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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by applicant)

Method Anti-bac cleaner

Product type 2

L-(+)-lactic acid

Case Number in R4BP: BC-UY050896-85

Evaluating Competent Authority: NL

Date: 24/05/2023

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1 CONCLUSION

APCP: The formulation type of the Method Anti-bac cleaner biocidal product family is AL (any other liquid). The representative product, which was used for the testing, is transparent liquid with fruity, floral, or green odour. The supported shelf-life of all products is 2 years in PET. The amount of the active substance, (L+)lactic acid, was determined with validated Gas chromatography. The products of this biocidal product family are classified as possibly corrosive to metals (H290). Further, the products are not classified for any other physical, chemical hazards.

EFFICACY: A biocidal product family was evaluated for ready to use products (with the active substance lactic acid) for the disinfection of non-porous surfaces without precleaning. The products are intended for non-professional household application. Bactericidal activity has been substantiated in clean and dirty conditions with a contact time of 5 min using the four required test bacteria in both a phase 2, step 1 and phase 2, step 2 test. The tests and test results are in agreement with the requirements in the efficacy guidance and therefore efficacy has been substantiated for this product family.

HUMAN HEALTH: This BPF is classified with H315 and H319. Based on systemic and local risk assessment, no adverse health effects are expected for non-professional users or the general public when using the products in the BPF. The following RMMs are prescribed to ensure safe use of the products:

- Avoid contact with eyes.
- Wash hands after use.
- Prevent contact of children with treated surfaces.
- Keep away from food, drink and animal feeding stuffs.

ENVIRONMENT: Method Anti-Bac cleaner product family are PT2 disinfection products containing the active substance L(+) lactic acid. Following products use, discharge of water from the STP to freshwater may occur, therefore the aquatic compartment and sediment compartment were assessed. Furthermore, the soil compartment may also be exposed when sewage sludge is applied to the soil, and therefore risks to soil organisms and groundwater were also assessed. Acceptable risk was demonstrated for all relevant environmental compartments following product use under worst-case assumptions.

One potential substance of concern was identified, ethanol. This substance was quantitatively assessed and demonstrated acceptable risk to potentially exposed compartments.

Therefore, use of Method Anti-bac cleaner as ready to use products for the disinfection of non-porous surfaces without precleaning that do not come into contact with food and feed, can be considered as safe for the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country
Method Anti-bac cleaner	Netherlands, Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	EPC NV
	Address	Industrieweg 3, 2390 Malle, Belgium
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	EPC NV
Address of manufacturer	Industrieweg 3, 2390 Malle, Belgium
Location of manufacturing sites	Industrieweg 3, 2390 Malle, Belgium

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem BV
Address of manufacturer	Arkelsedijk 46, 4206 AC, P.O. Box 21 4200 AA Gorinchem
Location of manufacturing sites	Arkelsedijk 46, 4206 AC, P.O. Box 21 4200 AA Gorinchem

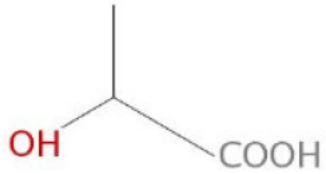
2.1.2 Product family composition and formulation

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	(S)-2-hydroxypropanoic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	607-743-00-5
Minimum purity / content	≥ 955 g/kg (dry weight)
Structural formula	

2.1.2.2 Candidate(s) for substitution

L-(+)-lactic acid is not candidate for substitution in accordance with Article 10(1) of Regulation 528/2012.

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
Lactic acid	(2S)-2-hydroxypropanoic acid	Active substance	79-33-4	201-196-2	3.0 (TK) 2.4 (TC) 2.3 (pure)	3.4 (TK) 2.7 (TC) 2.6 (pure)
Alkyl, C8-10, polyglucoside	D-Glucopyranose, oligomeric, C8-10 glycosides	Non-active substance	68515-73-1	500-220-1	1.6	1.6
Ethanol	Ethanol	Non-active substance	64-17-5	200-578-6	4	4

Please see the confidential annex for the full composition of the members of the family. Also refer to the SDS's of the individual constituents.

2.1.2.4 Information on technical equivalence

The source of the active substance is a reference source.

2.1.2.5 Information on the substance(s) of concern

In accordance with Annex A of the ECHA Guidance on the Biocidal Products Regulation: Volume III Human Health Parts B+C (version 4.0, December 2017) and Volume IV Environment Parts B+C (version 2.0, October 2017), the products were screened for the presence of substances of concern (SoC) in relation to human health and environment endpoints. All co-formulants were screened, as well as the known ingredients of the perfumes. Based on the screening it was concluded that the products contain one substance of concern for human health, Alkyl, C8-10, polyglucoside, as this substance contributes to the classification for eye irritation and one substance of concern for environment, ethanol.

In addition, as for one of the co-formulants Dutch workplace exposure limits are established, this substance is also identified as an additional SoC for human health by the eCA. As the latter substance is not considered to be a substance of concern in other Member States, the risk assessment for this substance is reported in the confidential annex.

The co-formulants, as well as the known ingredients of the perfumes, were screened for endocrine disruption properties in accordance with document 'CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants'. Based on the findings it was not considered necessary to evaluate any substance in detail in accordance with the Guidance for the

identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (EFSA Journal 2018;16(6):5311, Adopted 5 June 2018). This is also not considered needed for the active substance, as such assessment should be carried out in the context of the evaluation of the active substance itself, as part of the application for renewal of the substance in the future.

See the confidential annex for further details.

2.1.2.6 Type of formulation

AL (Any other liquid)

2.1.3 Hazard and precautionary statements[1]

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

[1] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Hazard category	Eye irritation, category 2 Skin irritation, category 2
Hazard statement	H319 Causes serious eye irritation H315 Causes skin irritation H290 May be corrosive to metals
Labelling	
Signal words	Warning
Hazard statements	H319 Causes serious eye irritation H315 Causes skin irritation H290: May be corrosive to metals
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P234: Keep only in original packaging. P264: Wash hands thoroughly after handling. 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. P337+P313: If eye irritation persists: Get medical advice/attention. 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 corrosion resistant container with a resistant inner liner.
Note	The precautionary statement P280 (wear protective gloves/protective clothing/eye protection/face protection) is considered not necessary, due to the intended use and based on the local risk assessment. An additional labelling with the RMM "Avoid contact with eyes" is considered appropriate instead. P321 is triggered by H315. However, this P-statement is highly recommended only in exceptional cases where specific treatment is known and required. No specific treatment is known, therefore P321 is not assigned.

2.1.4 Authorised use(s)

2.1.4.1 Use description[2]

Table 1. Use # 1 – Disinfection of surfaces that do not come into contact with food and feed.

Product Type	PT2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria
Field of use	Indoor Ready to use products for the disinfection of non-porous surfaces without precleaning that do not come into contact with food and feed. The products are intended for non-professional household application.
Application method(s)	Coarse spraying by trigger spray on the surfaces to be disinfected.
Application rate(s) and frequency	The products are ready-to-use and can be used on a daily basis. The product should be sprayed (approx. 56 mL/m^2) on surface, left for 5 minutes to disinfect and wiped with damp cloth after contact time. The products will be applied undiluted.
Category(ies) of users	Non-professional
Pack sizes and packaging material	490 mL; PET (transparent including UV filter) bottle, polyethylene trigger spray 828 mL PET (transparent including UV filter) bottle, polyethylene trigger spray

2.1.4.2 Use-specific instructions for use[3]

See section 2.1.5

2 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

3 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.3 Use-specific risk mitigation measures

See section 2.1.5

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

See section 2.1.5

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

See section 2.1.5

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

See section 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use[4]

Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

Make sure to wet surfaces completely by spraying the product onto the surface to be disinfected. Leave wet for 5 minutes to disinfect and thereafter wipe off with damp cloth.

2.1.5.2 Risk mitigation measures

Avoid contact with eyes.
Wash hands after use.
Prevent contact of children with treated surfaces.
Keep away from food, drink and animal feeding stuffs.
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read label before use.

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

Most important symptoms and effects, both acute and delayed:
Symptoms/effects after eye contact: eye irritation.

Description of first aid measures:
IF ON SKIN: wash with plenty of water. Thereafter take off all contaminated clothing and wash before reuse.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with licensed collector's sorting instructions.

[4] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

Store at room temperature. Protect from frost. The shelf-life is 2 years.

