 enucleated chicken eyes	Positive control = benzalkonium chloride (5%) Negative control = physiological saline Application time: 10 sec Rinse with 20 mL of physiological saline Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose.	Mean score : **AL-S2-3-0:** Corneal opacity: 0.0 Fluorescein retention: 2.0 Corneal swelling: 1% ➔ Combination = 1 × III, 2 × I **Positive control:** Corneal opacity: 3.0 Fluorescein retention: 3.0 Corneal swelling: 35% ➔ Combination = 3 × IV **Negative control:** Corneal opacity: 0.0 Fluorescein retention: 0.0 Corneal swelling: 0% ➔ Combination = 3 × I **Conclusion:** According to the OECD 438 guideline, with this combination (1 × III, 2 × I) , no classification can be determined for the product AL-S2-3-0	Minor deviation: Eyes incubated between 45 and 64 minutes instead of between 45 and 60 minutes (OECD 438 guideline) Results with eyes treated with the negative control: conformed to what was expected during the maximal time of incubation → no impact expected.	Barré T. (2018) Study Number: ICE-PH-18/0391

Isolated Chicken Eye Test Method OECD 438 GLP 1	AL-S9-3-0 30 µL to 3 enucleated chicken eyes	Positive control = benzalkonium chloride (5%) Negative control = physiological saline Application time: 10 sec Rinse with 20 mL of physiological saline Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose.	Mean score : **AL-S9-3-0:** Corneal opacity: 1.0 Fluorescein retention: 3.0 Corneal swelling: 3% ➔ Combination = 1 × I, 1 × II, 1 × IV **Positive control**: Corneal opacity: 3.0 Fluorescein retention: 3.0 Corneal swelling: 43% ➔ Combination = 3 × IV **Negative control:** Corneal opacity: 0.0 Fluorescein retention: 0.5 Corneal swelling: 0% ➔ Combination = 3 × I **Conclusion:** According to the OECD 439 guideline, with this combination (1 × I, 1 × II, 1 × IV), no classification can be determined for the product AL-S9-3-0	No deviations	Barré T. (2018) Study Number: ICE-PH-18/0394

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Eye Irritation/Corrosion OECD 405 GLP 1	Rabbit (New Zealand White) Females 3	AL-S2-3-0 0.1 mL into the conjunctival sac of one eye Ocular examinations 1h, 24h, 48h and 72 h following treatment	Corneal effects were all reversible within 21 days **Mean 24-48-72 hours (per animal):** Corneal opacity: 1.7/0.7/0.7 Iris: 0.7/0.0/0.0 Conjuctivivae: 1.3/0.0/0.3 (chemosis) 1.7/0.3/0.7 (redness) **Conclusion:** According to the OECD 435 guideline and CLP criteria, AL-S2-3-0 is not classified for eye irritation.	No major deviations	[redacted] (2018) Study Number: IO-OCDE-PH-18/0391

Acute Eye Irritation/Corrosion OECD 405 GLP 1	Rabbit (New Zealand White) Females 3	AL-S9-3-0 0.1 mL into the conjunctival sac of one eye Ocular examinations 1h, 24h, 48h and 72 h following treatment	Corneal effects were all reversible within 21 days **Mean 24-48-72 hours (per animal):** Corneal opacity: 1.7/0.3/1.7 Iris: 0.7/0.0/1.0 Conjuctivivae: 3.3/0.3/1.0 (chemosis) 2.0/0.3/1.7 (redness) ➔ In at least 2 of 3 tested animals: - corneal opacity ≥1 - iritis ≥1 - conjunctival redness ≥2 - conjuctival oedema (chemosis) ≥2 **Conclusion:** According to the OECD 435 guideline and CLP criteria, AL-S9-3-0 is classified for eye irritation (H319).	No major deviations	[redacted] (2018) Study Number: IO-OCDE-PH-18/0394

Meta SPC 1 and Meta SPC 2

The composition of the test item AL-S2-3-0 has been considered to cover (in terms of eye corrosion/irritation ingredients) the composition of meta SPC 1 and meta SPC 2 products (see justification in the confidential annex). Therefore, the results of the *in vitro* and *in vivo*

eye irritation studies performed with AL-S2-3-0 can be extrapolated to both meta SPC 1 and 2 products.

Since the product AL-S2-3-0 is not classified for eye irritation, the meta SPC 1 and 2 products are also considered not classified for eye irritation.

Meta SPC 9

The composition of the test item AL-S9-3-0 has been considered to cover (in terms of eye corrosion/irritation ingredients) the composition of meta SPC 9 products (see justification in the confidential annex). Therefore, the results of the *in vitro* and *in vivo* eye irritation studies performed with AL-S9-3-0 can be extrapolated to meta SPC 9.

Since the product AL-S9-3-0 is classified for eye irritation, the meta SPC 9 products are also classified for eye irritation (H319).

Meta SPC 3-4-6-7-8-10-11-12-13

No *in vitro*, *in vivo* or human data on the eye irritation potential of products pertaining to meta 3-4-6-7-8-10-11-12-13 are available.

Besides, none of the studies performed with test items AL-S2-3-0 and AL-S9-3-0 presented above can be used by read-across for the products of meta SPC 3-4-6-7-8-10-11-12-13.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The products of meta SPC 3-4-6-7-8-10-11-12-13 are considered to cause serious eye irritation.
Justification for the value/conclusion	No study on eye irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance (lactic acid) in the meta SPC 3-4-6-7-8-10-11-12-13 (3.2 to 24%), a classification Eye Dam.1 H318 (in accordance with Regulation EC/1272/2008) is needed.
Classification of the product according to CLP	Eye Dam.1 (H318)

Respiratory tract irritation

All meta SPC

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Not irritating to the respiratory tract
Classification of the product according to CLP	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation.

Skin sensitization

Meta SPC 9-10-11-13

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	No study on skin sensitisation was performed. Therefore, the classification is determined according to the CLP Regulation. No classification for skin sensitisation is required. However, several ingredients classified as sensitizing (Skin Sens. 1/1B or Skin Sens 1A) are present at a concentration greater or equal to 1/10 of the GCL or SCL (depending on categorisation). Therefore, EUH208 labelling for these ingredients is needed. For more details, please see confidential annex.
Classification of the product according to CLP	Not classified. Additional labelling information EUH208 required.

Meta SPC 1-2-3-4-6-7-8-12

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	No study on skin sensitisation was performed. Therefore, the classification is determined by calculation according to the CLP Regulation (please see confidential annex). No classification for skin sensitisation or additional labelling information is required.
Classification of the product according to CLP	Not classified

Respiratory sensitization (ADS)

All meta SPC

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract
Justification for the value/conclusion	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitisation.
Classification of the product according to CLP	Not classified.

Acute toxicity

Acute toxicity by oral route

Meta SPC 2

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route.
Justification for the selected value	The classification has been determined using the calculation method. None of the co-formulants/ingredients classified for acute oral toxicity is present at a relevant concentration to be taken into account in the calculation.
Classification of the product according to CLP	Not classified

Meta SPC 6

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route.
Justification for the selected value	The classification has been determined using the calculation method. One co-formulant is classified for acute oral toxicity Category 4 and present at a relevant concentration to be taken into account in the calculation. ATE_{mix} calculated as 100/ (1.2/500*) = 41667 mg/kg. This is > 2000 mg/kg. Therefore, no classification for acute oral toxicity is required.
Classification of the product according to CLP	Not classified.

**Converted acute toxicity point estimate of the co-formulant according to the CLP Guidance (2017)*

Meta SPC 10

Value used in the Risk Assessment – Acute oral toxicity

Value	Not acutely toxic via oral route.
Justification for the selected value	The classification has been determined using the calculation method. One co-formulant is classified for acute oral toxicity Category 4 and present at a relevant concentration to be taken into account in the calculation. ATE_{mix} calculated as 100/ (1.5/500*) = 33333 mg/kg. This is > 2000 mg/kg. Therefore, no classification for acute oral toxicity is required.
Classification of the product according to CLP	Not classified.

** Converted acute toxicity point estimate of the co-formulant according to the CLP Guidance (2017)*

Meta SPC 1-3-4-7-8-9-11-12-13

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route.
Justification for the selected value	None of the co-formulants/ingredients is classified for acute oral toxicity.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

All Meta SPC

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via inhalation route.
Justification for the selected value	None of the co-formulants/ingredients is classified for acute inhalation toxicity.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

All Meta SPC

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via dermal route.
Justification for the selected value	None of the co-formulants/ingredients is classified for acute dermal toxicity.
Classification of the product according to CLP	Not classified

Information on dermal absorption

Only local effects are triggered by lactic acid (no calculation regarding the estimation of level of exposure of lactic acid is necessary).

Therefore, in this context, the derivation of a dermal absorption is not relevant.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Meta SPC 13
An EU IOELV of 67.5 mg/m^3 is available for diethylene glycol monobutyl ether (2-(2-butoxyethoxy)ethanol), which is present in meta 13 at 5.5%.

Therefore, according to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, diethylene glycol monobutyl ether (2-(2-butoxyethoxy)ethanol) is considered as a SOC.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
	Primary (direct) exposure			Secondary (indirect) exposure			
Exposure path	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	Yes	Yes	Yes	Yes	Yes	Yes	n.a.
Dermal	Yes	Yes	Yes	Yes	Yes	Yes	n.a.
Oral	No	No	No	No	No	Yes	Yes

LACTIC ACID BASED PRODUCTS family is used by industrials/professionals for:

- Disinfection for hard surfaces of industry, institution, healthcare facilities and food preparation and handling areas by spraying/wiping/mopping/brushing/scrubbing (PT 2-4) - **Meta SPC 2-3-4-6-7-11-12-13**

LACTIC ACID BASED PRODUCTS family is used by non-professionals for:

For Meta SPC 1, 2, 8, 9 and 10 (PT2)
- Disinfectants for hard surfaces of domestic area by:

Spraying, Wiping, Brushing, Scrubbing for Meta SPC 1 and 2 plus mopping for Meta SPC 10 and Wiping, Brushing, Scrubbing, Mopping for Meta SPC 8 and 9

For Meta SPC 2 (PT4)
- Disinfectants for hard surfaces including food contact surfaces of domestic area by:

Spraying, Wiping, Brushing, Scrubbing

For Meta SPC 9 and 10 (PT3)
- Disinfectants for hard surfaces in companion animals' environment for private homes and pets shelters by:

Wiping, Brushing, Scrubbing, Mopping for Meta SPC 9 and Spraying, Wiping, Brushing, Scrubbing, Mopping for Meta SPC 10

The biocidal products are packed in:

- Trigger spray (from 500 mL to 1 L)
- Foam trigger (from 500 mL to 1 L)
- Bottle (from 250 mL to 1L)
- Drum (5-10L)
- Barrel (from 20L to 200 L)
- IBC (1000L)

Systemic effects

L(+)-lactic acid ***(all meta SPC)***

The primary mode of action of the active substance, *i.e* L(+)-lactic acid, is characterised by local effects and has a very low systemic toxicity. Therefore, derivation of any systemic toxicological reference value has been considered unnecessary during the approval of L(+)-lactic acid.

Besides, according to the CAR of L(+)-lactic acid (2017), systemic exposure of L(+)-lactic acid is expected to be clearly inferior to the endogenous production of L(+)-lactic acid (1667 mg/kg bw/d), even with type of application which lead to a consequent product exposure, *i.e* spraying. Therefore, for all meta SPC, no systemic exposure has been estimated for the active substance.

Local effects

Meta SPC 1

Meta SPC 1 is not classified for local effects but contains L(+)-lactic acid which has local effects. Therefore, a semi-quantitative risk assessment has been performed using the dermal NOAEC of 10%.

Meta SPC 2-3-4-6-7-8-9-10-11-12-13

Because of the classification of:

Meta SPC 2: H315
Meta SPC 3: H315-H318
Meta SPC 4: H318
Meta SPC 9: H315-H319
Meta SPC 6-7-8-10-11-12-13: H314-H318,
a qualitative risk assessment has been performed according to the Guidance on BPR: Volume III Part B+C.

Meta SPC 13 : *2-(2-butoxyethoxy)ethanol*

A local quantitative risk assessment for 2-(2-butoxyethoxy)ethanol has been performed using the EU IOELV of 67.5 mg/m^3.

List of scenarios

Local exposure assessment for META SPC 13

Use #1: Disinfectants for hard surfaces of industry, institution and healthcare facilities – professional user

Types of application for use 1:
Spraying, Wiping (applying product onto surface followed by wiping), Brushing, Scrubbing, Mopping (applying product onto surface followed by mopping)

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
PRIMARY EXPOSURE - Meta SPC 13 (2-(2-butoxyethoxy)ethanol) Use # 1			
1.	Manual mixing and loading	**Primary exposure – Dermal and inhalation exposure (dropplets)** Products of meta SPC 13 are manually loaded and mixed with water in a bucket or machine's tank (scrubber-dryers, single-disk scrubbers, high or low pressure sprayers) from a refill drum of 5 to 20L or a bottle of 250 mL-1L.	Industrials/ Professionals
2.	Semi-automatic mixing and loading	**Primary exposure – Dermal and inhalation exposure (dropplets)** Semi-automatic mixing and loading into a bucket or machine's tank (scrubber-dryers, single-disk scrubbers, high or low pressure sprayers).	Industrials/ Professionals
3.	Exposure to volatilized residues during mixing and loading	**Primary exposure – Inhalation exposure (vapors)** Due to the volatility of 2-(2-butoxyethoxy)ethanol, exposure to volatilized residues occurs during mixing and loading.	Industrials/ Professionals
4.	Spray application (low-pressure sprayer)	**Primary exposure – Dermal and inhalation exposure (aerosols)** Products of meta SPC 13 are sprayed on hard surfaces using a low-pressure sprayer, leading to dermal and inhalation exposure.	Industrials/ Professionals
5.	Spray application (high-pressure sprayer)	**Primary exposure – Dermal and inhalation exposure (aerosols)** Products of meta SPC 13 are sprayed on hard surfaces using a high-pressure sprayer, leading to dermal and inhalation exposure.	Industrials/ Professionals
6.	Cleaning of spray equipment	**Primary exposure – Dermal and inhalation exposure (dropplets)** After spray application, low or high-pressure sprayers are washed with water.	Industrials/ Professionals
7.	Application by wiping	**Primary exposure – Dermal and inhalation exposure (dropplets)** Products of meta SPC 13 are applied by wiping with a sponge or cloth.	Industrials/ Professionals

Summary table: scenarios			
8.	Application by manual mopping	**Primary exposure – Dermal and inhalation exposure (dropplets)** Products of meta SPC 13 are applied to the floor surface with an impregnated mop.	Industrials/ Professionals
9.	Application by semi-automatic mopping	**Primary exposure – Inhalation exposure** Products of meta SPC 13 are applied with semi-automatic machines, *e.g* scrubber-dryers and single-disk scrubbers.	Industrials/ Professionals

Industrial/Professional exposure

Meta SPC 13

Note:

According to the HEEG opinion 13 (2011), inhalation exposure to vapors of a substance can be neglected if the result of the followed equation is ≤1 :

$$\mathbf{0.328 \times [(molecular\ weight \times vapor\ pressure)/ AEL_{long\text{-}term}]}$$

According to REACH registration dossier, 2-(2-butoxyethoxy)ethanol has a vapor pressure of 2.9 Pa and a molecular weight 162.23 g/mol. No AEC has been set for 2-(2-butoxyethoxy)ethanol but the EU IOELV of 67.5 mg/m^3 is considered relevant to be used in the equation.

Applying these parameters in the equation above, the result of the equation is:

$$\mathbf{0.328 \times [(162.23 \times 2.9)/100] = 1.54}$$

The result of the equation is superior but close to 1. Thus, the evaporation of 2-(2-butoxyethoxy)ethanol is expected to be significant but not really important. Therefore, inhalation exposure to vapors of 2-(2-butoxyethoxy)ethanol has only been considered for scenarios where the product is at a concentrate form (5.5 % of 2-(2-butoxyethoxy)ethanol) *i.e* for mixing and loading scenario, but not after dilution (0.44% of 2-(2-butoxyethoxy)ethanol).

The only toxicological reference value of 2-(2-butoxyethoxy)ethanol being the EU IOELV of 67.5 mg/m^3, only inhalation exposure has been taken into account in the scenarios.

Scenario [1] – Manual mixing and loading from drums/bottles to buckets/machines' tank

Description of Scenario [1]
According to the applicant, the product must be diluted at 8% with water before application. Therefore, the final concentration of 2-butoxyethoxy)ethanol after dilution is 0.08 × 5.5 = 0.44%. Products of meta SPC 13 contained in drums of 5L to 20L, barrels of 20L or in bottles of 250 mL to 1L are manually loaded and mixed with water in a bucket or machine's tank (scrubber-dryers, single-disk scrubbers, high or-low pressure sprayers). Inhalation exposure to aerosols is expected to be low but considered relevant. Inhalation exposure to vapors is also considered and assessed in scenario 3. To assess the exposure during this task, according to the HEEG Opinion 1 (2008), Mixing and Loading Model 7 has been used. The indicative exposure value from the model is as follows: - Inhalation exposure: 0.94 mg/m^3

	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	5.5%	

Calculations for Scenario [1]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [1]	1/no PPE	0.05	n.a	n.a	0.05

Scenario [2] – Semi-automatic mixing and loading of the product from barrel/IBC to buckets/machines' tank

Description of Scenario [2]
Meta SPC 3 products are also delivered in barrels (120 to 220L) and IBC (1000L). Considering the high volume of these packagings, products of meta SPC 13 contained in barrels or in IBC are considered semi-automatically loaded and mixed with water and then transferred in buckets or machine's tank (scrubber-dryers, single-disk scrubbers, high or-low pressure sprayers).

Description of Scenario [2]			
Inhalation exposure to aerosols is expected to be low but considered relevant. Inhalation exposure to vapors is also considered and assessed in scenario 3. To assess the exposure during this task, Mixing and Loading Model 7 (pumping) has been used according to the HEEG Opinion 1 (2008). The indicative exposure value from the model is as follows: - Inhalation exposure: 22 mg/m^3			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	5.5%	

Calculations for Scenario [2]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [2]	1/no PPE	1.2	n.a	n.a	1.2

Scenario [3] – Inhalation exposure to vapors generated during manual and semi-automatic mixing and loading

Description of Scenario [3]			
Due to the volatility of 2-(2-butoxyethoxy)ethanol, the inhalation exposure to vapor during mixing and loading has been assessed using ConsExpo web and the model for all purpose cleaning liquid – mixing and loading. Vapor pressure of 2-(2-butoxyethoxy)ethanol is 2.9 Pa at 25°C, which is lower than vapour pressure of water (3.17 kPa at 25°C). Therefore, according to the Ad Hoc Recommendation 16, the model option "product is substance in pure form" has been chosen. Constant release area mode has been considered because of surface area does not increase over time during mixing and loading (ConsExpo Web Consumer Exposure models model documentation).			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	5.5%	
	Molecular weight (g/mol)	162.23	REACH Registration dossier

Description of Scenario [3]			
	Exposure duration (min)	0.75	ConsExpo default value
	Release area (m^2)	0.002	ConsExpo default value
	Release area mode	Constant	
	Room volume (m^3)	1	ConsExpo default value
	Ventilation rate (/h)	0.5	ConsExpo default value
	Vapor pressure (Pa) of **2-(2-butoxyethoxy)ethanol**	2.9	REACH Registration dossier
	Emission duration (min)	0.25	ConsExpo default value
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
	Inhalation rate (m^3/hr)	1.25	Ad Hoc Recommendation 14 (2017)

Calculations for Scenario [3]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [3]	1/no PPE	0.01	n.a	n.a	0.01

Scenario [4] – Spray application with low-pressure sprayer

Description of Scenario [4]
Products of meta SPC 13 can be applied by indoors spraying on hard surfaces to disinfect them using a low-pressure sprayer. Inhalation exposure to the aerosols is considered. To assess the exposure during the spray application with a trigger spray, the Spraying Model 1 from the BHHEM (2015) has been used. The indicative exposure value from the model is as follows:

Description of Scenario [4]			
- 104 mg bp/m^3 (inhalation)			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	0.44%	

Calculations for Scenario [4]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [4]	1/no PPE	0.46	n.a	n.a	0.46

Scenario [5] – Spray application with high-pressure sprayer

Description of Scenario [5]			
Products of meta SPC 13 can be applied by indoors spraying on hard surfaces or on outdoors surfaces like roadways to disinfect them using a high-pressure sprayer. Inhalation exposure to the aerosols is considered. To assess the exposure during the spray application with a trigger spray, the Spraying Model 2 from the BHHEM (2015) has been used. The indicative exposure value from the model is as follows: - 76 mg bp/m^3 (inhalation)			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	0.44%	

Calculations for Scenario [5]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m3)**
Scenario [5]	1/no PPE	0.33	7.43E-02	n.a	0.33

Scenario [6] – Cleaning of spray equipment

Inhalation exposure during cleaning of spray equipment (low or high-pressure sprayer) is expected to be negligible.

Scenario [7] – Application by wiping

Description of Scenario [7]			
Products of meta SPC 13 are applied by indoors wiping on hard surfaces to disinfect them using a cloth which has been previously soaked in the product or sprayed by the trigger spray. Inhalation exposure to dropplets is considered. To assess the exposure during wiping, Surface Desinfection Model 1 from the BHHEM (2015) has been used. The indicative exposure value from the model is as follows: - 22.2 mg bp/m^3 (inhalation)			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	0.44%	

Calculations for Scenario [7]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [7]	1/no PPE	0.1	n.a	n.a	0.1

Scenario [8] – Application by manual mopping

Description of Scenario [8]
Products of meta SPC 13 can be applied by indoors wiping mopping/washing on floors to disinfect them using a mop which has been previously soaked in the product or sprayed by the trigger spray. Inhalation exposure to dropplets is considered. To assess inhalation exposure during mopping, Surface Desinfection Model 1 from the BHHEM (2015) has been used.

Description of Scenario [8]			
The indicative exposure value from the model is as follows: - 22.2 mg bp/m^3 (inhalation)			
	Parameters	Value	Reference
Tier 1	Concentration of **2-(2-butoxyethoxy)ethanol**	0.44%	

Calculations for Scenario [8]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [8]	1/no PPE	0.1	n.a	n.a	0.1

Scenario [9] – Application by semi-automatic mopping

Application of products of meta SPC 13 with scrubber-dryers or single-disk scrubbers is considered as a semi-automatic application, where no significant inhalation exposure is expected.

Only inhalation exposure to aerosols and vapors of 2-(2-butoxyethoxy)ethanol during manual or semi-automatic loading of these machines is considered (see scenario 15-16-17).

Combined scenarios

The effects of 2-(2-butoxyethoxy)ethanol are rather concentration than time-dependent (EU IOELV converted in mg/m^3). Therefore, combined scenarios have been considered as not relevant.

However, for the mixing and loading phase, the exposure to both aerosols and vapors of the SoC 2-(2-butoxyethoxy)ethanol has been evaluated. In this case, the combination of exposure to both forms (aerosols and vapors) is of relevance.
Therefore, Scenario 1 and 3 as well as 2 and 3 has been combined.

Combined Calculations for Scenario [1+3] and [2+3]

Summary table: combined estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/m^3)**
Scenario [1 +3]	1/no PPE	0.06	n.a	n.a	0.06

Summary table: combined estimated exposure from industrial uses					
Scenario [2 +3]	1/no PPE	1.21	n.a	n.a	1.21

Non-professional exposure
Not relevant.

Exposure of the general public

Meta SPC 13

The EU IOELV of 2-(2-butoxyethoxy)ethanol (67.5 mg/m^3) is only applicable for industrial/professional users. Therefore, no assessment of secondary exposure is required for general public.

Meta SPC 2–3-4-6-7-8–9-10-11-12-13

When applied, products of meta SPC 2–3-4-6-7-8–9-10-11-12-13 are classified. Therefore, dermal exposure of the general public when touching treated surfaces can occur after application by professionals or non-professionals.

Monitoring data

Not applicable.

Dietary exposure
By definition PT 02 is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected for LACTIC ACID BASED PRODUCTS for PT 2 uses.

Regarding the uses on PT 3 and 4, residues in food or feed might be expected.

For L(+) lactic acid, the following evaluation was provided in the Assessment Report, 2007: "*L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by gastro intestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzeland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day.*

L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)."

Moreover, "*Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100*

g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set".

Substances of concern (SOC)

- 2-(2-butoxythoxy)ethanol

2-(2-butoxythoxy)ethanol is considered as a SOC because it has an IOELV. 2-(2-butoxythoxy)ethanol is not relevant for dietary exposure assessment.

List of scenarios

Not relevant

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Food	Lactic Acid (E 270) – Food additive	Quantum satis (Regulation (EU) 1129/2011)
2.	Veterinary	Lactic Acid - All food producing species	No MRL required (Regulation (EC) No 37/2010)
3.	Cosmetic	Lactic Acid – Used as buffering humectant or skin conditioning	Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000)

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant

Exposure associated with production, formulation and disposal of the biocidal product

Not applicable.

Aggregated exposure

Not applicable.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/RPE**	**Estimated uptake (mg/m^3)**
Meta SPC 13			
1.	Industrials/professionals	1/no RPE	0.05
2.	Industrials/professionals	1/no RPE	1.2
3.	Industrials/professionals	1/no RPE	0.01
4.	Industrials/professionals	1/no RPE	0.46
5.	Industrials/professionals	1/no RPE	0.33
6.	Industrials/professionals	1/no RPE	Negligible
7.	Industrials/professionals	1/no RPE	0.1
8.	Industrials/professionals	1/no RPE	0.1
9.	Industrials/professionals	1/no RPE	Negligible

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Lactic acid

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$NOAEC_{dermal*}$	Derived from rabbit irritation/corrosion studies	10%	1		
ARfD	According to the Assessment Report of L(+) lactic acid for PTs 2, 3 and 4: "Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set".				
ADI					

*Meta SPC 2-3-6-7-8-9-10-11-12-13 being already classified for skin corrosion (H314) or skin irritation (H315), dermal NOAEC has only been used for the semi-quantitative local risk assessment of meta SPC 1 and 4, which are not classified for skin effects.

2-(2-butoxyethoxy)ethanol

EU IOELV = 67.5 mg/m^3

Maximum residue limits or equivalent
Not relevant.

Specific reference value for groundwater

Not relevant

Risk for industrial/professional users

Systemic effects

Not relevant.

Local effects

Quantitative assessment (for 2-(2-butoxyethoxy)ethanol)

Scenarios combined	Tier	EU IOELV (mg/m^3)	Estimated uptake (mg/m^3)	Estimated uptake/ EU IOELV

				(%)
Meta SPC 13 (2-(2-butoxyethoxy)ethanol)				
1 - Manual mixing and loading	1/no RPE	67.5	0.05	0.08
2 – Semi-automatic mixing and loading			1.2	1.78
3 – Mixing and loading (vapors)			0.01	0.04
4 - Spraying (low-pressure)			0.46	0.68
5 - Spraying (high-pressure)			0.33	0.50
6 – Cleaning of spray equipment			Negligible	-
7 - Wiping			0.1	0.14
8 – Manual mopping			0.1	0.14
9 – Semi-automatic mopping			Negligible	-
Scenario [1 +3]	1/no PPE	67.5	0.06	0.09
Scenario [2 +3]	1/no PPE	67.5	1.21	1.79

Inhalation exposure is inferior to the EU IOELV of 2-(2-butoxyethoxy)ethanol without RPE for all scenarios.

Semi-quantitative assessment (for lactic acid)

Meta SPC 4 contains 4% of lactic acid. This is below the dermal NOAEC of 10%. Therefore, no risk is expected for dermal effects of lactic acid.

Qualitative assessment

Because of the classification of meta SPC 2 (H315), meta SPC 3 (H315-H318), meta SPC 4 (H318) and meta SPC 6-7-11-12-13 (H314/H318), a qualitative risk assessment has been performed according to the Guidance on BPR: Volume III Part B+C.