2.1.6 Other information

Application codes

2.1.7 Packaging of the biocidal product

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)
PET bottle	490 mL 828 mL	PET, transparent including UV filter	**Trigger sprayer:** Polyethylene: nozzle, discharge valve, piston, gasket Polypropylene: shroud, tube retainer, closure, trigger, dip tube, valve body Stainless Steel: spring, ball valve	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list with the new studies submitted for the product.

2.1.8.2 Access to documentation

Please refer to the reference list. The data submitter is the data owner.

2.2 Assessment of the biocidal product (family)

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

Table 2. Intended use # 1 – disinfection of surfaces that do not come into contact with food and feed.[5]

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria
Field of use	Ready to use product for the disinfection of surfaces that do not come into contact with food and feed. The products are intended for non-professional household application.
Application method(s)	Coarse spraying by trigger spray on the surfaces to be disinfected.
Application rate(s) and frequency	The products are ready-to-use and can be used on a daily basis. The product should be sprayed (approx. 1 mL/18 cm^2) on surface, left for 5 minutes to disinfect and wiped with damp cloth. The products will be applied undiluted.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	828 mL bottle, polyethylene

2.2.2 Physical, chemical and technical properties

Testing for physico-chemical properties was performed with the representative product of the family "Method Antibac all purpose cleaner wild rhubarb". The products within the family are all ready to use liquids (AL).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark: The 'Method Antibac all purpose cleaner wild rhubarb" is considered as a representative product of this BPF family, since all the products have the same composition and differs only by the used perfume.				
Physical state at 20 °C and 101.3 kPa	Visual inspection	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i.	Transparent liquid	[redacted]

[5] Copy this section as many times as necessary (one table per use).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch 1234144856		
Colour at 20 °C and 101.3 kPa	Visual inspection	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	Transparent	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	The type of odour depends on the type of used perfume: fruity, floral, green	
Acidity / alkalinity	OECD 122	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	The acidity of the product was determined since the pH of the aqueous biocidal product is not in the range of 4-10 (pH = 3.29). The acidity (25°C, undiluted product) is calculated as 1.60 ± 0.1% w/w of H_2SO_4	
pH	OECD 122	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	pH (25°C, undiluted product) = 3.29	
Relative density / bulk density	OECD 109	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	The relative density D_4^{20} (undiluted product) is 1.004.	
Storage stability test – **accelerated storage**	MT 46.3, relevant parameters measured according to OECD 122, OECD 109,	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i.	The accelerated storage stability study of the biocidal product was conducted in the original commercial PET containers at 54°C for a period of two weeks.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	similar to OECD 115 Validated GC	Batch 1234144856	The physical chemical properties of the biocidal product were tested also at 4°C for the periode of two weeks. Appearance: No physical changes of the product observed (transparent, aqueous liquid and fruity, floral, green odour) after 14 days storage at 4°C and 54°C. A.i. content (GC, validated) of the product after 14 days at 4°C: 2.59% ± 0.15% w/w. at 25°C: 2.52% ± 0.15% w/w. at 54°C: 2.53% ± 0.15% w/w (acceptable increase of 2%) The a.i. content before storage for all three tested temperatures was (RT): 2.47% ± 0.15% w/w No significant changes observed after storage. pH (undiluted product) after 14 days at 4°C = 3.24 at 54°C = 3.30 pH (undiluted product) before: 3.34 (± 0.15) No significant changes observed after storage. The relative density of the product after 14 days at 4°C is 1.005 kg/L. at 54°C is 1.005 kg/L. Relative density before: 1.005 kg/L (± 0.002) No significant changes observed after storage. The surface tension of the product (undiluted) after 14 days at 4°C is 26.67 mN/m at 54°C is 26.80 mN/m. The surface tension before: is 26.90 mN/m (± 0.30).	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No significant changes observed after storage. The weight loss of the product after 14 days at 54 °C is 1,48 g and is within acceptable range The reactivity towards container of the product after 14 days at 54 °C. No leakage, discoloration and deformation of the bottle has been observed. The product is a ready to use biocidal product applied via trigger-sprayer. The results of the spray pattern (mean of 5 bottles) after 14 days accelerated storage (54°C, undiluted product) are: The spray pattern: After 14 days at 54°C: - mean diameter measured at 20 cm distance: 135.5 mm - spray pattern: oval - mean angle spread at vertical orientation of the trigger sprayer: 37.4 ° Before storage: - mean diameter measured at 20 cm distance: 154.5 mm - spray pattern: oval - mean angle spread at vertical orientation of the trigger sprayer: 42 ° - After 2 weeks in accelerated storage at 54 °C, the spray pattern of the product Method Antibac all-purpose cleaner wild rhubarb is becoming marginally smaller. However, this is not seen as significantly different, and it is not expected to have an influence on the effectiveness of the product during its use.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The amount of spray delivered with each operation (mean of 5 bottles) after 2 weeks storage at 54 °C: 980µl (± 16). No nozzle blockages. Before storage: 962 (± 20) µL/stroke. No statistically significant changes of the amount of spray delivered during the 2 week storage period. No nozzle blockages observed during and after the storage period. The Droplet Size Distribution (DSD): After 2 weeks at 54 °C: 12.68 (± 3.63) % <50µm. Before storage: 15.58 (± 2.40) % <50µm. Dv50 after weeks at 54°C: 87,34 µm. Dv50 before storage: 101.36 µm. No statistically significant changes are found in the DSD during the 2 week storage period. In conclusion, the undiluted tested product is stable when stored in the commercial PET containers for 14 days at 4°C and 54°C.	
Storage stability test – **long term storage at ambient temperature**	Relevant parameters measured according to OECD 122, OECD 109, similar to OECD 115	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	A two-year shelf life study was performed with the product in its original PET packaging at room temperature A.i. content (GC, validated) of the product after 2 years at T-0: 2.47% ± 0.15% w/w. at T-2 years: 2.40% ± 0.15% w/w No significant changes observed after storage. pH (undiluted product) after 2 years at T-0: 3.29 ± 0.15 at T-2 years: 3.33 ± 0.15 No significant changes observed after storage.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The relative density of the product after 2 years at T-0: 1.004 ± 0.002 kg/L. at T-2 years: 1.004 ± 0.002 kg/L. No significant changes observed after storage. The surface tension of the product (undiluted) after 2 years at T-0: 27.22 ± 0.30 mN/m. at T-2 years: 26.28 ± 0.30 mN/m No significant changes observed after storage. The weight loss of the product after 2 years days: Test ongoing – results expected in July 2023 The reactivity towards container of the product after 2 years at room temperature. No leakage, discoloration and deformation of the bottle has been observed. The results of the spray pattern (mean of 5 bottles) at 20 cm distant, after 2 years storage at room temperature are: The spray pattern: - at t-0: 154.5 ± 23.14 mm - at t-2 years: 187 ± 17.89 mm - mean angle spread at vertical orientation of the trigger sprayer: - at t-0: 42 ± 5.68 ° - at t-2 year: 50 ± 4.47 ° After 2 years storage at room temperature, the spray pattern of the product Method Antibac all-purpose cleaner wild rhubarb is becoming a little bit wider. However, this is not seen as significantly different and it is not expected to have an influence on the effectiveness of the product during its use.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The amount of spray delivered with each operation (mean of 5 bottles) after 2 years storage at room temperature: Amount of spray at T-0: 962 ± 21 µl/stroke Amount of spray at T-2 years: 904 ± 35 µl/stroke The amount of spray is slightly lower after 2 years of storage, this is not seen as significantly different, and it is not expected to have an influence on the effectiveness of the product during its use. The Droplet Size Distribution (DSD): After 2 years storage at room temperature Test ongoing – results expected in July 2023 In conclusion, the tested product appeared to be stable after 2 years of storage at room temperature in the commercial PET packaging.	
Storage stability test – **low temperature stability test for liquids**			The product should be stored at room temperature only. This restriction is also included in the SPC.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Taking into account the composition of the products, being a largely aqueous solution, no effects of light is expected on the stability of the products. Furthermore to exclude any effect of light on the composition of the product, the product packaging includes a UV filter. Further, L(+) lactic acid is not photosensitive and cannot undergo direct photolysis in sunlight.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	Taking into account the composition of the products, being a largely aqueous solution, no effects of light, temperature and humidity are expected on the stability of the products. The effect of temperature on the products was addressed in the accelerated storage stability study and no effect of temperature was observed after two weeks at 54°C.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 1234144856	After two weeks at 54°C, the product in the original commercial packaging was found stable concerning olfactive and visual appearance. No leakage, discoloration or deformation of the bottle has been observed.	[redacted]
Wettability	-	-	Not required for liquids.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable since the product type is Ready to use (AL).	-
Wet sieve analysis and dry sieve test	-	-	Wet sieve test not relevant for a ready to use liquid. Dry sieve test not relevant for liquids.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable since the products type is AL.	-
Disintegration time	-	-	Not required for liquids.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	<u>The Droplet Size Distribution (DSD):</u> The average particle size distribution <50µm is 15,58%. The average Dv50 is 101.36 µm	-
Persistent foaming	-	-	Study not required for liquid products which are ready to use.	-
Flowability/Pourability/Dustability	-	-	Flowability: data waiving, this test is not required for liquids. Pourability: data waiving as the study is only required for suspension concentrations,	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			capsule suspensions and suspo-emulsions. Dustability: Data waiving, since this test is not required for liquids.	
Burning rate — smoke generators	-	-	Data waiving since the products are not smoke generators.	-
Burning completeness — smoke generators	-	-	Data waiving since the products are not smoke generators.	-
Composition of smoke — smoke generators	-	-	Data waiving since the products are not smoke generators. .	-
Spraying pattern — aerosols		-	Data waiving as the products are not supplied as aerosols.	
Physical compatibility	-	-	Only relevant for products that may require mixing with other products (according to product label). The products do not require mixing with other products. This endpoint is therefore waived.	-
Chemical compatibility	-	-	Only relevant for products that may require mixing with other products (according to product label). The product does not require mixing with other products. This endpoint is therefore waived.	-
Degree of dissolution and dilution stability	-	-	Data waiving, since the products in this BPF are ready to use products.	-
Surface tension	Pendant drop method,	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 123414485	The product contains surfactants, therefore surface tension is regarded relevant. The surface tension (RT, undiluted product) is 27.22 mN/m. The product is therefore regarded as surface active.	[redacted]
eCA remark: Although the pendant drop method is not included in the published guidelines, it is considered an acceptable method.				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Viscosity	ISO 3404 (modified) comparable to OECD 114	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 3587912 / 19-020500-0-BLG-001-00	The kinematic viscosity (20°C, undiluted product) is 1.4425 mm²/s. The kinematic viscosity (40°C, undiluted product) is 0.8964 mm²/s. No measurements of dynamic viscosity at different shear rates were performed as based on the nature of the product and the composition it is not expected to be a non-newtonian liquid.	[redacted]