Hazard	**Characteristics of the product**						**Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)**		**Risk**
Hazard category	*Effects in terms of C&L*	*Additional relevant hazard information*	*PT*	*Who is exposed?*	*Tasks, uses, processes*	*Potential exposure route*	*Frequency and duration of potential exposure*	*Degree of potential exposure (mg/m³)*	*Conclusion on risk assessment*
Meta SPC 2 – Application by spraying/wiping/brushing/scrubbing/mopping (RTU) – Uses #3-4									
Low	Skin Irrit.2, H315	-	2-4	Professionals	Spraying on hard surfaces Wiping on hard surfaces Brushing Scrubbing Mopping Cleaning of toilet bowls (spraying + brushing)	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills during loading of the trigger spray - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
Meta SPC 3 – Application by spraying/wiping/brushing/scrubbing/mopping/ (RTU) - Uses #1-2									

Low	Skin Irrit.2, H315	-	2-4	Professionals	Spraying on hard surfaces Wiping on hard surfaces Brushing Scrubbing Mopping Cleaning of toilet bowls (spraying + brushing)	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills during loading of the trigger spray - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
Very high	Eye Dam.1, H318	-	2-4	Professionals	Spraying on hard surfaces Wiping on hard surfaces Brushing Mopping Scrubbing Cleaning of toilet bowls (spraying + brushing)	Ocular	Few minutes per day or less	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no(liquid or solid) aerosol formation e.g exposure below or similar to brief contact with technical RMM and PPE as touching of	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills - The spray application must be downward in order to avoid any facial exposure. The risk is acceptable considering the following PPE: - goggles

								contaminated surfaces	
Meta SPC 4 – Application by spraying/wiping/brushing/scrubbing/mopping (RTU) – Use #1									
Very high	Eye Dam.1, H318	-	2-4	Professionals	Spraying on hard surfaces Wiping on hard surfaces Brushing Scrubbing Mopping	Ocular	Few minutes per day or less	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no(liquid or solid) aerosol formation e.g exposure below or similar to brief contact with technical RMM and PPE as touching of contaminated surfaces	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills during loading of the trigger spray - The spray application must be downward in order to avoid any facial exposure. The risk is acceptable considering the following PPE: - goggles
Meta SPC 6 – Application by spraying/wiping/brushing/scrubbing/mopping – Uses #1-2-3-4									
Concentrate									
Very high	Skin Corr. 1C, H314 Eye Dam.1, H318	-	2-4	Professionals	Mixing and loading	Dermal Ocular	Few minutes per day or less	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no(liquid or solid) aerosol formation e.g exposure below or similar to brief contact	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills - Minimisation of manual phases The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall

								with technical RMM and PPE as touching of contaminate surfaces	
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-4	Professionals	Spraying on hard surfaces Cleaning of spray equipment Wiping on hard surfaces Brushing Scrubbing Mopping Cleaning of toilet bowls (spraying + brushing)	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
Meta SPC 7 – Application by spraying/wiping/brushing/scrubbing/mopping - Uses #1-2-3-4									
Concentrate									
Very high	Skin Corr. 1C, H314	-	2-4	Professionals	Mixing and Loading	Dermal Ocular	Equal to or less than one once per week and equal to or less than few minutes per day	Pratically no exposure, e.g use of toilet cleaners	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills - Minimisation of manual phases

	Eye Dam.1, H318								The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-4	Professionals	Spraying on hard surfaces Cleaning of spray equipment Wiping on hard surfaces Brushing Scrubbing Mopping Cleaning of toilet bowls	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
Meta SPC 11 – Application by spraying/wiping/brushing/scrubbing/mopping – Use #1									
Concentrate									
Very high	Skin Corr. 1C, H314 Eye Dam.1, H318	-	2-4	Professionals	Mixing and Loading	Dermal Ocular	Equal to or less than one once per week and equal to or less than few minutes per day	Pratically no exposure, e.g use of toilet cleaners	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills - Minimisation of manual phases The risk is acceptable considering the following PPE:

									- face shield - substance/task appropriate gloves - protection coverall
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-4	Professionals	Spraying on hard surfaces Cleaning of spray equipment Brushing Scrubbing Mopping Cleaning of toilet bowls	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
Meta SPC 12 – Application by brushing/scrubbing (RTU) – Use #1									
Very high	Skin Corr. 1C, H314	-	2	Professionals	Cleaning of toilet bowls (pouring and brushing)	Dermal	Equal to or less than one once per week and equal to or less than few minutes per day	Practically no exposure, e.g use of toilet cleaners	Considering the protection offered by the cap with directional nozzle of the bottle to pour the product in toilet bowls and following PPE : - substance/task appropriate gloves - protection coverall ; the risk is acceptable.
Very high	Eye Dam.1, H318	-	2	Professionals	Cleaning of toilet bowls (pouring and brushing)	Ocular	Equal to or less than one once per week and equal to or less than few minutes per day	Practically no exposure, e.g use of toilet cleaners	Considering the type of application, no ocular exposure is expected. The risk is considered acceptable.

Meta SPC 13 – Application by spraying/wiping/brushing/scrubbing/mopping – Use #1									
Concentrate									
Very high	Skin Corr. 1C, H314 Eye Dam.1, H318	-	2	Professionals	Mixing and Loading	Dermal Ocular	Equal to or less than one once per week and equal to or less than few minutes per day	Practically no exposure, e.g use of toilet cleaners	Considering that the product will be applied by a professional, RMM must be applied: - Minimisation of splashes and spills - Minimisation of manual phases The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-4	Professionals	Spraying on hard surfaces Cleaning of spray equipment Wiping on hard surfaces Brushing Scrubbing Mopping	Dermal	More than few minutes but equal to or less than few hours per day	Controlled exposure, e.g respiratory exposure below or similar to spray application with high ventilation or technical RMM and PPE e.g cleaning and maintenance work with high ventilation or technical RMM and PPE	Considering that the product will be applied by a professional, RMM must be applied: - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with freshly treated surfaces (for bystanders) The risk is acceptable considering the following PPE: - face shield - substance/task appropriate gloves - protection coverall

Conclusion for industrial/professional users

The risk is considered acceptable considering systemic and local effects for all meta SPC.

The following PPE and RMM are needed:

*Meta SPC **2** (Uses #3-4) - **3** (Uses #1-2)*

PPE during loading of the trigger spray and application:

- ✓ Face shield
- ✓ Substance/task appropriate gloves
- ✓ Protection coverall

RMM:

- Minimisation of splashes and spills during loading of the trigger spray
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with freshly treated surfaces (for bystanders)

*Meta SPC **4** (Use #1)*

PPE during loading of the trigger spray and application:

- Goggles

RMM:

- Minimisation of splashes and spills during loading of the trigger spray
- The spray application must be downward in order to avoid any facial exposure.

*Meta SPC **6** (Uses #1-2-3-4) - **7** (Uses #1-2-3-4) - **11** (Use #1) -**13** (Use #1)*

During mixing and loading:

PPE:

- Face shield
- Substance/task appropriate gloves
- Protection coverall

RMM:

- Minimisation of splashes and spills
- Minimisation of manual phases

During application and cleaning of spray equipment:

PPE:

- Face shield
- Substance/task appropriate gloves
- Protection coverall

RMM:

- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with freshly treated surfaces (for bystanders)

*Meta SPC **12** (Use #1)*

PPE during application:

- Substance/task appropriate gloves
- Protection coverall

Risk for non-professional users

Systemic effects

Systemic exposure of L(+)-lactic acid is expected to be negligible. Therefore, for meta SPC with non-professional uses (meta SPC 1-2-8-9-10), no risk is expected for systemic effects of L(+)-lactic acid.

Semi-quantitative assessment (for lactic acid)

Meta SPC 1 contains 2.4% of lactic acid. This is below the dermal NOAEC of 10%. Therefore, no risk is expected for dermal effects of lactic acid.

Qualitative assessment

Because of the classification of meta SPC 2 (H315), meta SPC 9 (H315-H319) and meta SPC 8-10 (H314/H318), a qualitative risk assessment has been performed according to the Guidance on BPR: Volume III Part B+C.

Hazard	**Characteristics of the product**						**Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)**		**Risk**
Hazard category	*Effects in terms of C&L*	*Additional relevant hazard information*	*PT*	*Who is exposed?*	*Tasks, uses, processes*	*Potential exposure route*	*Frequency and duration of potential exposure*	*Degree of potential exposure (mg/m³)*	*Conclusion on risk assessment*
Meta SPC 2 – Application by spraying/wiping/brushing/scrubbing (RTU) – Use #1-2									
Low	Skin Irrit.2, H315	-	2-4	Non-professional	Spraying on hard surfaces Wiping on hard surfaces Brushing Scrubbing Cleaning of toilet bowls (spraying + brushing)	Dermal	Equal to or less than one hour per day	e.g use of dish cleaning product or low volume outdoor spray application	Considering that the product will be applied by a non-professional, RMM must be applied: - Minimisation of splashes and spills during loading of the trigger spray - The spray application must be downward in order to avoid any facial exposure - Avoidance of contact with treated surfaces - Wash hands after application Considering that these recommendations can be followed during this task, the risk is acceptable.
Meta SPC 8 – Application by wiping/brushing/scrubbing/mopping – Use #1									
Concentrate									
High	Skin Corr. 1C, H314	-	2	Non-professional	Mixing and Loading	Dermal Ocular	Equal to or less than one once per week and equal to or less than few minutes per day	Pratically no exposure, e.g use of toilet cleaners	Considering that the product will be used by a non-professional and in the absence of a protection offered by a cap with directional nozzle of the bottle to pour the product, **the**

	Eye Dam.1, H318								**risk is considered unacceptable (see confidential annex for more details).**
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2	Non-professional	Wiping on hard surfaces Brushing Scrubbing Mopping Cleaning of toilet bowls (pouring + brushing)	Dermal Ocular	Equal to or less than one hour per day	e.g use of dish cleaning product or low volume outdoor spray application	Considering that the product will be applied by a non-professional, RMM must be applied: - Avoidance of contact with treated surfaces - Avoid touching the eyes with hands during application - Wash hands after application Considering that these recommendations can be followed during this task, the risk is acceptable.
Meta SPC 9 – Application by spraying/wiping/brushing/scrubbing/mopping (RTU) – Uses #1-2									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-3	Non-professional	Cleaning of spray equipment Wiping on hard surfaces Mopping Scrubbing Cleaning of toilet bowls (brushing)	Dermal Ocular	Equal to or less than one hour per day	e.g use of dish cleaning product or low volume outdoor spray application	Considering that the product will be applied by a non-professional, RMM must be applied: - Minimisation of splashes and spills during loading of trigger spray or knapsack sprayer - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with treated surfaces - Avoid touching the eyes with hands during application - Wash hands after application Considering that these recommendations can be followed during this task, the risk is acceptable according to RMMs.
Meta SPC 10 – Application by spraying/wiping/brushing/scrubbing/mopping (concentrate) – Uses #1-2									
Concentrate									
High	Skin Corr. 1C, H314	-	2-3	Non-professional	Mixing and Loading	Dermal	Equal to or less than one once per week and equal to or less than few minutes per day	Pratically no exposure, e.g use of toilet cleaners	Considering that the product will be used by a non-professional and in the absence of a protection offered by a cap with directional nozzle of the bottle to pour the product, **the**

	Eye Dam.1, H318								**risk is considered unacceptable (see confidential annex for more details).**
After dilution									
Low	Skin Irrit.2, H315 Eye Irrit.2, H319	-	2-3	Non-professional	Spraying Wiping on hard surfaces Brushing Mopping Scrubbing	Dermal Ocular	Equal to or less than one hour per day	e.g use of dish cleaning product or low volume outdoor spray application	Considering that the product will be applied by a non-professional, RMM must be applied: - The spray application must be downward in order to avoid any facial exposure. - Avoidance of contact with treated surfaces - Avoid touching the eyes with hands during application - Wash hands after application Considering that these recommendations can be followed during this task, the risk is acceptable according to RMMs.

Conclusion for non professional users

*Meta SPC **1** (Use #1)*

The risk is acceptable considering systemic and local effects without RMM.

*Meta SPC **2** (Uses #1-2)*

The risk is considered acceptable considering systemic and local effects.

The following RMM are needed:

- Minimisation of splashes and spills during loading of the trigger spray
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with treated surfaces
- Wash hands after application

*Meta SPC **9** (Uses #1-2)*

The risk is considered acceptable considering systemic and local effects.

- Minimisation of splashes and spills during loading of the trigger spray or knapsack sprayer.
- The spray application must be downward in order to avoid any facial exposure.
- Avoidance of contact with treated surfaces
- Avoid touching the eyes with hands during application
- Wash hands after application

*Meta SPC **8** (Use #1) – **10** (Uses #1-2)*

The risk is acceptable considering systemic effects but unacceptable considering local effects due to the lack of a protection offered by a cap with directional nozzle of the bottle to pour the product and avoid a dermal/ocular exposure to the concentrate product which is corrosive.

Risk for the general public (secondary exposure)

*Meta SPC **1** (Use #1)*

The risk is acceptable without RMM.

*Meta SPC **2–3-4-6-7-8–9-10-11-12-13** (all uses)*

When applied, products of meta SPC 2–3-4-6-7-8–9-10-11-12-13 are classified. Therefore, dermal exposure of the general public when touching treated surfaces can occur after application by professionals or non-professionals.

Considering the addition of RMM "Avoidance of contact with treated surfaces", the risk is acceptable.

Risk for consumers via residues in food

By definition, PT 02 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs.

Regarding PT 03 and 04 uses, considering properties of L(+) lactic acid, no significant exposure via food is expected. Based on the low concentration of L(+) lactic acid, the endogenous production and the authorized used of this active substance as food additive (E 270), significant indirect exposure in food is not expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

2.2.7 Risk assessment for animal health

Systemic effects

Only meta SPC 9 and 10 lead to potential secondary exposure of companion animals (dogs/cats) or livestock animals like rabbits or poultry after treatment of their housings (hutches, henhouses, kennels, etc).
No SoCs are present in meta SPC 9 and 10. Therefore, only exposure to L(+) lactic acid is expected.
For kitten or puppy, dermal exposure by contact and oral exposure by licking and grooming is expected. For rabbits and poultrys, only dermal exposure is expected due to the absence of licking comportment.
According to the assessment report of L(+) lactic acid (2017), the endogenous production of lactic acid for dogs and rats is 3 and 6 g/kg bw/d respectively. This is clearly superior to the endogenous production of humans (1.67 g/kg bw/d).
In absence of data, the endogenous production for kittens, rabbits and poultry has been considered similar to those of dogs, and consequently superior to endogenous production for humans.
Therefore, considering that for humans, systemic exposure to L(+) lactic acid is negligible compared to the endogenous production and an acceptable risk has been considered for all exposed persons (adults and infants), the risk for animal health is considered to be covered by human health assessment.

Local effects

During their application, products of meta SPC 9 (*Use #2)* and meta SPC 10 (*Use #2)* are classified for skin irritation (H315). Therefore, dermal exposure of companion's animals during contact of treated surfaces and therefore to the irritant products can occur after application by non-professionals.

To avoid such exposure, the RMM "Keep companion's animal away from fresly treated surfaces until dry" is needed.

2.2.8 Risk assessment for the environment

The application methods claimed were revised by the applicant during the evaluation of the dossier. These updated claims correspond to deletion of some application methods in various meta SPCs. These modification are included and materialized as strikethrough text in the Intented uses part (see 2.2.1).

These changes were considered in the efficacy section but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions which consider only the updated claims.

The products from LACTIC ACID BASED FAMILY are PT02, PT03, and PT04 disinfectants containing L(+) Lactic acid that are applied for the disinfection of hard surfaces not intended for direct application to humans or animals (PT2), disinfection for veterinary hygiene (PT3) and disinfectants in food and feed area (TP4). The biocidal product family (BPF) contains several biocidal products (BP) grouped into twelve sub-groups (Meta-SPC). The data on active substance are provided by the assessment report of L(+) Lactic acid for PT02, 03, 04 (Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report L(+) Lactic acid Product-type 02, 03 and 04, June 2017). The available ecotoxicological information and e-fate data are used for risk assessment for the environment.

Two environmental substances of concern (SoC) have been identified for the LACTIC ACID BASED FAMILY:
- Amines, coco alkyldimethyl, N-oxides (meta-SPC 11; CAS 61788-90-7) and
- OTNE (meta-SPC 9, 10, 13; EC: 915-730-3).

A quantitative assessment of these constituents has been performed.

Details about the classification of co-formulants as substance of concern (SoC) or not can be found in the confidential PAR.

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No new environmental studies have been carried out with the products of the LACTIC ACID BASED FAMILY. The classification of the different meta-SPC has been calculated from classifications of the active substance and co-formulants (see the table below and the detailed composition in the confidential annex).

	Meta-SPC 1	Meta-SPC 2	Meta-SPC 3	Meta-SPC 4	Meta-SPC 6	Meta-SPC 7	Meta-SPC 8	Meta-SPC 9	Meta-SPC 10	Meta-SPC 11	Meta-SPC 12	Meta-SPC 13
Classification	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	H412	H412	H412	n.c.	H412

n.c.: Not classified

Further Ecotoxicological studies

No new data is available

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data is available

Supervised trials to assess risks to non-target organisms under field conditions

No new data is available

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data is available

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No new data is available

Foreseeable routes of entry into the environment on the basis of the use envisaged

Refer to the exposure assessment below

Further studies on fate and behaviour in the environment (ADS)

At WGII2020, it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to

increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

For soil concentration calculations, a DT50 of 30 days was stated without the need of further studies.

Leaching behaviour (ADS)

No new data is available

Testing for distribution and dissipation in soil (ADS)

No new data is available

Testing for distribution and dissipation in water and sediment (ADS)

No new data is available

Testing for distribution and dissipation in air (ADS)

No new data is available

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant

Based on the L(+) Lactic acid assessment report, the relevant PNECs for the environmental risk characterisation are reported below.

Summary table on PNEC values for L(+) Lactic acid			
$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{soil}$**
[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
10	3.9	4.8*	1.9*

* The PNECsoil and the PNECsediment are derived using the equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017, equations 89 and 91).

The PNEC values for:

- Amines, coco alkyldimethyl, N-oxides (CAS 61788-90-7) are from updated data from ECHA registration dossier of the similar substance: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS 308062-28-4) https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191) – 07/2020,

- OTNE (EC: 915-730-3) are from the updated data from ECHA registration dossier (https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15069) – 07/2020.

	Summary table on PNEC values for substances of concern (SoC)			
	$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{soil}$**
Substance of concern (SoC)	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
Amines, coco alkyldimethyl, N-oxides (**Meta-SPC 11 ;** CAS 61788-90-7)	24	3.4E-02	1.32*	1.05*
OTNE (**Meta-SPC 9, 10, 13;** EC:915-730-3)	10	4.4E-03	1.62	1.35

* The PNECsoil and/or the PNECsediment are derived using the equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017, equations 89 and 91).

2.2.8.2 Exposure assessment

The products of the LACTIC ACID BASED FAMILY are PT02, PT03 and PT04 biocides divided in 12 Meta-SPC.

The claimed uses and the scenarios covering each of them are presented in the following table:

Meta-SPC	PT	Claimed use from SPC	Description of use	Covered by
1	2	1.1	PT2 - RTU product used for the disinfection of households surfaces including toilets bowls (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach
2	2, 4	2.1 2.2 2.3 2.4	PT2 - RTU product used for the disinfection of households surfaces including toilets bowls (non-pro) PT2/4 - RTU product used for the disinfection of households food contact surfaces and devices for baby care and other risk groups. (non-pro) PT2/4: RTU product used for the disinfection for industry, institution and healthcare facilities and food preparation and handling area.	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 7: Indoor - Private use of disinfectants used in food and feed areas PT4- Scenario 8: Indoor - Disinfection in food and feed area
3	2, 4	3.1 3.2	PT2/4 - RTU disinfectants for hard surfaces for industry, institution, healthcare facilities, health care and food preparation and handling area PT2 - RTU disinfectants for hard surfaces for industry, institution, healthcare facilities and health care	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area
4	2, 4	4.1	PT2/4 - RTU disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area

6	2, 4	6.1 6.2 6.3 6.4	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area
7	2, 4	7.1 7.2 7.3 7.4	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling area PT2 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities areas	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area
8	2	8.1	PT2 - Concentrated disinfectants for hard surfaces of domestic area including toilets bowls (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach
9	2, 3	9.1 9.2	PT2 - RTU disinfectants for hard surfaces of domestic area including toilets bowls (non-pro) PT2/3 - RTU disinfectants for hard surfaces in companion animals' environment for private homes (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT3- Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission to the STP
10	2, 3	10.1 10.2	PT2 - Concentrated disinfectants for hard surfaces of domestic area (non-pro) PT2/3 - Concentrated disinfectants for hard surfaces in companion animals' environment for private homes (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT3- Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission to the STP
11	2, 4	11.1	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach

				PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area
12	2	12.1	PT2 - RTU disinfectants used for the disinfection of toilet bowls in industry, institution, healthcare facilities and health care	PT2- Scenario 1b: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications) - Disinfection of the lavatory only
13	2	13.1	PT2 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities including roadways (marketplaces, city events...) and waste containers and the floor around.	PT2- Scenario 1a: Indoor - Disinfection of of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT2- Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP PT2- Scenario 5: Outdoor - Disinfection of road ways direct emission to surface water

In order to make a worst case risk assessment covering all the relevant Meta-SPC, a comparison of the different parameters has been done in each relevant scenario's dedicated section for active substance L(+) Lactic acid and SoC OTNE. The other SoC Amines, coco alkyldimethyl, N-oxides (Meta-SPC 11) is present in only one Meta-SPC.

Assessed PT	PT 2

Assessed scenarios	Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications) Scenario 1b: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications) - Disinfection of the lavatory only (inside of toilet bowls) Scenario 2: Indoor - Disinfection of industrial areas Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP Scenario 5: Outdoor - Disinfection of road ways direct emission to surface water
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), 2011 https://echa.europa.eu/documents/10162/16908203/pt_6_7_8_9_10_assessment_of_direct_emission_surface_water_urban_areas_en.pdf/56073606-24c6-4b77-89ea-bfeec98d5943. Assessment of direct emission to surface water in urban areas (UBA, 2014)
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L(+) Lactic acid Product-type 02, 03 and 04, June 2017 Technical Agreements for Biocides v2.1, December 2019
Groundwater simulation	FOCUS PEARL 4.4.4
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

Assessed PT	PT 3
Assessed scenarios	Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission to the STP

ESD(s) used	Adapted from Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001 Adaptation of the Emission scenario document for biocides used as masonry preservatives, EUBEES, 2002
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L(+) Lactic acid Product-type 02, 03 and 04, June 2017 Technical Agreements for Biocides v2.1, December 2019
Groundwater simulation	FOCUS PEARL 4.4.4
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

Assessed PT	PT 4
Assessed scenarios	Scenario 7: Indoor - Private use of disinfectants used in food and feed areas Scenario 8: Indoor - Disinfection in food and feed area
ESD(s) used	Assessment of private use of disinfectants used in food and feed areas Version 1 (WG-I-2018) - Technical Agreements for Biocides Environment (ENV) V. 2.1, ENV 70, 2019 Emission Scenario Document for Product Type 4: Desinfectants used in food and feed areas, 2011
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L(+) Lactic acid Product-type 02, 03 and 04, June 2017 Technical Agreements for Biocides v2.1, December 2019
Groundwater simulation	FOCUS PEARL 4.4.4
Confidential Annexes	No

Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

Emission estimation

PT02 - Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications)
Covering Meta-SPC 1, 2, 3, 4, 6, 7, 8, 9, 10, 11 & 13

Worst case L(+) Lactic acid concentration for scenario 1a:

Substance: L(+) Lactic acid	**Meta-SPC 1**	**Meta-SPC 2**	**Meta-SPC 3**	**Meta-SPC 4**	**Meta-SPC 6**	**Meta-SPC 7**	**Meta-SPC 8**	**Meta-SPC 9**	**Meta-SPC 10**	**Meta-SPC 11**	**Meta-SPC 13**
Technical concentration of active substance (% w/w)	2.4	3	4	3.2	24	12	16	2.4	8	24	8
Dilution factor	RTU	RTU	RTU	RTU	0.1	0.1	0.06	RTU	0.1	0.015	0.08
Density	A density of 1 is considered for the assessment										
Concentration of substance in working solution (% w/v)	2.4	3	**4**	3.2	2.4	1.2	0.96	2.4	0.8	0.36	0.64

Worst case SoC OTNE concentration for scenario 1a:

Substance: SoC OTNE	**Meta-SPC 9**	**Meta-SPC 10**	**Meta-SPC 13**
Technical concentration of active substance (% w/w)	0.9	0.9	0.9
Dilution factor	x	0.1	0.08
Density	A density of 1 is considered for the assessment		
Concentration of substance in working solution (% w/v)	**0.9**	0.09 used for refinement as META-SPC 9 leads to non acceptable risks	0.072

Concerning the substance of concern:
- Amines, coco alkyldimethyl, N-oxides is included only in Meta SPC 11 at a concentration of 0.10% (40% in AROMOX 16.7% *1.5% dilution).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1a: Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption			
Number of inhabitants feeding one STP *Nlocal*	10 000	[-]	Default
Fraction released to wastewater F_{water}	1	[-]	Default
Concentration of substance in the product $C_{product}$ Lactic acid Amines, coco alkyldimethyl, N-oxides OTNE (meta-SPC 9) OTNE refinement (meta-SPC 10)	 4.00E-02 1.00E-03 9.00E-03 9.00E-04	kg.l^{-1}	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
Consumption per capita (general purpose + lavatory) $Q_{product}$	0.007	l.cap-1.d^{-1}	Default for household and institutional disinfection and toilet bowls
Penetration factor of disinfectant F_{penetr}	0.5	[-]	Default

Calculations for Scenario 1a

Elocalwater = Nlocal * Qproduct * Cproduct * Fpenetr * Fwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission (Elocal$_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	1.40	
Amines, coco alkyldimethyl, N-oxides	STP	3.51E-02	
OTNE (meta-SPC 9) OTNE refinement (meta-SPC 10)	STP	3.15E-01 3.15E-02	

PT02 – Scenario 1b: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications) - Disinfection of the lavatory only (inside of toilet bowls)

Covering Meta-SPC 12

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1b: Indoor - Disinfection of the lavatory (inside of toilet bowls)			
Number of inhabitants feeding one STP *Nlocal*	10 000	[-]	Default
Fraction released to wastewater F_{water}	1	[-]	Default
Concentration of substance in the product $C_{product}$	0.16	$kg.l^{-1}$	Considering that, for all the Meta-SPC, product density may vary from 1.004 to 1.077, a density of 1 is considered for the assessment
Consumption per capita (general purpose + lavatory) $Q_{product}$	0.002	$l.cap\text{-}1.d^{-1}$	Default
Penetration factor of disinfectant F_{penetr}	0.5	[-]	Default

Calculations for Scenario 1b

Elocalwater = Nlocal * Qproduct * Cproduct * Fpenetr * Fwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	1.6	

PT02 - Scenario 2: Indoor - Disinfection of industrial areas
Covering Meta-SPC 2, 3, 4, 6, 7, 11 & 13

Worst case L(+) Lactic acid concentration for scenario 2 (Small scale application RTU):

For meta-SPC 2, 3 and 4, products are ready-to-use trigger sprays applied directly on surfaces or on a wipe. Therefore a small-scale application has been considered.

Substance: L(+) Lactic acid	**Meta-SPC 2**	**Meta-SPC 3**	**Meta-SPC 4**

Technical concentration of active substance (% w/w)	3	4	3.2
Dilution factor	RTU	RTU	RTU
Density	A density of 1 is considered for the assessment		
Concentration of substance in working solution (% w/v)	3	**4**	3.2

Worst case L(+) Lactic acid concentration for scenario 2 (Large scale application):

Substance: L(+) Lactic acid	**Meta-SPC 6**	**Meta-SPC 7**	**Meta-SPC 11**	**Meta-SPC 13**
Technical concentration of active substance (% w/w)	24	12	24	8
Dilution factor	0.1	0.1	0.015	0.08
Density	A density of 1 is considered for the assessment			
Concentration of substance in working solution (% w/v)	**2.4**	1.2	0.36	0.64

Concerning the substances of concern:
For small scale RTU products:
- No substance of concern identified

For large scale applications:
- Amines, coco alkyldimethyl, N-oxides is included in Meta-SPC 11 only at a concentration of 0.10% (0.40% in AROMOX 16.7% *1.5% dilution).
- OTNE in Meta-SPC 13 is at a concentration of 0.072% (0.9% * 8% dilution).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: Disinfection of industrial areas			
Application rate of biocidal product $V_{product}$	0.04 (small scale) 0.1 (large scale)	$l.m^{-2}$	Default
Concentration of substance in the product $C_{product}$			

Lactic acid Amines, coco alkyldimethyl, N-oxides OTNE	4.00E-02 (small scale) 2.40E-02 (large scale) 1.00E-03 7.20E-04	kg.l^{-1}	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
Surface area/volume to be disinfected Area	25 (small scale) 1000 (large scale)	m^2	Default
Number of applications per day Nappl	1	d^{-1}	Default
Fraction of substance disintegrated during or after application Fdis	0	[-]	Default
Fraction released to wastewater Fwater	1	[-]	Default

Calculations for Scenario 2

Elocalwater = Vproduct * Cproduct * (Area or Volume)* Nappl * (1-Fdis) * Fwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission (Elocal$_{compartment}$) [kg/d^{-1}]**	**Remarks**
Small scale			
L(+) Lactic acid	STP	4.00E-02	
Large scale			
L(+) Lactic acid	STP	2.40	
Amines, coco alkyldimethyl, N-oxides	STP	1.00E-01	
OTNE	STP	7.20E-02	

PT02 - Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector

Covering Meta-SPC 2, 3, 4, 6, 7, 11 & 13

Worst case L(+) Lactic acid concentration for scenario 3:

Substance: L(+) Lactic acid	**Meta-SPC 2**	**Meta-SPC 3**	**Meta-SPC 4**	**Meta-SPC 6**	**Meta-SPC 7**	**Meta-SPC 11**	**Meta-SPC 13**

Technical concentration of active substance (% w/w)	3	4	3.2	24	12	24	8
Dilution factor	RTU	RTU	RTU	0.1	0.1	0.015	0.08
Density	A density of 1 is considered for the assessment						
Concentration of substance in working solution (% w/v)	3	**4**	3.2	2.4	1.2	0.36	0.64

Concerning the substances of concern:
- Amines, coco alkyldimethyl, N-oxides is included only in Meta SPC 11 at a concentration of 0.10% (40% in AROMOX 16.7% *1.5% dilution).
- OTNE in Meta-SPC 13 is at a concentration of 0.072% (0.9% * 8% dilution).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector			
Fractions released to wastewater $Fsan_{water}$ $Fobj_{water}$	 0.55 0.95	[-]	Default
Concentration of substance in the product $C_{product}$ Lactic acid Amines, coco alkyldimethyl, N-oxides OTNE	 4.00E-02 1.00E-03 7.2E-04	$kg.l^{-1}$	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
Amount of water with active substance-sanitary purpose Q_{water_san}	25	$l.d^{-1}$	Default

Calculations for Scenario 3

$Elocalwater_{sanitary}$ = Qwater_san * Csan * Fsanwater
$Elocalwater_{brushes}$ = Qwater_obj * Cobj * Fobjwater
$Elocalwater_{total}$ = Qwater_san * Csan * Fsanwater + Qwater_obj * Cobj * Fobjwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	1.50	
Amines, coco alkyldimethyl, N-oxides	STP	3.75E-02	
OTNE	STP	2.70E-02	

PT02 - Scenario 4: Outdoor - Disinfection of roadways indirect emission via STP
Covering Meta-SPC 13

The products in Meta-SPC 13 are intended to be used for the disinfection of roadways and waste containers indoor and outdoor. The products are dedicated for disinfection of marketplaces and streets after one-time events. For the majority of cities, the average frequency of market event is one time per week. However, as a worst case, daily frequency is considered in the exposure scenario.