Conclusion on the physical, chemical and technical properties of the product

The physico-chemical testing was performed on the representative product 'Method Antibac all purpose cleaner wild rhubarb. Considering a comparable composition of all products within the family (refer to confidential annex) the obtained results are considered to be representative for all products of the family.

The representative product is a 2.47% (w/w) formulation of lactic acid in aqueous solution containing additives. At ambient conditions the product is a transparent aqueous solution with a fruity, floral, green odour. The pH of the undiluted product (aqueous solution) is 3.29. The alkalinity/acidity of the undiluted product is calculated as 1.60% w/w of H_2SO_4. The relative density (D^{20}_4) of the undiluted product is 1.004. The kinematic viscosity is 1.4425 mm²/s at 20°C and 0.8964 mm²/s at 40°C.

The undiluted product is surface active (27.22 mN/m). The product is not intended to be mixed with other products.

The content of the active substance in the product remained stable in the accelerated storage stability studies. Also the above mentioned physico-chemical properties of the product remained stable during accelerated storage. Several spray characteristics (spray pattern - diameter, angle, amount of spray delivered with each operation, absence of nozzle blockages) also remained stable during accelerated storage. A shelf-life of two years is considered acceptable based on accelerated data and long-term (2 years) storage stability data.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark: The 'Method Antibac all purpose cleaner wild rhubarb" is considered as a representative product of this BPF family, since all the products have the same composition and differs only by the used perfume.				
Explosives		-	Data waiving: The DSC scan demonstrates that there is no exothermic decomposition	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with energy larger than 500J/g below 500°C	
Flammable gases	-	-	Not required for liquids.	-
Flammable aerosols	-	-	Not required for liquids.	-
Oxidising gases	-	-	Not required for liquids.	-
Gases under pressure	-	-	Not required for liquids.	-
Flammable liquids	According to EN ISO 3679	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 3587912 / 19-020500-0-BLG-001-00	The flash-point of the product was determined to be 63°C (undiluted product) and therefore, the product is not classified as a flammable liquid.	[redacted]
Flammable solids	-	-	Not required for liquids.	-
Self-reactive substances and mixtures	-	-	Data waiving: The DSC scan demonstrates that there is no exothermic decomposition with energy larger than 300J/g below 500°C	[redacted]
Pyrophoric liquids	-	-	Experience in handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures	-
Pyrophoric solids	-	-	Not required for liquids.	-
Self-heating substances and mixtures	-	-	In general, the phenomenon of self-heating applies only to solids or liquids absorbed on a large surface. Since the products in this BPF are ready to use liquids, this	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			endpoint can be waived.	
Substances and mixtures which in contact with water emit flammable gases	-	-	Taking into account the composition of the products (i.e. aqueous solutions), this endpoint can be waived.	-
Oxidising liquids	-	-	Data waiving: According to the Guidance on the application of the CLP criteria, section 2.13.4.1.1, for organic substances or mixtures the classification procedure for this hazard class, i.e., oxidising liquids, need not to be applied if the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. This is the case for the Method Anti-bac cleaner biocidal products, therefore, the data on oxidising liquids can be waived.	-
Oxidising solids	-	-	Not required for liquids.	-
Organic peroxides	-	-	Data waiving: The products do not contain substances with peroxide structures.	-
Corrosive to metals	According to UN test C.1 section 37.4	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb"	The corrosivity of the product to metals was determined at 55	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		and contains 2.47% w/w a.i. Batch 20-002805-0-BLG-001-01	°C ± 1 for 168h± 1h. to be positive towards aluminium (non-clad type 7075-T6), and steelC1020. The highest mass loss for Aluminium was determined as 2,25% (halfway) and 12,64% for steel (submerged). Both Aluminium and Steel showed pitting (280 µm for Al halfway and 200 µm for Steel halfway)	
Auto-ignition temperatures of products (liquids and gases)	According to ASTM E659	The test substance is the product "Method Antibac all purpose cleaner wild rhubarb" and contains 2.47% w/w a.i. Batch 20-003132-0-BLG-001-00	The auto-ignition temp (AIT) of the product was determined to be > 570°C (undiluted product, at atmospheric pressure of 1011 mbar, relative humidity of 30%).	[redacted]
Relative self-ignition temperature for solids	-	-	Not required for liquids.	-
Dust explosion hazard	-	-	Not required for liquids.	-

Conclusion on the physical hazards and respective characteristics of the product
Based on the corrosivity test results the product should be classified as H290 "may be corrosive to metals". Further the products in this biocidal product family are not classified for any other physical hazard.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

substance)									
Active substance (lactic acid) in the product	GC	Fortification of 80%, 100% and 12% of nominal concentration.	Measured at 5 different concentrations in duplicate Range: 1.0–4.0% w/w y=2.6039x R^2 = 0.998	Specificity was studied by analysing 8 blank samples, No interference ≥3% from matrix (here referred as a blank) was detected. Since the formulation of the whole BPF is exactly the same, except for fragrance, it can be stated that the blank is representative for the whole BPF.	88–94%(from 80% fortification) 91–100% (from 100% fortification) -93–98% (from 120% fortification)	mean at 80%: 91,6 % recovery - mean at 100 %: 94,6 % recovery - mean at 120 % : 94,9 % recovery	Precision: n=8 RSD= 2.03 % (This complies with Horwitz criterion)	NA	

An analytical method to determine the active substance content in the product is available (GC method). Validation of the method is performed using method CB-GC-L-009, conform NEN 7777. Repeatability, reproducibility, linearity and recovery is included in the validation of the method. Details of the method are included.