No scenario is available for this type of outdoor use in PT02. So, it is suggested to use the scenario for disinfectants applied in industrial areas described in the ESD for PT02. Indeed, the hard surfaces in industrial premises and roadways could present comparable levels of contamination. However, the surface area to be disinfected "Large scale application" is not adapted for an average surface aera of marketplaces. Consequently, the surface AREA is updated at 15 000 m² as proposed by the applicant. Based on the information provided for two marketplaces, this value seems realistic. For instance, a marketplace in Paris, called "Place d'Aligre" has a surface area of 8050 m² [2] or for the marketplace "Place des Lices" in Vannes, the surface is 5000 m² [3]. Moreover, 15 000 m² represent the surface area equivalent to two football stadiums.

The applicant argued that this first suggested scenario represents a worst case for the uses of the products in Meta-SPC 13 and proposed a Tier 2 approach, considering an average use once a week instead of everyday, and a quantity of product used per application lower compared to the quantity estimated in Tier 1 (0.1 L/m^2). According to the customer practices, the product volume used per year in a city like Valencia in Spain is around 5000 L, therefore this volume has been rounded to 125 L per week. Considering a daily scenario, with the volume of 18 L/day (125/7), a treated surface area of 2250 m² per day has to be calculated. This Tier 2 approach was rejected because this type of treatment is considered to be a one-time event occurring on a short period of time.

Use for disinfection of waste containers and the around floor is covered by Scenario 1a when applied inside buildings, and is covered by scenario 4 and 5 when outside buiding.

[2] Nomenclature officielle des voies de Paris (place d'Aligre) [Internet]. [cited 2019 Mar 8]. Available from: http://www.v2asp.paris.fr/commun/v2asp/v2/nomenclature_voies/Voieactu/0217.nom.htm

[3] Place des Lices (Vannes). In: Wikipédia [Internet]. 2019 [cited 2019 Mar 8]. Available from: https://fr.wikipedia.org/w/index.php?title=Place_des_Lices_(Vannes)&oldid=155763344

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP			
Application rate of biocidal product $V_{product}$	0.1	$l.m^{-2}$	Default value of application rate for large scale (TAB ENV 26)
Concentration of substance in the product $C_{product}$ Lactic acid OTNE	 6.40E-03 7.20E-04	 $kg.l^{-1}$	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
AREA	15 000	m^2	Considering average surface AREA of marketplaces in France
Number of applications per day Napp	1	d^{-1}	Default
Fraction released to wastewater F_{water}	1	[-]	Default

Calculations for Scenario 4

Elocalwater = Vform * Cform * Area * Nappl * Fwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	9.60	
OTNE	STP	1.08	

PT02 - Scenario 5: Outdoor - Disinfection of roadways direct emission to surface water
Covering Meta-SPC 13

For the outdoor use of the products in Meta-SPC 13, an assessment of direct emission to surface water in urban areas is also taken into account (TAB ENV 28). Acccording to the

scenario descriptions, the scenario "Direct rainwater discharge to surface water" in case of a separate sewer system is more representative. This scenario is used for the assessment of the direct emission to surface water in urban areas.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 5: Outdoor - Disinfection of roadways direct emission to surface water			
Application rate of biocidal product $V_{product}$	0.1	$l.m^{-2}$	Default value of application rate for large scale (TAB ENV 26)
Concentration of substance in the product $C_{product}$ Lactic acid OTNE	 6.40E-03 7.20E-04	 $kg.l^{-1}$	 Considering that, for all the Meta-SPC, product density may vary from 1.004 to 1.077, a density of 1 is considered for the assessment
AREA	15 000	m^2	Considering average surface AREA of marketplaces in France
Number of applications per day Napp	1	d^{-1}	Default
Fraction released to wastewater F_{water}	1	[-]	Default

Calculations for Scenario 5

Elocalwater = Vform * Cform * Area * Nappl * Fwater

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{FRESHWATER}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	FRESHWATER	9.60	
OTNE	FRESHWATER	1.08	

PT03 - Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission via STP
Covering Meta-SPC 9 & 10

Worst case L(+) Lactic acid concentration for scenario 6:

Substance: L(+) Lactic acid	**Meta-SPC 9**	**Meta-SPC 10**
Technical concentration of active substance (% w/w)	2.4	8
Dilution factor	RTU	0.1
Density	A density of 1 is considered for the assessment	
Concentration of substance in working solution (% w/v)	**2.4**	0.8 used for refinement as META-SPC 9 leads to non acceptable risks

Worst case SoC OTNE concentration for scenario 6:

Substance: SoC OTNE	**Meta-SPC 9**	**Meta-SPC 10**
Technical concentration of active substance (% w/w)	0.9	0.9
Dilution factor	RTU	0.1
Density	A density of 1 is considered for the assessment	
Concentration of substance in working solution (% w/v)	**0.9**	0.09 used for refinement as META-SPC 9 leads to non acceptable risks

The uses in Meta-SPC 9 & 10 concern the disinfection of animal housing and pet shelters in private homes and associated equipment, for example the cages for dogs, birds and rabbits and litter trays for cats.

The indoor use is covered with PT02 - Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption

approach. Indeed, the PT02 emission scenario is based on average consumption data of detergents for surface cleaning collected from the population. It can thus be assumed that these data do not distinguish between the quantities of detergents/disinfectants used to clean, for example, the floor of the house or the cage of a pet.

Pets shelters (dog kennels) and animal housing (hutches, henhouses,…) can also be located in outdoor environment including gardens. In a worst-case situation, the evaluated housing will be a dog kennel located in a backyard. Disinfected surfaces are the interior floor and interior walls. The application takes place on hard surfaces, and after a rinsing step, all product will therefore runoff through the kennel opening to the located soil in front of the kennel opening. Direct emission to soil from disinfection of pet case and litter trays does not need to be assessed, since disinfection of pet cases and litter trays is usually performed indoors (TAB ENV58).

Dog kennels could also be built outdoor on concrete or tiled floor. In that case, the animal housing will be connected to a sewage treatment plant (STP). Therefore, the scenario 6 include indirect emission of the product via STP where daily application and 100% of emission to STP are intended.

1. Treated surface size:

For the risk assessment, a kennel of 1 x 1 x 1 meter is considered. These dimensions cover a kennel for a large dog. Surfaces to be disinfected are the kennel floor and interior walls.

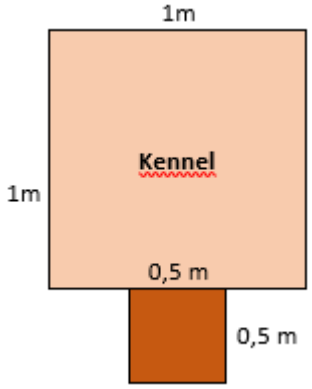

Figure 3: Sizing of a dog kennel and of the soil area receiving the product

- Kennel floor: The entire floor will be disinfected, which is a surface of 1 m².
- Kennel walls: Walls will be disinfected for a total surface of 4 m².

The total stable surface that is disinfected is **5 m²**.

2. Receiving compartment sizes:

It is considered that emissions can occur to a 0.5-meter band surrounding the emission point, and to a soil depth of 0.5 meter (considering a small scale application). It is considered that the kennel door has a width of 0.5 meters.

- Volume of the receiving compartment = (0.5*0.5) * 0.5 = **0.125 m³**

Based on the previous data, environmental emissions for the scenario 6 are calculated with the following inputs.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission via STP			
Concentration of substance in the product $C_{product}$ Lactic acid (meta-SPC 9) Lactic acid (meta-SPC 10) OTNE (meta-SPC 9) OTNE refinement (meta-SPC 10)	 2.4E-02 8.0E-03 9.0E-03 9.0E-04	$kg.l^{-1}$	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
Application rate of biocidal product $V_{product}$	0.04	$l.m^{-2}$	Default
Quantity of active ingredient applied *Qai* Lactic acid (meta-SPC 9) Lactic acid (meta-SPC 10) OTNE (meta-SPC 9) OTNE refinement (meta-SPC 10)	 9.6E-04 3.2E-04 3.6E-04 3.6E-05	kg/ m²	$Qai = C_{product} * V_{product}$
Area of the treated animal housing *AREA*	5	m²	See calculations 1 above
Number of houses connected to the STP N_{local}	4000	d^{-1}	Default
Simultaneity factor $F_{simutaneity}$	0.225	[-]	Extrapolation from TAB ENV 145 Fsimultaneity (Tier 2) = 0.45 * Freq(daily=1) * Npets(worst case=1) * Fpen(Default=0.5)
Fraction of substance disintegrated during or after application F_{dis}	0	[-]	Default

Fraction released to water F_{water}	1	[-]	Default
Receiving soil volume *Vsoil*	0.125	m³	See calculations 2 above
Bulk density of wet soil RHO_{soil}	1700	kg ww/ m³	Default value (ESD PT18, 2008)

Calculations for Scenario 6

Direct emission to soil:

$Elocal_{soil}$=Qai*AREA

Indirect emission via STP:

$Elocal_{water}$ = Qai*AREA* N_{local} * $F_{simutaneity}$ * (1-F_{dis}) * F_{water}

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
Direct release to soil			
L(+) Lactic acid (meta-SPC 9)	Soil	4.80E-03	
L(+) Lactic acid refinement (meta-SPC 10)	Soil	1.60E-03	
OTNE (meta-SPC 9)	Soil	1.80E-03	
OTNE refinement (meta-SPC 10)	Soil	1.80E-04	
Indirect release via the STP			
L(+) Lactic acid (meta-SPC 9)	STP	4.32	
OTNE (meta-SPC 9)	STP	1.62	
OTNE refinement (meta-SPC 10)	STP	1.62E-01	

PT04 - Scenario 7 Indoor - Private use of disinfectants used in food and feed areas
Covering Meta-SPC 2

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 7: Indoor - Private use of disinfectants used in food and feed areas			
Application rate of the biocidal product	0.04	L/m^2	Application rate of 0.04 L/m^2 (TAB ENV 26)
Concentration of active substance in biocidal product	30	g/L	Concentration of 3.0% technical a.s. and considering that

			product density may vary from 1.004 to 1.077 for all meta-SPC, a density of 1 is considered for the assessment
Number of households feeding one STP	4000	-	Default
Fraction of households using product	0.1	-	Default
Disinfected surface area of a private kitchen	2	m^2	Default
Number of applications	1	1/d	Default
Fraction Released to wastewater	1	-	Default
Fraction released to air	0	-	Default
Penetration factor fo disinfectant	0.5	-	Default

Calculations for Scenario 7

$Elocal_{water} = (C_{form} * Q_{appl} * Nlocal * F_{house} * Nappl * AREA_{surface} * F_{penetr} * F_{water}) / 1000$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	4.80E-01	

PT04 - Scenario 8: Indoor - Disinfection in food and feed area
Covering Meta-SPC 2, 3, 4, 6, 7 & 11

Worst case L(+) Lactic acid concentration for scenario 8 (Small scale application RTU):
For meta-SPC 2, 3 and 4, products are ready-to-use trigger sprays applied directly on surfaces or on a wipe. Therefore a small-scale application has been considered.

Substance: L(+) Lactic acid	**Meta-SPC 2**	**Meta-SPC 3**	**Meta-SPC 4**
Technical concentration of active substance (% w/w)	3	4	3.2
Dilution factor	RTU	RTU	RTU
Density	A density of 1 is considered for the assessment		

Concentration of substance in working solution (% w/v)	3	**4**	3.2

Worst case L(+) Lactic acid concentration for scenario 8 (Large scale application):

Substance: L(+) Lactic acid	**Meta-SPC 6**	**Meta-SPC 7**	**Meta-SPC 11**
Technical concentration of active substance (% w/w)	24	12	24
Dilution factor	0.1	0.1	0.015
Density	A density of 1 is considered for the assessment		
Concentration of substance in working solution (% w/v)	**2.4**	1.2	0.36

Amines, coco alkyldimethyl, N-oxides is included only in Meta SPC 11 at a concentration of 0.1002% (40 % in AROMOX 16.7% *1.5% dilution) and they will be assessed based on large scale application only.

A surface area of 10 000m2 as given for the Slaughterhouse in Emission Scenario Document for Product Type 4: Desinfectants used in food and feed areas, 2011, was use as a worst case scenario covering large scale application.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 8: Indoor - Disinfection in food and feed area			
Application rate of the biocidal product	0.04 (small scale) 0.1 (large scale)	L/m^2	TAB ENV 26
Concentration of substance in the product $C_{product}$			

Lactic acid Amines, coco alkyldimethyl, N-oxides	4.00E-02 (small scale) 2.40E-02 (large scale) 1.00E-03 (large scale)	$kg.l^{-1}$	Considering that product density may vary from 1.004 to 1.077 for all the Meta-SPC, a density of 1 is considered for the assessment
Surface area	50 (small scale) 10 000 (large scale)	m^2	Default TAB ENV 67
Number of applications	1	1/d	Default
Fraction Released to wastewater	1	-	Default

Calculations for Scenario 8

Elocalwater = C_{form} * Q_{appl} * AREAsurface * Nappl * Fwater /1000

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
Small scale			
L(+) Lactic acid	STP	8.00E-02	
Large scale			
L(+) Lactic acid	STP	2.40E+01	
Amines, coco alkyldimethyl, N-oxides	STP	1.00	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
Scenario 1a – PT02 Institutional areas	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 1b – PT02 Lavatory	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 2 – PT02 Industrial areas	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes

Identification of relevant receiving compartments based on the exposure pathway								
Scenario 3 – PT02 Disinfection of rooms, furniture and objects in medical sector	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 4 – PT02 Road ways indirect emission via STP	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 5 – PT02 Road ways direct emission to surface water	Yes	Yes	N.R.	N.R.	No	N.R.	No	No
Scenario 6 – PT03 Animal housing direct emission to soil	No	No	N.R.	N.R.	No	N.R.	Yes	Yes
Scenario 6 – PT03 Animal housing indirect emission via STP	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 7 – PT04 Private use in food and feed areas	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes
Scenario 8 – PT04 Disinfection in food and feed area	Yes	Yes	N.R.	N.R.	Yes	N.R.	Yes	Yes

Considering the intended uses and the properties of the active substance and SoCs (low vapour pressure and Henry's Law Constant), exposure to air is expected to be insignificant; therefore, a risk assessment for this compartment is not necessary.