Sample preparation: a weighed amount of the sample is heat treated with a phosphoric acid solution. After cooling and the addition of an internal standard solution and acetonitrile an aliquot of this solution is treated with MTBSTFA to silylate the carboxyl

groups of the fatty acid. The derivatization enhances the chromatography parameters of the GC. The detector used for the GC analysis is a FID (Flame Ionization Detector)

Analytical methods for monitoring								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Covered by data in the active substance dossier.									

Analytical methods for soil								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Covered by data in the active substance dossier.									

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Covered by data in the active substance dossier.									

Analytical methods for water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Covered by data in the active substance dossier.									

Analytical methods for animal and human body fluids and tissues								
Analyte (type of analyte e.g. active	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

substance)									
Covered by data in the active substance dossier.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Covered by data in the active substance dossier.									

Conclusion on the methods for detection and identificationof the product
A gas chromatographic method for the quantitative analysis of the active substance lactic acid in the product, with acceptable validation parameters, is available. Validation of the method is performed by the lab Intertek Caleb Brett using method CB-GC-L-009, conform NEN 7777.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product family Method Anti-bac cleaner consists of three bactericidal surface sprays containing 2.4% L(+) lactic acid. The products are used for the disinfection of hard non-porous surfaces, which are not used for direct contact with food or feeding stuffs (PT2) and are intended for non-professional household application.

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

The organisms to be controlled are bacteria. The organisms to be protected are humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering

L(+)-lactic acid is able to inhibit the growth of many types of bacteria, including gram-negative species of the families *Enterobacteriaceae* and *Pseudomonadaceae*. The antibacterial action of lactic acid is largely assigned to its ability in the undissociated form to penetrate the cytoplasmic membrane, resulting in reduced intracellular pH and disruption of the transmembrane proton motive force. (

2.2.5.4 Mode of action, including time delay

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, such as decrease of the membrane permeability for amino acids, organic acids, and phosphates resulting in the uncoupling of both substrate transport and oxidative phosphorylation from the electrin transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.(ECHA 1322-02_Assessment_Report PT02,03,04)

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide surface spray	*Disinfectants for hard surfaces, households use*	*L(+)-lactic acid at 2,4% in product formulation Method Anti-Bac, batch 20180403_1*	*P. aeruginosa (ATCC 15442) E. coli (ATCC 10536) S. aureus (ATCC 6538) E. hirae (ATCC 10541) E. coli K12 (NCTC 10538)*	EN 1276:2009 and EN 1276:2009A/C Quantitive suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics uses in food, industrial, domestic and institutional areas (Phase 2, step 1)	Interfering substance: Clean conditions (0,3 g/L bovine albumin) Product formulation test concentrations: 10, 50 and 80 % (v/v) Contact time: T = 5 min±10 s Test temperature: 20°C±1°C Incubation temperature: 37°C±1°C	LogR >5: *P. aeruginosa: 10, 50 and 80%(v/v) E. coli: 10, 50 and 80%(v/v) S. aureus: 50 and 80%(v/v) E. hirae): 10, 50 and 80%(v/v) E. coli K12: 10, 50 and 80%(v/v)* LogR <5: *S. aureus: 10%(v/v)*	[redacted]
Bactericide surface spray	*Disinfectants for hard surfaces, households use*	*L(+)-lactic acid at 2,4% in product formulation Method Anti-Bac, batch 20180403_1*	*P. aeruginosa (ATCC 15442) E. coli (ATCC 10536) S. aureus (ATCC 6538) E. hirae (ATCC 10541) E. coli K12 (NCTC 10538)*	EN 1276:2009 and EN 1276:2009A/C Quantitive suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics uses in food, industrial, domestic and institutional	Interfering substance: Dirty conditions (3,0 g/L bovine albumin) Product formulation test concentrations: 10, 50 and 80 % (v/v) Contact time: T = 5 min±10 s Test temperature: 20°C±1°C	LogR >5: *P. aeruginosa: 10, 50 and 80%(v/v) E. coli: 10, 50 and 80%(v/v) S. aureus: 80%(v/v) E. hirae: 50 and 80%(v/v) E. coli K12: 50 and 80%(v/v)*	[redacted]

				areas (Phase 2, step 1)	Incubation temperature: 37°C±1°C	LogR <5: *S. aureus: 10 and 50%(v/v) E. hirae: 10%(v/v) E. coli K12: 10%(v/v)*	
Bactericide surface spray	*Disinfectants for hard surfaces, households use*	*L(+)-lactic acid at 2,4% in product formulation Method Anti-Bac, batch 20180403_1*	*P. aeruginosa (ATCC 15442) E. coli K12 (NCTC 10538) S. aureus (ATCC 6538) E. hirae (ATCC 10541) E. coli (ATCC 10536)*	EN 13697:2015 Quantitive non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants uses in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (Phase 2, step 2)	Interfering substance: Clean conditions (0,3 g/L bovine albumin; only when testing of *P. aeruginosa* 8,5 g/L skim milk was used according tothe norm) Product formulation test concentrations: 10, 50 and 100 % (v/v) Contact time: T = 5 min±10 s Test temperature: 20°C±1°C Incubation temperature: 37°C±1°C (Bacteria), 30°C±1°C (Yeast*)	LogR >4: *P. aeruginosa: 50 and 100%(v/v) S. aureus: 50 and 100%(v/v) E. hirae: 50 and 100%(v/v) E. coli: 50 and 100%(v/v)* LogR <4: *P. aeruginosa: 10%(v/v) S. aureus: 10%(v/v) E. hirae: 10%(v/v) E. coli: 10%(v/v) E. coli K12: 10 and 50%(v/v)*	
Bactericide surface spray	*Disinfectants for hard surfaces, households use*	*L(+)-lactic acid at 2,4% in product formulation Method Anti-Bac, batch 20180403_1*	*P. aeruginosa (ATCC 15442) E. coli K12 (NCTC 10538) S. aureus (ATCC 6538) E. hirae (ATCC 10541)*	EN 13697:2015 Quantitive non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants uses in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (Phase 2, step 2)	Interfering substance: Dirty conditions (3,0 g/L bovine albumin) Product formulation test concentrations: 10, 50 and 100 % (v/v) Contact time: T = 5 min±10 s Test temperature: 20°C±1°C Incubation temperature: 37°C±1°C (Bacteria), 30°C±1°C (Yeast*)	LogR >4: *P. aeruginosa: 50 and 100%(v/v) S. aureus: 50 and 100%(v/v) E. hirae): 50 and 100%(v/v) E. coli K12: 100%(v/v)* LogR <4: *P. aeruginosa: 10%(v/v) S. aureus: 10%(v/v) E. hirae): 10%(v/v) E. coli K12: 10*	

						and 50%(v/v)	
Bactericide surface spray	*Disinfectants for hard surfaces, households use*	*L(+)-lactic acid at 2,4% in product formulation Method Anti-Bac*	*E. coli (ATCC 10536)*	EN 13697:2015 Quantitive non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants uses in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (Phase 2, step 2)	Interfering substance: Dirty conditions (3,0 g/L bovine albumin) Product formulation test concentrations: 10, 50 and 100 % (v/v) Contact time: T = 5 min±10 s Test temperature: 20°C±1°C Incubation temperature: 37°C±1°C	LogR >4: *E. coli: 50 and 100%(v/v)* LogR <4: *E. coli 10%(v/v)*	[redacted]

Conclusion on the efficacy of the product

In accordance with Guidance on the BPR: Volume II Parts B+C, version 3.0 (April 2018), efficacy testing of hard surface disinfectants, tiered approach was followed to test the biocidal product family Method Anti-bac cleaner. All the members of the Meta SPC contain the same amount of active substance and the same concentration of all other co-formulants, with the only exception of 0.3% fragrance which differs between the products. Physical chemical properties of "Method anti-bac all-purpose cleaner wild rhubarb" (batch 20180403_1) such as pH value are the same for all products in this Meta SPC. The three fragrances are used interchangeable and do not have a negative influence on the efficacy of the active substance. It is therefore concluded that Method anti-bac all-purpose cleaner wild rhubarb (batch 20180403_1) can be considered as worst case composition to be taken into account for efficacy core assessment. The other two products would have been similar candidates for this case.

Next to the active substance the formulations contain two substances which are recognized as active substances for PT2 under the BPR (please refer to the confidential annex). However, as these substances are present at very low concentrations, which are far below the efficacious concentrations for these substances, they are not expected to have any influence on the efficacy of the formulation.