Input parameters (only set values) for calculating the fate and distribution in the environment of L(+) Lactic acid			
Input	Value	Unit	Remarks
Molecular weight	90.08	$g.mol^{-1}$	Assessment Report L(+) lactic acid Product-type 02, 03 and 04, June 2017
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at 12°C)	1.00E+06	mg/l	Completely miscible with water
Log Octanol/water partition coefficient	-0.74	Log 10	Assessment Report L(+) lactic acid Product-type 02, 03 and 04, June 2017
Organic carbon/water partition coefficient (Koc)	20	l/kg	
Biodegradability	Readily biodegradable failing the 10-days window criterion	-	

DT_{50} for degradation in soil (at 12ºC)	30	d	30d as refinement for 90d value in AR (WGII2020)
ktotal (0.2 m relevant for STP)	2.61E-02	d-1	Calculated

Calculated fate and distribution in the STP of L(+) Lactic acid		
Compartment	Percentage [%]	Remarks
Air	2.50E-05	Simple treat v4.0
Water	22.5	
Sludge	0.20	
Degraded in STP	77.3	

Input parameters (only set values) for calculating the fate and distribution in the environment of Amines, coco alkyldimethyl, N-oxides			
Input	Value	Unit	Remarks
Molecular weight	243	$g.mol^{-1}$	ECHA registration dossier of the similar substance: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (n° CAS : 308062-28-4 https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191)
Vapour pressure (at 20°C)	7.5E-05	Pa	
Water solubility (at 20°C)	409.5	g/l	
Log Octanol/water partition coefficient (at 20°C)	<2.7	Log 10	
Organic carbon/water partition coefficient (Koc)	1746.4	l/kg	Arithmetic mean was calculated based on 3 different types of soils by using Kom converted into Koc (*1.724)
Biodegradability	Readily biodegradable with 10-days window criterion	-	ECHA registration dossier of the similar substance: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (n° CAS : 308062-28-4 https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191)
DT_{50} for degradation in soil (at 12ºC)	30	d	Default (readily biodegradable)
ktotal (0.2m relevant for STP)	2.32E-02	d-1	Calculated

Calculated fate and distribution in the STP of Amines, coco alkyldimethyl, N-oxides		
Compartment	Percentage [%]	Remarks
Air	9.17E-07	Simple treat v4.0
Water	7.09	
Sludge	13.26	
Degraded in STP	79.65	

Input parameters (only set values) for calculating the fate and distribution in the environment of OTNE			
Input	Value	Unit	Remarks
Molecular weight	234.38	$g.mol^{-1}$	ECHA registration dossier (https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15069)
Vapour pressure (at 23°C)	0.233	Pa	
Water solubility (at 20°C)	2.68	mg/l	
Log Octanol/water partition coefficient (at 30°C)	5.65	Log 10	
Organic carbon/water partition coefficient (Koc)	12589	l/kg	
Biodegradability	Not readily biodegradable	-	
DT_{50} for degradation in soil (at 12ºC)	17.4	d	ECHA registration dossier (https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15069) Recalculated by using the new equation to transferred to environmental temperature and considering the worst case (6 days) at 23°C.*
ktotal (0.2m relevant for STP)	4.09E-02	d-1	Calculated

* DT_{50} for degradation in soil (at 12ºC) of 14.4 d is obtained by using equation 28 (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017). This difference has no impact in the conclusions of this product assessment report.

Calculated fate and distribution in the STP of OTNE		
Compartment	Percentage [%]	Remarks
Air	8.25	Simple treat v4.0
Water	34.28	
Sludge	57.47	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values of L(+) Lactic acid

	PEC_{STP}	**PEC_{water}**	**PEC_{sed} (EPM covered by water)**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1a – PT02 Institutional areas	1.58E-01	1.57E-02	n.r.	3.61E-03	**2.34**
Scenario 1b – PT02 Lavatory	1.80E-01	1.80E-02	n.r.	4.13E-03	**2.67**
Scenario 2 – PT02 Industrial areas					
Small scale	4.50E-03	4.50E-04	n.r	1.03E-04	6.67E-02
Large scale	2.70E-01	2.70E-02		6.19E-03	**4.00**
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	1.69E-01	1.69E-02	n.r.	3.87E-03	**2.50**
Scenario 4 – PT02 Road ways indirect emission via STP	1.08	1.08E-01	n.r.	2.48E-02	**1.60E+01**
Scenario 5 – PT02 Road ways direct emission to surface water	n.r.	1.60	n.r.	n.r.	n.r.
Scenario 6 – PT03 Animal housing direct emission to soil					
Meta-SPC 9	n.r.	n.r.	n.r.	2.26E+01	**4.80E+04**
Refinement Meta-SPC 10	n.r.	n.r.	n.r.	7.53	**1.60E+04**
Scenario 6 – PT03 Outdoor animal housing indirect emission via STP	4.86E-01	4.86E-02	n.r.	1.12E-02	**7.21**
Scenario 7 – PT04 Private use in food and feed areas	5.40E-02	5.40E-03	n.r.	1.24E-03	**8.01E-01**
Scenario 8 – PT04 Disinfection in food and feed area					
Small scale (catering kitchens/canteens	9.00E-03	9.00E-04	n.r.	2.06E-04	**1.33E-01**
Large scale (slaughterhouse)	2.70	2.70E-01	n.r.	6.19E-02	**4.00E+01**

Summary table on calculated PEC values of amines, coco alkyldimethyl, N-oxides					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed} (EPM covered by water)**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1a – PT02 Institutional areas	1.24E-03	1.23E-04	n.r.	6.24E-03	6.61E-02
Scenario 2 – PT02 Industrial areas (large scale applications)	3.55E-03	3.52E-04	n.r.	1.78E-02	**1.89E-01**
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	1.33E-03	1.32E-04	n.r.	6.67E-03	7.07E-02
Scenario 8 – PT04 Disinfection in food and feed area (large scale applications)	3.55E-02	3.52E-03	n.r.	1.78E-01	**1.89**

Summary table on calculated PEC values of OTNE					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1a – PT02 Institutional areas					
Meta-SPC 9	5.40E-02	5.30E-03	1.45	1.94E-01	**2.06E-01**
Refinement Meta-SPC 10	5.40E-03	5.30E-04	1.45E-01	1.94E-02	2.06E-02
Scenario 2 – PT02 Industrial areas (large scale applications)	1.23E-02	1.21E-03	3.32E-01	4.44E-02	4.71E-02
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	4.63E-03	4.54E-04	1.25E-01	1.67E-02	1.77E-02
Scenario 4 – PT02 Road ways indirect emission via STP	1.85E-01	1.82E-02	4.99	6.66E-01	**7.07E-01**
Scenario 5 – PT02 Road ways direct emission to surface water	-	1.77E-01*	4.85E+01	-	-
Scenario 6 – PT03 Animal housing direct emission to soil	-	-	-		
Meta-SPC 9	-	-	-	8.47	**38.1**

Refinement Meta-SPC 10	-	-	-	8.47E-01	**3.81**
Scenario 6 – PT03 Animal housing indirect emission via STP					
Meta-SPC 9	2.78E-01	2.73E-02	7.48	9.99E-01	**1.06**
Refinement Meta-SPC 10	2.78E-02	2.73E-03	7.48E-01	9.99E-02	**1.06E-01**

*The following calculations have to be considered (TAB ENV 28: The assessment of direct emission to surface water in urban areas, WGIII2014):

$Clocal_{rw\_eff} = Elocal_{rainwater} / EFFLUENT_{rainwater}$

Where: $Elocal_{rainwater}$	daily emission to the rainwater sewer	[kg d^{-1}]	
$EFFLUENT_{rainwater}$	effluent discharge rate of wastewater sewer	[L d^{-1}]	0.6E+06
$Clocal_{rw\_eff}$	concentration in rainwater	[kg L^{-1}]	

The concentration of the active substance L(+) Lactic acid in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). A qualitative argumentation for non performing Focus Pearl refinement is developed in the following section "Risk characterization".

In scenario 2 (PT02 Industrial areas - large scale applications) and in scenario 8 (PT04 Disinfection in food and feed area), the concentration of the substance of concern amines, coco alkyldimethyl, N-oxides in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). Thus, the groundwater assessment must be refined with a second tier model (FOCUS Pearl 4.4.4).

Emissions to Groundwater : Inputs for refinement (FOCUS PEARL 4.4.4)		
Input parameters amines, coco alkyldimethyl, N-oxides	**Value**	**Reference**
Molecular weight (g/mol)	243	ECHA registration dossier of the similar substance: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (n° CAS : 308062-28-4 https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191)
Water solubility (mg/l) at 20°C	4.095E+05	
Koc (L/kg)	1746.4	
Saturated vapour pressure (Pa) at 20°C	7.50E-05	
DT50 in soil (d) at 12°C	30	Default
Kom (=Koc/1.724) (L/kg)	1013	TAB 2.1 ENV 23

Freundlich exponent	1	TAB 2.1 ENV 22
Plant uptake factor	0	TAB 2.1 ENV 23
Molar activation energy (kJ/mol)	65.4	WG-IV 2019

Input parameters related to Scenarios			
Crop	Agricultural land (maize)	Grassland (alfalfa)	Remarks
Sewage sludge application rate (kg/ha)	5000 kg/ha	1000 kg/ha	D
Number of applications/interval (d)	1 sewage sludge application /yr		D
Application date	Relative application: 20 days before crop event "emergence"	Absolute application: 1st of March	D
Incorporation depth (cm)	20	10	D
Concentration of a.s. in dry sewage sludge, Csludge (mg/kg)	1.97E+02		S (summed values from Scenario 1, 2, 3 & 8)
Application rate (kg /ha/application)	9.86E-01	1.97E-01	Calculations are made based on the TAB Env V2, ENV-36

The results of the FOCUS modelings are presented below:

Emissions to Groundwater : PEC_{gw} in µg/L (FOCUS PEARL 4.4.4) – amines, coco alkyldimethyl, N-oxides		
Output		
INDIRECT EXPOSURE via the STP		
Crop	Agricultural land (maize)	Grassland (alfala)
CHATEAUDUN	0.00	0.00

HAMBURG	0.00	0.00
JOKIOINEN	-	0.00
KREMSMUENSTER	0.00	0.00
OKEHAMPTON	0.00	0.00
PIACENZA	0.00	0.00
PORTO	0.00	0.00
SEVILLA	0.00	0.00
THIVA	0.00	0.00

For all the locations, the indirect exposure via STP for agricultural land and grassland show concentrations of amines, coco alkyldimethyl, N-oxides below the threshold value of 0.1 µg/L after FOCUS refinement.

In scenario 1a, 4, 7 and 8, the concentration of the substance of concern OTNE in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). Thus, the groundwater assessment must be refined with a second tier model (FOCUS Pearl 4.4.4).

Emissions to Groundwater : Inputs for refinement (FOCUS PEARL 4.4.4)		
Input parameters OTNE	**Value**	**Reference**
Molecular weight (g/mol)	234.38	ECHA registration dossier (https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15069)
Water solubility (mg/l) at 20°C	2.68	
Koc (L/kg)	12589	
Saturated vapour pressure (Pa) at 23°C	0.233	
DT50 in soil (d) at 12°C	17.4	
Kom (=Koc/1.724) (L/kg)	7302.204	TAB 2.1 ENV 23
Freundlich exponent	1	TAB 2.1 ENV 22
Plant uptake factor	0	TAB 2.1 ENV 23

Molar activation energy (kJ/mol)	65.4	WG-IV 2019

Input parameters related to Scenarios			
Crop	Agricultural land (maize)	Grassland (alfalfa)	Remarks
Sewage sludge application rate (kg/ha)	5000 kg/ha	1000 kg/ha	D
Number of applications/interval (d)	1 sewage sludge application /yr		D
Application date	Relative application: 20 days before crop event "emergence"	Absolute application: 1st of March	D
Incorporation depth (cm)	20	10	D
Concentration of a.s. in dry sewage sludge, Csludge (mg/kg)	2.27E+03		S (summed values from Scenario 1, 2, 3, 4 & 6)
Application rate (kg /ha/application)	1.13E+01	2.27	Calculations are made based on the TAB Env V2, ENV-36

The results of the FOCUS modelings are presented below:

Emissions to Groundwater : PEC_{gw} in µg/L (FOCUS PEARL 4.4.4) – OTNE		
Output		
INDIRECT EXPOSURE via the STP – OTNE		
Crop	Agricultural land (maize)	Grassland (alfala)
CHATEAUDUN	0.00	0.00
HAMBURG	0.00	0.00
JOKIOINEN	-	0.00
KREMSMUENSTER	0.00	0.00
OKEHAMPTON	0.00	0.00

PIACENZA	0.00	0.00
PORTO	0.00	0.00
SEVILLA	0.00	0.00
THIVA	0.00	0.00

For all the locations, the indirect exposure via STP for agricultural land and grassland show concentrations of OTNE below the threshold value of 0.1 µg/L after FOCUS refinement.

Primary and secondary poisoning

Primary poisoning

Primary poisoning via the direct consumption of the products by birds and mammals is unlikely. For indoor application, the product is not accessible for poisoning. In the case of outdoor uses (Scenarios 4, 5 and 6), the product is expected to dry fast and does not contains food additives that might be attractive to non-target species. Therefore, primary poisoning is not considered relevant for this evaluation.

Secondary poisoning

The secondary poisoning assessment is not relevant for the active substance L(+) Lactic acid and for Amines, coco alkyldimethyl, N-oxides. These substances are unlikely to bioaccumulate in aquatic or terrestrial environment according to the ECHA Guidance Vol IV Part B+C. They have a low Log Kow (<3) and a BCF <100 (see table below). These values indicate a negligible potential for bioconcentration in biota and no accumulation of this substance in the food chain is expected.