Considering the use of this product as hard surfaces disinfectant in areas not including healthcare (household), as Phase 2, step 1 a quantitative suspension test has been performed according to test method EN 1276:2009 to evaluate bactericidal activity of the product at concentrations 10, 50 and 80% v/v of the working concentration under clean [redacted]) and dirty [redacted]) conditions with a 5 minute contact time

and 20°C test temperature. As chemical neutralizer a solution of 3 g/L Lecithin, 30 g/L Polysorbate 80, 5 g/L sodium thiosulphate, 1g/L L-histidine, 8.5 g/L sodium chloride and 1.0 g/L tryptone (sterilised by autoclave) was used.

Under clean conditions all validation acceptance criteria were met, however only for *S. aureus* a reduction in viability below log5 at one concentration (10%) was seen. All other strains showed viability reduction >log 5 for all concentrations. All other validation tests within this procedure were considered valid. It could be concluded that the biocidal product possesses bactericidal activity of >log5 at a concentration of 10, 50 and 80% v/v of the working concentration against *P. aeruginosa* ATCC 15442, *E. coli* ATCC 10536, *E. hirae* ATCC 10541 and *E.coli* K12 NCTC 10538 and at a concentration of 50 and 80%v/v of the working concentration against *S. aureus* ATCC 6538 as was tested after 5 minutes at 20°C under clean conditions.

Under dirty conditions, no reduction in viability below log5 was observed for *P. aeruginosa* and *E.coli*. All other strains showed at minimum one dilution per test with a reduction in viability lower than log5. All other validation tests performed under dirty conditions were considered valid. It could therefore be concluded that the biocidal product possesses bactericidal activity of >log5 at a concentration of 10, 50 and 80% v/v of the working concentration against *P. aeruginosa* ATCC 15442 and *E. coli* ATCC 10536, at a concentration of 50 and 80% v/v of the working concentration against *E. hirae* ATCC 10541 and *E.coli* K12 NCTC 10538 and at a concentration of 80% v/v of the working concentration against *S. aureus* ATCC 6538, as was determined after 5 minutes at 20°C under dirty conditions.

For Phase 2, step 2 a quantitative surface test has been performed according to test method EN 13697:2015 to evaluate bactericidal activity of the product at concentrations 10, 50 and 100% v/v of the working concentration under clean [redacted] and dirty conditions [redacted]) and [redacted] with a 5 minute contact time and 20°C test temperature. As chemical neutralizer a solution of 3 g/L Lecithin, 30 g/L Polysorbate 80, 5 g/L sodium thiosulphate, 1g/L L-histidine, 8.5 g/L sodium chloride and 1.0 g/L tryptone (sterilised by autoclave) was used.

Under clean conditions, a reduction in viability below log 4 was observed at a concentration of 10% (v/v) for *P. aeruginosa*, *S. aureus*, *E. hirae* and *E. coli*, all validation acceptance criteria for these strains were considered valid. It could be concluded that the biocidal product possesses bactericidal activity of >log4 at a concentration of 50 and 100% v/v of the working concentration against *P. aeruginosa* ATCC 15442, *E. coli* ATCC 10536, *E. hirae* ATCC 10541 and *S. aureus* ATCC 6538, as was tested after 5 minutes at 20°C under clean conditions.

Under dirty conditions, a reduction in viability below log 4 was observed at a concentration of 10% (v/v) for *P. aeruginosa*, *S. aureus*, *E. hirae* and at a concentration of 10 and 50% (v/v) for *E. coli* K12. All validation acceptance criteria were considered valid. It could therefore be concluded that the biocidal product possesses bactericidal activity of >log4 at a concentration of 50 and 100% v/v of the working concentration against *P. aeruginosa* ATCC 15442, *E. hirae* ATCC 10541 and *S. aureus* ATCC 6538 and at 100% of working concentration against *E. coli* K12 NCTC 10538, as was tested after 5 minutes at 20°C under dirty conditions.

In a separate experiment under dirty conditions, a reduction in viability below log 4 was observed at a concentration of 10% (v/v) for *E. coli*. It could be concluded that the biocidal product possesses bactericidal activity of >log4 at a concentration of 50 and 100% v/v of the working concentration against *E. coli* ATCC 10536, as was tested after 5 minutes at 20°C under dirty conditions.

The efficacy of Method Anti-Bac cleaner product family as disinfectants for hard surfaces, in households was successfully demonstrated against bacteria. The products were shown to be efficacious at concentrations ≥50% (v/v) of the working concentration against all tested strains under clean conditions and at 100% (v/v) of the working concentration against all tested strains under dirty conditions, with a 5 minutes contact time and at 20°C.

2.2.5.6 Occurrence of resistance and resistance management

Development of resistance is considered unlikely due to the non-specific mode of action of L(+)-lactic acid (CAR, 2017).

2.2.5.7 Known limitations

L(+)-Lactic acid is effective against Gram-negative bacteria in the absence of surfactants. Gram-positive bacteria are generally less sensitive to L(+)-Lactic acid, but are rendered susceptible by surfactants (

2.2.5.8 Evaluation of the label claims

The efficacy of Method Anti-Bac cleaner product family as disinfectants for hard surfaces, in households was successfully demonstrated against bacteria. The products were shown to be efficacious at concentrations ≥50% (v/v) of the working concentration against all tested strains under clean conditions and at 100% (v/v) of the working concentration against all tested strains under dirty conditions, with a 5 minutes contact time and at 20°C.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The products are not intended to be used in combination with other products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The whole BPF can be considered as irritating to skin
Justification for the value/conclusion	Based on the available data on the components and their concentration, the products do meet criteria for classification for skin irritation.
Classification of the product according to CLP	Skin Irrit. 2, H315

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) Annex I 1.1.1 and 1.1.3

Serious eye damage/eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The whole BPF can be considered as irritating to eyes
Justification for the value/conclusion	Based on the available data on the components and their concentration, the products meet the criteria for classification as Irritating to Eyes. In accordance with article 11(2) of the CLP Regulation, the cut-off value for the hazard Eye Dam. 1, H318 is 1%. The active substance and the substance of concern (SoC) Alkyl, C8-10, polyglucoside are the 2 components that need to be taken into account for determining whether the products need to be classified for serious eye damage, based on their concentration in the products. As for the SoC Alkyl, C8-10, polyglucoside a specific concentration limit of >10% (active matter) is established for this hazard based on the available study, please refer to section *Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)* below for more information. Based on the results it was concluded, that a dilution of 10% active matter Alkyl, C8-10, polyglucoside does not cause ocular corrosion or severe irritation in the Bovine Corneal Opacity and Permeability Test (BCOP Test) under the test conditions chosen. As all products in the BPF contain this substance in only 1.575% (active matter)

	and applying an SCL of 10, the products meet the criteria for classification as Irritating to Eyes. An assessment on similar tested mixtures, using the DETNET database is also supporting the classification of the mixture as H319. The full assessment can be found in the confidential Annex.
Classification of the product according to CLP	Eye Irrit. 2, H319

Data waiving	
Information requirement	Eye irritation
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	Not irritating
Justification for the value/conclusion	Based on the available data on the components and their concentration, the products do not meet the criteria for classification.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory tract irritation
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The whole BPF can be considered as not sensitizing
Justification for the value/conclusion	Based on CLP calculation the available data on the components and their concentration, the products do not meet the criteria for classification. → the whole BPF (Biocidal product family) doesn't contain ingredients classified as Skin Sens. above the respective threshold. See example for wild rhubarb in the confidential annex.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Skin sensitization
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	The whole BPF can be considered as not sensitizing
Justification for the value/conclusion	Based on the available data on the components and their concentration, the products do not meet the criteria for classification. The BPF does not contain ingredients classified as respiratory sensitization.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory sensitization
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value/conclusion	The whole BPF can be considered as not acute oral toxic
Justification for the selected value	Based on the available data on the components and their concentration, the products do not meet the criteria for classification as all ingredients classified as acute oral toxic are present below the generic cut-off concentrations.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute oral toxicity
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value/Conclusion	The whole BPF can be considered as not acute inhalation toxic
Justification for the selected value	Based on the available data on the components and their concentration, the products do not meet the criteria for classification as all ingredients classified as acute inhalation toxic are present below the generic cut-off concentrations.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value/Conclusion	The whole BPF can be considered as not acute toxic
Justification for the selected value	Based on the available data on the components and their concentration, the products do not meet the criteria for classification, as all ingredients classified as acute dermal toxic are present below the generic cut-off concentrations
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute dermal toxicity
Justification	According to Column 3 of Annex III, testing on the product/mixture does not need to be conducted as there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Information on dermal absorption

For the products there is no information available on dermal absorption. Therefore the dermal absorption is assessed in accordance with the EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873). In accordance with the Evaluation Manual for the Authorisation of biocides (v. 3.0, January 2019), while the EFSA 2017 guidance is compulsory for use for biocidal products under the BPR from March 2020 onwards, the default values of this guidance can be used before the indicated time.