Summary table on Log K_{ow} and BCF values			
	Log K_{ow}	**BCF $_{fish}$**	**BCF $_{earthworm}$**
L(+) Lactic acid	-0.74	4.80E-02	6.78
Amines, coco alkyldimethyl, N-oxides	2.7	-	-
OTNE	5.65	391	5361

However, secondary poisoning evaluation was performed for OTNE, which is use indoor in Scenarios 1a and 2 and outdoor in Scenarios 4, 5, and 6. As soil and surface water are potential receiving compartments, there could be at risk for secondary poisoning of birds and mammals by consumption of earthworms or fish. For OTNE only PNEC oral mammal is available for the evaluation, therefore only the risk for mammals was assessed.

Input parameters for calculations of secondary poisoning			
Input	**Value**	**Unit**	**Remarks**
Bioconcentration factor for mammals [BCF_{fish}]	391	[L/kg_{wet}]	Test OCDE 305
Bioconcentration factor for earthworms [$BCF_{earthworms}$]	5361	[$L/kg_{wet\ fish}$]	QSAR value

Biomagnification factor [BMF]	1	-	Default value based on BCF < 2000.
Proportion of predators alimentation coming from local area [$FOOD_{local}$]	0.5	-	Default value (ECHA Guidance Volume IV (Parts B+C, 2017))*
Fraction of gut loading in worm [F_{gut}]	0.1	[$kg_{dwt}.kg^{-1}_{wwt}$]	
Conversion factor for soil concentration wet-dry weight soil [$CONV_{soil}$]	1.13	[$kg_{wwt}.kg^{-1}_{dwt}$]	
$PNEC_{oral,predator\ mammal}$	2.67E+01	[mg/kg_{food}]	

*50 % of the diet comes from PEClocal

For all scenarios that lead to emissions to surface water or soil, the resulting concentrations in mammals are calculated according to the ECHA Guidance Volume IV Part B+C (2017).

Summary table on calculated secondary poisoning PEC values for mammals		
	Aquatic food chain	**Terrestrial food chain**
	$PEC_{oral,predator,aquatic}$ [mg/kg_{wwFISH}]	**$PEC_{oral,predator,terrestrial}$** [$mg/kg_{wwEARTHWORMS}$]
Scenario 1 – PT02 Institutional areas Meta-SPC 9 as worst case	1.04	4.98E-01
Scenario 2 – PT02 Industrial areas	2.37E-01	1.14E-01
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	8.88E-02	4.27E-02
Scenario 4 – PT02 Road ways indirect emission via STP	3.55	1.71
Scenario 5 – PT02 Road ways direct emission to surface water (as worst case)	3.45E+01	-
Scenario 6 – PT03 Animal housing direct emission to soil	-	1.39E+01
Scenario 6 – PT03 Animal housing indirect emission via STP	5.33	2.56

2.2.8.3 Risk characterisation

Atmosphere

Emissions and PECs in air are considered as negligible. It can be concluded that the use of the products of LACTIC ACID BASED PRODUCTS will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP), Aquatic compartment, Terrestrial compartment and Groundwater

Summary table on calculated PEC/PNEC values of L(+) Lactic acid					
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$** **PNEC EPM: covered by surface water**	**PEC/PNEC$_{soil}$**	**GW (µg/L)**
Scenario 1a – PT02 Institutional areas	1.58E-02	4.04E-03	n.r.	1.90E-03	**2.34**
Scenario 1b – PT02 Institutional areas (lavatory only)	1.80E-02	4.62E-03	n.r.	2.17E-03	**2.67**
Scenario 2 – PT02 Industrial areas Small scale Large scale	 4.50E-04 2.70E-02	 1.15E-04 6.92E-03	 n.r. n.r.	 5.43E-05 3.26E-03	 < 0.1 **4.0**
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	1.69E-02	4.33E-03	n.r.	2.04E-03	**2.50**
Scenario 4 – PT02 Road ways indirect emission via STP	1.08E-01	2.77E-02	n.r.	1.30E-02	**1.60E+01**
Scenario 5 – PT02 Road ways direct emission to surface water	n.r.	4.10E-01	n.r.	n.r.	n.r.
Scenario 6 – PT03 Animal housing direct emission to soil Meta-SPC 9 Refinement Meta-SPC 10				 **11.9** **3.96**	 **4.80E+04** **1.60E+04**
Scenario 6 – PT03 Animal housing indirect emission via STP	4.86E-02	1.25E-02	n.r.	5.87E-03	**7.21**
Scenario 7 – PT04 Private use in food and feed areas	5.40E-03	1.39E-03	n.r.	6.52E-04	**0.80**
Scenario 8 – PT04 Disinfection in food and feed area Small scale	 9.00E-04	 2.31E-04	 n.r.	 1.09E-04	 **0.13**

Large scale	2.70E-01	6.92E-02	n.r.	3.26E-02	**40.00**

Conclusion:
For the active substance L(+) Lactic acid, risks to the STP, aquatic and terrestrial compartments are acceptable for the use of the products of LACTIC ACID BASED PRODUCTS.

At WGII2020, it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.
For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

Therefore, for the active substance L(+) Lactic acid, risks are acceptable for all compartments under all the scenarios.

Summary table on calculated PEC/PNEC values of Amines, coco alkyldimethyl, N-oxides					
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$** **PNEC EPM: covered by surface water**	**PEC/PNEC$_{soil}$**	**GW *(µg/L)**
Scenario 1a – PT02 Institutional areas	5.18E-05	3.63E-03	n.r.	5.94E-03	< 0.1
Scenario 2 – PT02 Industrial areas Large scale	1.48E-04	1.03E-02	n.r.	1.69E-02	< 0.1
Scenario 3 - PT02 Disinfection of rooms, furniture and	5.54E-05	3.88E-03	n.r	6.36E-03	< 0.1

objects in medical sector					
Scenario 8 – PT04 Disinfection in food and feed area Large scale	1.48E-03	1.04E-01	n.r.	1.70E-01	< 0.1

* After Focus refinement

Conclusion:
For the substance of concern Amines, coco alkyldimethyl, N-oxides, risks to the STP, aquatic and terrestrial compartments and for groundwater are acceptable for the use of the products of LACTIC ACID BASED PRODUCTS.

Summary table on calculated PEC/PNEC values of OTNE

	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{soil}$**	**GW* (µg/L)**
Scenario 1a – PT02 Institutional areas					
Meta-SPC 9	5.40E-03	**1.20**	8.98E-01	1.44E-01	< 0.1
Refinement Meta-SPC 10	5.40E-04	1.20E-01	8.98E-02	1.44E-02	< 0.1
Scenario 2 – PT02 Industrial areas Large Scale	1.23E-03	2.75E-01	2.05E-01	3.29E-02	< 0.1
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	4.63E-04	1.03E-01	7.69E-02	1.23E-02	< 0.1
Scenario 4 – PT02 Road ways indirect emission via STP	1.85E-02	**4.13**	**3.08**	4.93E-01	< 0.1
Scenario 5 – PT02 Road ways direct emission to surface water	-	**4.02E+01**	**2.99E+01**	-	-
Scenario 6 – PT03 Animal housing direct emission to soil	-	-	-		
Meta-SPC 9				**6.27**	< 0.1
Refinement Meta-SPC 10				6.27E-01	< 0.1
Scenario 6 – PT03 Animal housing indirect emission via STP					
Meta-SPC 9	2.78E-02	**6.19**	**4.62**	7.40E-01	< 0.1
Refinement Meta-SPC 10	2.78E-03	6.19E-01	4.62E-01	7.40E-02	< 0.1

* FOCUS refinement

Conclusion: For the substance of concern OTNE, risks to the STP, and for groundwater are acceptable for the use of the products of LACTIC ACID BASED PRODUCTS. However, risk are not acceptable in Scenario 1 (Meta-SPC 9) for surface water, in Scenario 4 (Meta-SPC 13), 5 (Meta-SPC 13) and 6 (via STP-Meta SPC 9) for the aquatic compartment (surface water and sediment) and in Scenario 6 (direct emission to soil-Meta-SPC 9) for terrestrial compartment.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not expected as direct exposure of the environment is not an intended use. Therefore, risk are acceptable for primary poisoning.

Secondary poisoning

As detailed in the exposure assessment section above, Active substance L(+) Lactic Acid, SoCs Amines, coco alkyldimethyl, N-oxides have a log Kow <3 and a BCF <100. Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

For SoC OTNE the summary table for Risk ratio calculation is presented below:

Summary table on secondary poisoning		
Scenario	**PEC/PNEC$_{mammals}$ aquatic**	**PEC/PNEC$_{mammals}$ terrestrial**
Scenario 1 – PT02 Institutional areas	3.88E-02	1.86E-03
Scenario 2 – PT02 Industrial areas	8.87E-03	4.26E-03
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	3.33E-03	1.60E-03
Scenario 4 – PT02 Road ways indirect emission via STP	1.33E-01	6.39E-02
Scenario 5 – PT02 Road ways direct emission to surface water	**1.29**	-
Scenario 6 – PT03 Animal housing direct emission to soil	-	5.22E-01
Scenario 6 – PT03 Animal housing indirect emission via STP	2.00E-01	9.59E-02

Conclusion: For all the assessed substance, risks of primary and secondary poisoning are acceptable for the use of the products of LACTIC ACID BASED PRODUCTS, except for scenario 5.

Mixture toxicity

All the environmental compartments are concerned for this assessment and two co-formulants have been identified as substances of concern for the environment according to Article 3 of the Regulation (EU) No 528/2012. These substances are Amines, coco alkyldimethyl, N-oxides, and OTNE.

These substances are included in the products in Meta-SPC 3, 9, 10, 11 and 13. Scenario 1b and scenario 7 are not relevant for the assessment because they only include L(+)Lactic acid and no other co-formulant classified as SoC. Moreover, scenario 1a for Meta-SPC 9, scenarios 4, 5 and 6 (direct release to soil) already show unacceptable risks for one individual substance and are not include in the mixture assessment.

No synergistic interaction is foreseen between L(+) Lactic acid and SoCs.

Considering that only a qualitative assessment is required for active substance L(+) Lactic acid, it has not been included in the mixture risk assessment calculation for groundwater. The result of mixture toxicity assessment of the products of LACTIC ACID BASED PRODUCTS containing the active substance L(+) Lactic acid (except for groundwater), SoC Amines, coco alkyldimethyl, N-oxides and SoC OTNE is summarized in the following table.

$\Sigma PEC/PNEC_{water}$ covers the risks for the sediment and the aggregated values are not presented.

Summary table on calculated ΣPEC/PNEC values				
	$\Sigma PEC/PNEC_{STP}$	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{Soil}$**	**ΣPEC_{GW}* (µg/L)**
Scenario 1a – PT02 Institutional areas (L(+) Lactic acid + Amines, coco alkyldimethyl, N-oxides + OTNE **For OTNE: Meta-SPC 10 as a refinement of Meta SPC 9 that leads to unacceptable risks for OTNE alone**	1.63E-02	1.28E-01	2.22E-02	<0.5
Scenario 2 – PT02 Industrial areas, Large Scale (L(+) Lactic acid + Amines, coco alkyldimethyl, N-oxides + OTNE) **Large scale applications as a worst case**	2.84E-02	2.93E-01	5.31E-02	<0.5
Scenario 3 - PT02 Disinfection of rooms, furniture and objects in medical sector	1.74E-02	1.11E-01	2.07E-02	<0.5

(L(+) Lactic acid + Amines, coco alkyldimethyl, N-oxides + OTNE)				
Scenario 6 – PT03 Animal housing indirect emission via STP (L(+) Lactic acid and OTNE) **For OTNE: Meta-SPC 10 as a refinement of Meta SPC 9 that leads to unacceptable risks for OTNE alone**	5.14E-02	6.32E-01	7.98E-02	<0.5
Scenario 8 – PT04 Disinfection in food and feed area (large scale) (L(+) Lactic acid + Amines, coco alkyldimethyl, N-oxides)	2.72E-01	1.74E-01	2.02E-01	<0.5

*Considering that only a qualitative assessment is required for active substance L(+) Lactic acid, it has not been included in the mixture risk assessment calculation for groundwater.

Conclusion: It can be concluded that the mixture toxicity assessment shows acceptable risks for all the compartments and groundwater for the use of the products of LACTIC ACID BASED PRODUCTS that show acceptable risks for the different substances individually.

Aggregated exposure (combined for relevant emmission sources)

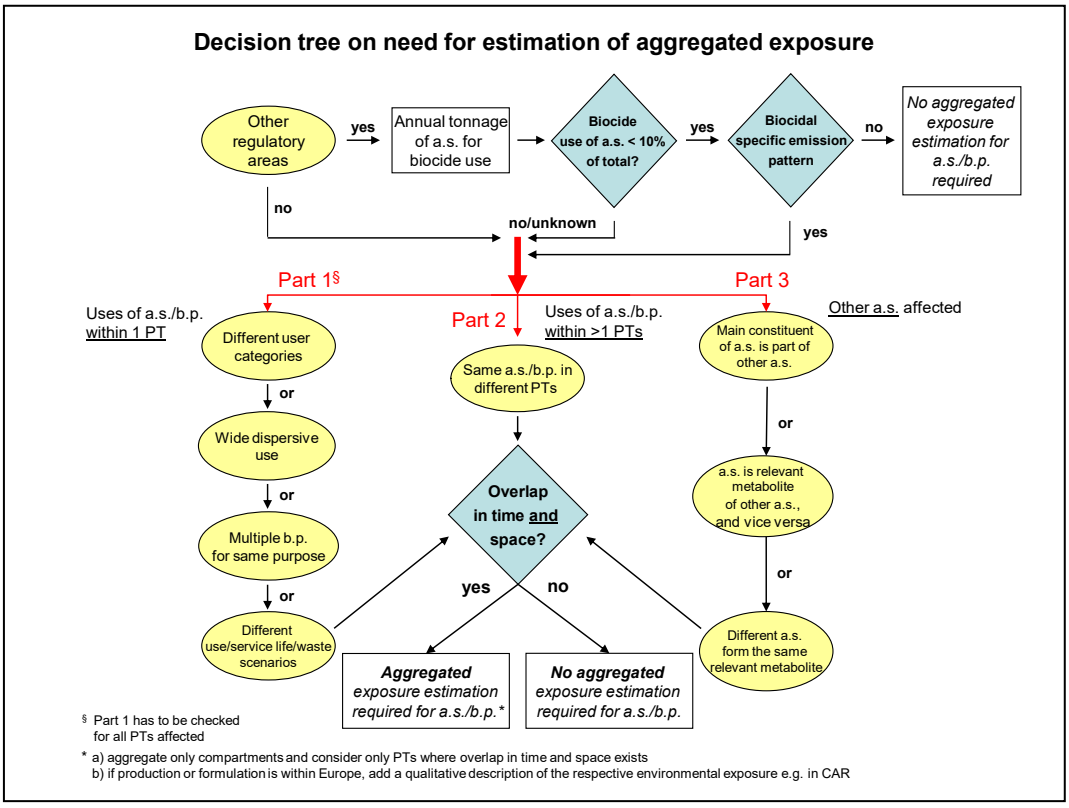

Figure 1: Decision tree on the need for estimation of aggregated exposure

According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant. The decision tree above was used to evaluate the need for estimation of aggregated exposure.

Since the amount of L(+)Lactic acid that is used annually in biocidal products accounts for less than 10% compared to the annual production and import volume of L(+) Lactic acid in the EU, no aggregated risk assessment was performed. Moreover, scenarios 1 (Meta-SPC 9), 4, 5 and 6 (direct release to soil) already show unacceptable risks and are not include in the aggregated exposure assessment.

For SoCs, an aggregated exposure has to be evaluated for each substance: Amines, coco alkyldimethyl, N-oxides and OTNE.

Summary table on calculated ΣPEC/PNEC values					
Substance	**$\Sigma PEC/PNEC_{STP}$**	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{sed}$**	**$\Sigma PEC/PNEC_{soil}$**	**ΣPEC_{GW} (µg/L)**
Amines, coco alkyldimethyl, N-oxides	1.73E-03	1.22E-01	n.r.	1.99E-01	< 0.1

Scenario 1a, 2, 3 & 8 (large scale)					
OTNE* Scenario 1a, 2, 3, 6 (via STP)	5.01E-03	**1.12**	n.r. (covered by surface water)	1.34E-01	< 0.1
Total	6.75E-03	**1.24**	n.r.	3.33E-01	

* After refinement with Meta-SPC 10

Conclusion: Unacceptable risks are observed for surface water following the aggregate assessment of the use of the products of LACTIC ACID BASED PRODUCTS.

Considering the releases to different STP in function of the sector where the products are applied, this aggregated approach is an unrealistic worst case. In fact, we can consider that wide dispersive uses are only under scenario 1a (Institutional areas) and scenario 6 (Animal housing indirect emission via STP). Otherwise it seems unrealistic to sum up the emissions from industrial areas (scenario 2), heath care areas (scenario 3) and food and feed areas/slaugtherhouse (scenario 8) that release their waste water to separate STP. Moreover the proposed scenarios are the worst ones covering all the related uses. Finally, as all the uses lead to acceptable risks separately, the product family can be authorised awaiting the rules from ECHA/Commission to derive conclusions from the aggregated risk assessment.

Considering all these points, the aggregate risk assessment can be considered acceptable for the authorised uses.

Overall conclusion on the risk assessment for the environment of the product				
Summary table for the risk assessment of the products LACTIC ACID BASED PRODUCTS				
	STP	**Surface water covering sediment**	Soil	Groundwater
PT02 Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach Meta-SPC 9 (absolute worst case) Meta-SPC 10 (as a refinement covering all the other relevant Meta-SPC) This scenario also covers the releases of indoor disinfection of animal housing	Acceptable Acceptable	**Unacceptable** Acceptable	Acceptable Acceptable	Acceptable
PT02 Scenario 1b: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (toilet bowls only)	Acceptable	Acceptable	Acceptable	
PT02 Scenario 2: Indoor - Disinfection of industrial areas	Acceptable	Acceptable	Acceptable	
PT02 Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector	Acceptable	Acceptable	Acceptable	

PT02 Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP (Meta-SPC 13)	Acceptable	**Unacceptable**	Acceptable	
PT02 Scenario 5: Outdoor - Disinfection of road ways direct emission to surface water (Meta-SPC 13)	Acceptable	**Unacceptable**	Acceptable	
PT02 Scenario 6: Outdoor - Disinfection of domestic animal housing (direct emission soil) Meta-SPC 9 (absolute worst case) Meta-SPC 10 (as a refinement)	n.r. n.r.	n.r. n.r.	**Unacceptable** Acceptable	
PT02 Scenario 6: Outdoor - Disinfection of domestic animal housing (indirect emission via STP) Meta-SPC 9 (absolute worst case) Meta-SPC 10 (as a refinement)	Acceptable Acceptable	**Unacceptable** Acceptable	Acceptable Acceptable	
PT04 Scenario 7: Indoor - Private use of disinfectants used in food and feed areas	Acceptable	Acceptable	Acceptable	
PT04 Scenario 8 Indoor - Disinfection of large scale feed and food areas	Acceptable	Acceptable	Acceptable	

Meta-SPC	PT	Claimed use from SPC	Description of use	Covered by	Conclusions
1	2	1.1	PT2 - RTU product used for the disinfection of households surfaces including toilets bowls (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach	Acceptable
2	2, 4	2.1 2.2 2.3 2.4	PT2 - RTU product used for the disinfection of households surfaces including toilets bowls (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach	Acceptable
		2.2	PT2/4 - RTU product used for the disinfection of households food contact surfaces and devices for baby care and other risk groups. (non-pro)	PT4- Scenario 7: Indoor - Private use of disinfectants used in food and feed areas	Acceptable
		2.3 2.4	PT2/4: RTU product used for the disinfection for industry, institution and healthcare facilities and food preparation and handling area.	PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable

3	2, 4	3.1 3.2	PT2/4 - RTU disinfectants for hard surfaces for industry, institution, healthcare facilities, health care and food preparation and handling area PT2 - RTU disinfectants for hard surfaces for industry, institution, healthcare facilities and health care	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable
4	2, 4	4.1	PT2/4 - RTU disinfectants for hard surfaces of industry, institution, healthcare facilities and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable

6	2, 4	6.1 6.2 6.3 6.4	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable
7	2, 4	7.1 7.2 7.3 7.4	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution, healthcare facilities, health care and food preparation and handling area PT2 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities areas	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable

8	2	8.1	PT2 - Concentrated disinfectants for hard surfaces of domestic area including toilets bowls (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach	Acceptable
9	2, 3	9.1 9.2	PT2 - RTU disinfectants for hard surfaces of domestic area including toilets bowls (non-pro) PT3 - RTU disinfectants for hard surfaces in companion animals' environment for private homes (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption areas PT3- Scenario 6: Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission to the STP	**Non acceptable risks for the aquatic compartment for use 9.1** **Non acceptable risks for the aquatic and terrestrial compartments for use 9.2**
10	2, 3	10.1 10.2	PT2 - Concentrated disinfectants for hard surfaces of domestic area (non-pro) PT3 - Concentrated disinfectants for hard surfaces in companion animals' environment for private homes (non-pro)	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT3- Scenario 6: Indoor & Outdoor - Disinfection of domestic animal housing - direct emission to soil and indirect emission to the STP	Acceptable risks for use 10.1 Acceptable riss for use 10.2 providing the application of the RMM: ***Do not rinse the treated surfaces when the product is used outdoor***

11	2, 4	11.1	PT2/4 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities and food preparation and handling area	PT2- Scenario 1a: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT4- Scenario 8: Indoor - Disinfection in food and feed area	Acceptable
12	2	12.1	PT2 - RTU disinfectants used for the disinfection of toilet bowls in industry, institution, healthcare facilities and health care	PT2- Scenario 1b: Indoor - Disinfection of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach (household and institutional applications) - Disinfection of the lavatory only	Acceptable

13	2	13.1	PT2 - Concentrated disinfectants for hard surfaces of industry, institution and healthcare facilities including roadways (marketplaces, city events...) and waste containers and the floor around.	PT2- Scenario 1a: Indoor - Disinfection of of institutional areas - releases of disinfectants used for sanitary purposes based on average consumption approach PT2- Scenario 2: Indoor - Disinfection of industrial areas PT2- Scenario 3: Indoor – Disinfection of rooms, furniture and objects in medical sector PT2- Scenario 4: Outdoor - Disinfection of road ways indirect emission via STP PT2- Scenario 5: Outdoor - Disinfection of road ways direct emission to surface water	Acceptable for indoor disinfection of hard surfaces of industry, institution and healthcare facilities including waste containers and the floor around **Unacceptable** for outdoor disinfection especially roadways (marketplaces, city events...) The disinfection of roadways (marketplaces, city events...) is not proposed for the authorisation and the following RMM is proposed: ***The product is for an indoor use only***

2.2.9 Measures to protect man, animals and the environment

See the SPC

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

3 ANNEXES[4]

3.1 List of studies for the biocidal product family

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in DESINFECTANT ECOCERT, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 17-901011-001 Defitraces GLP	yes	Action Pin
Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S7-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-038 Defitraces GLP	yes	Action Pin
Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S8-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-043 Defitraces GLP	yes	Action Pin
Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S9-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-048 Defitraces GLP	yes	Action Pin

4 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S10-2-1, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-054 Defitraces GLP	yes	Action Pin
Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S12-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-062 Defitraces GLP	yes	Action Pin
Ricau H.	2018	Validation of the analytical method for the determination of lactic acid in AL-S13-2-1, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-064 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in AL-S1-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-012 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in AL-S2-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-016 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in AL-S3-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-020 Defitraces GLP	yes	Action Pin

Ricau H.	2019	Validation of the analytical method for the determination of citric acid in AL-S3-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-021 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in AL-S4-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-026 Defitraces GLP	yes	Action Pin
Ricau H.	2020	Validation of the analytical method for the determination of lactic acid in AL-S6-2-0, In compliance with SANCO/3030/99 rev. 5 from 22/03/2019 Report No 19-901011-018 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of lactic acid in AL-S11-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-059 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of potassium sorbate in AL-S11-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-060 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of amines, coco alkyldimethyl, N-oxides in AL-S11-2-0, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-066	yes	Action Pin

		Defitraces GLP		
Ricau H.	2019	Validation of the analytical method for the determination of butyldiglycol in AL-S13-2-1, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-065 Defitraces GLP	yes	Action Pin
Ricau H.	2019	Validation of the analytical method for the determination of butyldiglycol in AL-S10-2-1, In compliance with SANCO/3030/99 rev. 4 from 11/07/00 Report No 18-901011-055 Defitraces GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S1-2-0 Report No 18-901011-008 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S1-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-009 Defitraces GLP	yes	Action Pin
Bulidon N.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S1-2-0 Report No IC 860008-1 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S2-2-0 Report No 18-901011-013 Defitraces GLP	yes	Action Pin

Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S2-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-014 Defitraces GLP	yes	Action Pin
Bulidon N.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S2-2-0 Report No IC 860008-2 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S3-2-0 Report No 18-901011-017 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S3-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-018 Defitraces GLP	yes	Action Pin
Fourny P.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S3-2-0 Report No IC 860008-3 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S4-2-0 Report No 18-901011-022 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S4-2-0, in compliance with CIPAC Handbook J - MT	yes	Action Pin

		46.3 method (2000) Report No 18-901011-023 Defitraces GLP		
Demangel B.	2020	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S4-2-0 - Spray droplet size distribution by laser diffraction at T = 0, In compliance with Technical Monograph No. 17, 2nd edition CropLife International Report No 18-901011-024 Defitraces GLP	yes	Action Pin
Fourny P.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S4-2-0 Report No IC 860008-4 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2020	Physico-chemical tests on AL-S6-2-0 Report No 19-901011-015 Defitraces GLP	yes	Action Pin
Halbwachs P. and Ricau H.	2020	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S6-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 19-901011-016 Defitraces GLP	yes	Action Pin
Fourny P.	2016	Determination of the corrosiveness of a solution in the presence of steel and aluminium alloy "Enzypin détartrant disinfectant sanitaires concentré" Report No PV/066/16/LC Institut de la Corrosion Non GLP	yes	Action Pin

Demangel B.	2019	Physico-chemical tests on AL-S7-2-0 Report No 18-901011-035 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S7-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-036 Defitraces GLP	yes	Action Pin
Fourny P.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S7-2-0 Report No IC 860008-5 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S8-2-0 Report No 18-901011-039 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S8-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-040 Defitraces GLP	yes	Action Pin
Bulidon N.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S8-2-0 Report No IC 860008-6 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S9-2-0 Report No 18-901011-044 Defitraces GLP	yes	Action Pin

Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S9-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-045 Defitraces GLP	yes	Action Pin
Bulidon N.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S9-2-0 Report No IC 860008-7 Institut de la Corrosion Non GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S10-2-1 Report No 18-901011-049 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S10-2-1, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-051 Defitraces GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests after a low temperature storage procedure for 7 days at 0 ± 2 °C on AL-S10-2-1, In compliance with CIPAC MT 39.3 CIPAC Handbook J (2000) Report No 18-901011-050 Defitraces GLP	yes	Action Pin
Bulidon N.	2020	Immersion test according to the Manual of Tests and Criteria of the United Nations part 37- classification of corrosive substances of Class 8 – AL-S10-2-1 Report No IC 860008-8 Institut de la Corrosion Non GLP	yes	Action Pin

Demangel B.	2019	Physico-chemical tests on AL-S11-2-0 Report No 18-901011-056 Defitraces GLP	yes	Action Pin
Demangel B. and Ricau H.	2019	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on AL-S11-2-0, In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report No 18-901011-057 Defitraces GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S12-2-0 Report No 18-901011-061 Defitraces GLP	yes	Action Pin
Demangel B.	2019	Physico-chemical tests on AL-S13-2-1 Report No 18-901011-063 Defitraces GLP	yes	Action Pin
Coste E.	2023	Determination of exothermic reactions by DSC method on AL-S1-2-0 Report No 22-901011-003 Defitraces GLP	yes	Action Pin
Coste E.	2019	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S1-2-0 Report No 22-901011-003 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S2-2-0 Report No 22-901011-004 Defitraces GLP	yes	Action Pin
Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S2-2-0 Report No 22-901011-015 Defitraces GLP	yes	Action Pin

Coste E.	2020	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S3-2-0 Report No 22-901011-019 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S3-2-0 Report No 22-901011-005 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S4-2-0 Report No 22-901011-006 Defitraces GLP	yes	Action Pin
Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S4-2-0 Report No 22-901011-024 Defitraces GLP	yes	Action Pin
Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S11-2-0 Report No 22-901011-058 Defitraces GLP	yes	Action Pin
Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S8-2-0 Report No 22-901011-041 Defitraces GLP	yes	Action Pin
Coste E.	2022	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S6-2-0 Report No 22-901011-017 Defitraces GLP	yes	Action Pin

Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S7-2-0 Report No 22-901011-037 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S6-2-0 Report No 22-901011-007 Defitraces GLP	yes	Action Pin
Coste E.	2021	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on AL-S10-2-1 Report No 22-901011-052 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S7-2-0 Report No 22-901011-008 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S10-2-1 Report No 22-901011-010 Defitraces GLP	yes	Action Pin
Coste E.	2022	Determination of exothermic reactions by DSC method on AL-S8-2-0 Report No 22-901011-009 Defitraces GLP	yes	Action Pin

3.2 Output tables from exposure assessment tools

Primary exposure meta SPC 13.xlsx

3.3 Confidential annex

See the confidential PAR.