As the products are ready-for-use aqueous dilutions, a default dermal absorption value of 50% should be applied, in accordance with the EFSA Guidance (2017).

Oral and inhalation absorption is considered to be 100%.

Value used in the Risk Assessment – Dermal absorption	
Substance	L-(+)-lactic acid
Value	50%
Justification for the selected value	Default value according to the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Information on dermal absorption (ethanol)

For dermal absorption of ethanol, the default value of 50% will be used in accordance with the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products. For the products there is no information available on dermal absorption.

Oral and inhalation absorption is considered to be 100%.

Value used in the Risk Assessment – Dermal absorption	
Substance	Ethanol
Value	50%
Justification for the selected value	Default value according to the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products.

For the co-formulant for which the Dutch workplace exposure limits are established and which was identified as an additional SoC for human health by the eCA, the relevant data, as well as the exposure and risk assessment, are included in the confidential annex.

Information on SCL of Alkyl, C8-10, polyglucoside

The substance of concern (SoC) for human health, Alkyl, C8-10, polyglucoside, was tested as an aqueous solution in an *in vitro* eye irritation test according to OECD 437 (BCOP):

Test substance	Guideline	Mean opacity value	Mean permeability value	Mean *In Vitro* Irritancy Score (IVIS)
10% (w/w) of Alkyl, C8-10, polyglucoside (SoC) in water	OECD 437 (2013)	1.1	0.038	1.6

The substance of concern for human health Alkyl, C8-10, polyglucoside is corrosive to eyes at a concentration of >10% and is not classified for serious eye damage/eye irritation at a concentration of ≤10% based on the results of this study, as the IVIS ≤ 3.

Available toxicological data relating to a mixture

There is no toxicological data relating to the products available.

Other

Screening non-active substance(s) for endocrine disrupting potential

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting (ED) properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). Hence, as requested by the evaluating Member State Competent Authority Netherlands, a screen for indications of ED potential has been performed for Method Anti-bac cleaner.
According to the EU Commission's guidance note on 'The Implementation of scientific criteria for the determination of endocrine-disrupting properties in the content of biocidal product authorisation (CA-March18-Doc.7.3.b-final, paragraph 23) the detailed evaluation of a non-active substance (co-formulant) per the ECHA/EFSA guidance should only occur where there are indications of ED properties based on the existing knowledge and the available scientific information. A guidance for the initial screening of the available information on co-formulants has been prepared by the UK CA (CG-34-2019-02 AP 16.5) and was used in the current assessment.

The overview of the results of the initial ED screening for the co-formulants in Method Anti-bac cleaner product family in accordance with the guidance document CG-34-2019-02 APn 16.5 is summarised in confidential Annex. All co-formulants identified from the safety data sheets for all ingredients and the finished product were included in the screen. For one co-formulant an ED concern has been raised, due to substance being included in the CoRAP list (. CA NL concluded that the ED assessment for this co-formulant can await the outcome of the discussions at EU level as there are no significant ED indications from US

EPA EDSP21 programma. If this co-formulant is concluded to possess ED potency the authorisation of the product needs to be re-evaluated.
None of the other co-formulants included in Method Anti-bac cleaner product family were identified as requiring further, detailed evaluation for ED potential.

2.2.6.2 Exposure assessment

The calculated exposure estimates provided in this section refer to the active substance. For the substance of concern Alkyl, C8-10, polyglucoside it is not needed to calculate exposure estimates, as the relevant hazard for this substance is serious eye damage, triggering a qualitative assessment instead.

Identification of main paths of human exposure towards active substance and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	No	No	Yes	No	No	Yes	No
Dermal	No	No	Yes	No	No	Yes	No
Oral	No	No	Yes	No	No	Yes	No

List of scenarios

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)
1.	Disinfection of surfaces indoors (spraying part)	Using the ready-for-use trigger spray, a consumer sprays the product onto the surface; then, it is left on the surface to soak in for 5 minutes.	Non-professional users (consumers)
2.	Disinfection of surfaces indoors (wiping part)	The wetted surface is wiped with a wet cloth.	Non-professional users (consumers)
3.	Rubbing off	Secondary exposure to the products may occur after spray application. Infants might be exposed dermally by rubbing off surfaces and subsequently orally by licking their hands.	General public

Industrial exposure

Not applicable.

Professional exposure

Not applicable.

Non-professional exposure

Scenario 1: Disinfection of surfaces indoors (spraying part)

Description of Scenario 1
Using the ready-for-use trigger spray, a consumer sprays the product onto the surface; then, it is left on the surface to soak in for 5 minutes (after which the surface is wiped, see below). The exposure scenario 'Disinfectants for use indoors'; 'Exposure during spraying' from the model ConsExpo Web (version 1.1.0) was used to perform the calculations. The active substance is considered non-volatile and therefore exposure to spray was modelled. For estimating dermal exposure, the exposure model direct contact, constant rate was used.

	Parameters	Value
Tier 1	Frequency	365 per year [1]
	Spray duration	2 min
	Exposure duration	60 min [1]
	Room volume	15 m^3 [1]
	Room height	2.5 m [1]
	Ventilation rate	2.5 h^{-1} [1]
	Mass generation rate	0.8 g/s [1]
	Airborne fraction	0.008 [1]
	Weight fraction compound	0.024
	Density non-volatile	1.2 g/cm^3 [4]
	Inhalation cut-off diameter	15 µm [1]
	Inhalation rate	1.25 m^3/hour [3]
	Body weight	60 kg [2]
	Dermal absorption	50% [3]
	Inhalation absorption	100% (default)
	Dermal contact rate	46 mg/min [1]

[1] ConsExpo Web (version 1.1.0), using input from factsheet on indoor use of disinfectants, spraying

[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure on default human factor values for use in exposure assessments for biocidal products (2017)

[3] Default value according to the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products

[4] The density of the non-volatile fraction of the substance is here estimated to be the density of the active substance and major detergents used, which is around 1.2 g/cm^3

Calculations for Scenario 1

Calculations for Scenario 1
It has been determined that it takes 56 g/m^2 to completely moisten the surface with the products, while the scenario assumes that on a daily basis, a surface of 1.71 m^2 is wettened. Therefore the spray duration is set to 2 minutes, as in that period an amount of 96 g is sprayed, needed for moistening 1.71 m^2.
The resulting exposure estimates are presented in Annex 3.2. The total internal exposure is calculated to be 0.023 mg/kg bw/day.

Scenario 2: Disinfection of surfaces indoors (wiping part)

Description of Scenario 2		
The wetted surface is wiped with a wet cloth. The exposure scenario 'Disinfectants for use indoors'; 'Exposure during wiping' from the model ConsExpo Web (version 1.1.0) was used to perform the calculations. The exposure model direct contact, instant application was used.		
	Parameters	Value
Tier 1	Frequency	365 per year [1]
	Exposed area	215 cm^2
	Weight fraction compound	0.024
	Product amount on skin	0.02g
	1	Retention factor (fraction)
	Dermal absorption	50% [3]
	Body weight	60 kg [2]

[1] ConsExpo Web (version 1.1.0) using the inputs from the factsheet incorporated in the model for this use

[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure on default human factor values for use in exposure assessments for biocidal products (2017)
[3] Default value according to the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products

Calculations for Scenario 2
The scenario direct contact, instant application for wiping, uses a default product amount on skin of 0.02 g. With a weight fraction of 0.024, an exposed area of 215 cm^2 and a retention factor of 1, this results in a dermal load of 2.2 x 10^{-3} mg/cm^2, a total amount on the skin of 0.48 mg, an external dose of 8.0 x 10^{-3} mg/kg bw and, with 50% absorption, an internal exposure of 4.0E^{-03} mg/kg bw/day.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**
Scenario 1	Tier 1/no PPE	0.0046	0.018	negligible	0.023
Scenario 2	Tier 1/no PPE	negligible	0.04	negligible	0.004

Combined scenarios

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day**	**Estimated total uptake [mg/kg bw/day]**
Scenarios 1 and 2	0.0046	0.022	negligible	0.027

Exposure of the general public

Scenario 3: Rubbing off

Description of Scenario 3		
Secondary exposure to the products may occur after spray application. As a worst case, exposure of infants via contact with treated surfaces is considered. It is expected that adults will not touch the treated surfaces; furthermore, as the ratio of the skin surface to the body weight for adults is much lower, also their internal exposure in mg/kg bw will be lower. Infants might be exposed dermally by rubbing off surfaces and subsequently orally by licking their hands. The external dermal exposure is calculated using the secondary exposure scenario 'Child touching treated surfaces and hand to mouth transfer' from Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.		
	Parameters	Value
Tier 1	Exposed area	234 cm^2 [1]
	Film thickness on exposed area	0.01 cm [1]
	Density of the products	1004 mg/cm^3
	Transfer coefficient to exposed area	100% [2]
	Weight fraction compound	0.024
	Amount of the external dermal exposure ingested	10% [3]
	Dermal absorption	50% [5]
	Oral absorption	100% (default)
	Bodyweight toddler	8kg [1]

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

[2] As the surface is wet, a transfer coefficient of 100% is used

[3] In accordance with HEEG opinion 7

[5] Default value according to the EFSA Guidance on dermal absorption (2017) for water-based non-concentrated products

Calculations for Scenario 3

Calculations for Scenario 3

An external dermal exposure of 56.4 mg/day is calculated, as presented in Annex 3.2.
Via hand-to-mouth contact, 10% of the calculated external dermal exposure is ingested, leaving 90% for dermal uptake.
The total internal exposure is calculated to be 3.876 mg/kg bw/day.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**
Scenario 3	Tier 1/no PPE	negligible	3.172	0.705	3.876

Combined scenarios

Not applicable

Monitoring data

Monitoring data are not available.

Dietary exposure

Dietary exposure from the use of these products is not foreseen.
As in the use instructions is mentioned 'Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals', dietary exposure from the use of these products is not foreseen.
In addition the risk mitigation measure 'Keep away from food, drink and animal feedingstuffs' applies.

Exposure associated with production, formulation and disposal of the biocidal product

Assessment of exposure associated with production, formulation and disposal of the products is not considered needed, as such an assessment is considered to be addressed under the REACH regulation.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
Scenarios 1 and 2	**non-professionals**	Tier 1/no PPE	0.025
3	**infants**	Tier 1/no PPE	3.876

2.2.6.3 Risk characterisation for human health

In this section the quantitative and qualitative risk characterisation for the active substance and the qualitative risk characterisation for the substance of concern (SoC) D-Alkyl, C8-10, polyglucoside and the BPF is reported. The assessment of the SoC ethanol is presented in the Confidential Annex.
L-(+)-lactic acid is a naturally occurring substance found in plants, animals and humans. Major sources of L-(+)-lactic acid in humans are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) by gastrointestinal microorganisms and uptake via food (e.g. from milk and milk products). Moreover, the substance is approved in the EU as a food additive without an ADI or upper limit.
Because of the high baseline exposure of humans by food and endogenous metabolism (and because of the low systemic toxicity), derivation of any systemic toxicological reference dose was regarded unnecessary in the Assessment Report on L-(+)-lactic acid.

Considering the intended uses, exposure is therefore compared with endogenous production (>100 g/person/day; >1667 mg/kg bw/day for an adult and >10000 mg/kg bw/day for a toddler) and dietary exposure (>1 g/person/day; >16.67 mg/kg bw/day for an adult and >100 mg/kg bw/day for a toddler).

Reference values of the active substance to be used in Risk Characterisation

Reference	Value
Endogenous production (adult)	1667 mg/kg bw/day
Endogenous production (toddler)	10000 mg/kg bw/day
Dietary exposure (adult)	16.67 mg/kg bw/day
Dietary exposure (toddler)	100 mg/kg bw/day

Maximum residue limits or equivalent

No MRLs or equivalent have been set.

Risk for industrial users

Not applicable.

Risk for professional users

Not applicable.

Risk for non-professional users

Primary exposure to L-(+)-lactic acid by application of the biocidal products is very low compared to endogenous formation and the minimum daily food intake.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL	Reference value(s)	Estimated uptake	Estimated uptake/	Acceptable (yes/no)

		mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	Reference value(s) (%)	
Scenario 1: Disinfection of surfaces indoors (spraying part)	Tier 1 / no PPE	N.A.	1667 [1] 16.67 [2]	0.023	<1%	yes
Scenario 2: Disinfection of surfaces indoors (wiping part)	Tier 1 / no PPE	N.A.	1667 [1] 16.67 [2]	0.04	<1%	yes

[1] Endogenous production (adult)

[2] Dietary exposure (adult)

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	Reference value(s) mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ Reference value(s) (%)	Acceptable (yes/no)
Scenarios 1 and 2	Tier 1 / no PPE	N.A.	1667 [1] 16.67 [2]	0.027	<1%	yes

[1] Endogenous production (adult)

[2] Dietary exposure (adult)

Local effects

Based on the classification of the constituents and their concentrations in the products, the biocidal products are considered to be irritating to eyes (H319). No quantitative dose-response information is available. Therefore a qualitative risk assessment for this effect has been performed as summarized in the table below.

The risk of eye irritation was concluded to be acceptable for all non-professional uses.

The precautionary statement P280 is considered not necessary due to the intended use. An additional labelling with "Avoid contact with eyes" in the instructions for use is considered appropriate instead.

Conclusion

Exposure to L-(+)-lactic acid and exposure to the substance of concern Alkyl, C8-10, polyglucoside due to the use of the biocidal products does not reveal any risk to human health for non-professional users.

Hazard			Exposure							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	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Low	Eye irrit. Cat 2, H319	-	2	Non-professionals	Spraying on a surface; Wiping with a cloth	Skin; Eye (hand to eye transfer)	2 minutes per day, daily	n.r. very low exposure expected (residues on skin rubbed in eye if instructions are not followed)	labelling as eye irritant instructions for use minimizing exposure packaging reducing risk for eye exposure as trigger spray is a targeted application with a clear application direction. No splashes possible washing of hands after use	Acceptable: +Reversible effect +non-professionals following instructions for use +packaging reducing risk (no splashes possible)	adherence to it, including washing of hands may vary (↑↓)
Low	Skin Irrit 2, H315	-	2	General public: adults	Spraying on a surface using a ready-for-use tigger spray	Skin; Eye (hand to eye transfer)	2 minutes per day, daily	92 mg / person	labelling as skin irritant instructions for use washing of hands after use	Acceptable: +reversible effect +non-professionals following instructions for use +used for short duration	Adherence to instructions for use, including washing of hands may vary (↑↓)

Low	Skin Irrit 2, H315	-	2	General public: adults	Wiping a wetted surface with a wet cloth	Skin; Eye (hand to eye transfer)	Few minutes per day, daily	100 mg / person	labelling as skin irritant instructions for use washing of hands after use	Acceptable: +reversible effect +non-professionals following instructions for use +used for short duration	Adherence to instructions for use, including washing of hands may vary (↑↓)

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	Reference value(s) mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ Reference value(s)(%)	Acceptable (yes/no)
Scenario 1: rubbing off	Tier 1 / no PPE	N.A.	10000[1] 100[2]	3.876	<1% 3.876%	yes

[1] Endogenous production (toddler)

[2] Dietary exposure (toddler)

Combined scenarios

Not applicable.

Local effects

Based on the classification of the constituents and their concentrations in the products, the biocidal products are irritating to the skin and eyes (H315 and H319). No quantitative dose-response information is available. Therefore a qualitative risk assessment for this effect has been performed as summarized in the table below.

Based on the risk of hand to eye transfer of infants, it is suggested to add an additional labelling with "Prevent contact of children with treated surfaces" in the instructions for use. Taking this additional labelling into account, the risk of eye irritation was concluded to be acceptable for the general public.

Conclusion

Exposure to L-(+)-lactic acid and exposure to the substance of concern Alkyl, C8-10, polyglucoside due to the use of the biocidal products does not reveal any risk to human health for the general public.

Hazard			Exposure							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	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Low	Eye irrit Cat 2, H319	-	2	Toddlers	Not applicable	Skin; Eye (hand to eye transfer)	< 5 minutes per day	n.r. very low exposure expected (residues on skin after treated surface was touched and rubbed in eye)	labelling 'Prevent contact of children with treated surfaces'	Acceptable: +Reversible effect +labelling	washing of hands may vary (↑↓)
Low	Skin Irrit 2, H315	-	2	General public: Toddlers	Not applicable	Skin; Eye (hand to eye transfer)	< 5 minutes per day	56.4 mg / person	labelling as skin irritant RMM 'Prevent contact of children with treated surfaces'	Acceptable: +reversible effect +labelling	Adherence to RMM 'Prevent contact of children with treated surfaces' may vary (↑↓)

Risk for consumers via residues in food

Not applicable as no residues in food are likely to occur as a result of the use.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Risk for non-professional users

Based on the quantitative and qualitative risk assessment it is concluded that combined exposure to the active substance, substance of concern Alkyl, C8-10, polyglucoside and the additional substance of concern identified by the eCA based on the national legislation due to the use of the biocidal products does not reveal any risk to human health for non-professional users.

Risk for the general public

Based on the quantitative and qualitative risk assessments and considering that the uptake of the active substance and of the additional substance of concern identified by the eCA is low, compared to endogenous formation and daily (food) intake, and that this uptake takes place during a short life period, it is concluded that combined exposure to the active substance, substance of concern Alkyl, C8-10, polyglucoside and the additional substance of concern identified by the eCA based on the national legislation due to the use of the biocidal products does not reveal any risk to human health for the general public.

2.2.7 Risk assessment for animal health

Companion animals (pets) can be indirectly exposed to the products. The Technical Agreements for Biocides (Human Health), v. 2.0, November 2018 suggest that risk assessment for pets can be considered to be covered by the human health risk assessment, even though the exposure patterns will differ. In the present case, exposure of companion animals is considered to be covered by the exposure of a toddler, considering the fact that the toddlers represent the sensitive subpopulation, will also be exposed via dermal and oral routes and in general have a comparable body weight. It also should be noted that lactic acid is an endogenous substance and is also consumed in big quantities as a part of normal diet, also by pets. The exposure of a toddler to the active substance was calculated to be only 3.876% of the normal dietary exposure; thus even in case of lower body weights of certain types of pets the exposure to lactic acid due to the use of the biocidal products is expected to be significantly below the normal dietary intake. Furthermore, the following RMM is included in the intended use: Keep away from food, drink and animal feedingstuffs which mitigates exposure of animals via feed. Additional labelling instructions are not considered needed.

2.2.8 Risk assessment for the environment

The final use products contain only one active substance, i.e. L(+) lactic acid and one Substance of Concern (SoC), namely ethanol. In the following sections the data available for the active substance are presented where relevant. Due to the chemical properties of ethanol, the SoC will be assessed qualitatively.

2.2.8.1 Effects assessment on the environment

All relevant PNECs for the active substance L(+) lactic acid are presented in the table below:

Hazard assessment conclusion for the environment		
Compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	PNEC: 3.90 mg a.s./L	CAR (2017)
Sediments (freshwater)	PNEC: 4.8 mg a.s./kg ww *	CAR (2017)
Sewage treatment plant (STP)	PNEC: 10 mg a.s./L	CAR (2017)
Soil	PNEC: 1.90 mg a.s./kg ww *	CAR (2017)

* Please note that PNEC values for sediment and soil are presented as mg/kg wetweight (ww) and are derived by applying the equilibrium partitioning method.

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

Based on the available information on the components and their concentrations in the final use products, no environmental classification is required.

Further Ecotoxicological studies

Further data is not available.

Data waiving

Information requirement	No further data needed.
Justification	Ecotoxicological data available for the active substance provide sufficient information.

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

To examine if any of the co-formulants contained in the BPF may possess ED properties, a screening was performed in line with the harmonised approach for ED alert assessment for co-formulants as agreed in the coordination group ("CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants").

For an overview of the ED screening please refer to the Confidential Annex.

For one co-formulant an ED concern has been raised, due to substance being included in the CoRAP list. CA NL concluded that the ED assessment for this co-formulants can await the outcome of the discussions at EU level as there are no significant ED indications from US EPA EDSP21 programma. If this co-formulants are concluded to possess ED potency the authorisation of the product needs to be re-evaluated.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data is available.

Data waiving	
Information requirement	Data not needed.

Justification	The primary receiving compartment is the sewage treatment plant (STP), after which the aquatic compartment may be exposed. The active substance is not expected to bioaccumulate, as the Kow and Koc are very low (0.18 L/kg and 20 L/kg respectively), and therefore the risk assessment for the aquatic compartment is considered to also be protective of the sediment compartment. The soil compartment may also be exposed when sewage sludge is applied to the soil and a PNEC can be calculated using the equilibrium partitioning method (EPM). Hence, the available data on toxicity to activated sludge and aquatic organisms are sufficient for the risk assessment.

Supervised trials to assess risks to non-target organisms under field conditions

No data is available.

Data waiving	
Information requirement	Data not needed.
Justification	The final use products are not bait or granular formulations, and are intended for use indoors. Therefore, direct exposure to non-target organisms under field conditions is not expected.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data is available.

Data waiving	
Information requirement	Data not needed.

Justification	The final use products are not bait or granular formulations and is intended for use indoors. Therefore, direct exposure to non-target organisms is not expected.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No data is available.

Data waiving	
Information requirement	Data not needed
Justification	The final use products are intended for indoor use only. The primary receiving compartment is the sewage treatment plant (STP), after which the aquatic and soil compartments may be exposed. The active substance does not bioaccumulate, as the Kow and Koc are very low (0.18 L/kg and 20 L/kg respectively). Hence, the available data on toxicity to activated sludge and aquatic organisms are sufficient for the risk assessment.

Foreseeable routes of entry into the environment on the basis of the use envisaged

The final use products are intended for use as disinfectants for sanitary purposes in the private sector (disinfection of surfaces that do not come into contact with food and feed by non-professionals).

Release to the environment will be via waste water only, and therefore the primary receiving compartment is the sewage treatment plant (STP). Discharge of water from the STP to freshwater may occur, so the aquatic compartment and sediment compartment may be exposed. The soil compartment may also be exposed when sewage sludge is applied to the soil, and therefore risks to soil organisms and groundwater are also assessed.

Further studies on fate and behaviour in the environment (ADS)

No data is available

Data waiving	
Information requirement	Data not needed
Justification	The fate and behaviour in the environment of the final use products are covered by the data available for the active substance *

* Please note that additional information on the biodegradation potential of the active substance L(+) lactic acid is used for assessment of this endpoint. Please refer to Annex 3.3 for more detail.

Leaching behaviour (ADS)

No data is available as the final use products are not treated articles.

Testing for distribution and dissipation in soil (ADS)

No data is available.

Data waiving	
Information requirement	Data not needed
Justification	The primary receiving compartment is the sewage treatment plant (STP). The soil compartment may also be exposed when sewage sludge is applied to the soil. The active substance is readily biodegradable and has a very low Koc (20 L/kg). Default values for distribution and dissipation in soil will be used in the risk assessment and no further data are required.

Testing for distribution and dissipation in water and sediment (ADS)

No data is available.

Data waiving

Information requirement	Data not needed
Justification	The fate of the final use products are covered by the data available for the active substance.

Testing for distribution and dissipation in air (ADS)

No data is available.

Data waiving	
Information requirement	Data not needed
Justification	The active substance is well soluble in water and readily biodegradable. Furthermore, its vapour pressure is low. Moreover, the final use products are intended for indoor use. Therefore, transformation in air is not relevant.

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)

No data is available.

Data waiving	
Information requirement	No data needed
Justification	The final use products are not intended for spraying near surface waters.

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)

No data is available.

Data waiving	
Information requirement	No data needed
Justification	The final use products are not intended for spraying outside, and there is no potential for formation of dust as the products are used in aqueous solutions.

2.2.8.2 Exposure assessment

The final use products are intended for use as disinfectants for sanitary purposes in the private sector (disinfection of surfaces that do not come into contact with food and feed by non-professionals). The application rate is approximately 0.56 L/m^2.

The products are used indoor and release to the environment will be via waste water only. Therefore, the primary receiving compartment is the sewage treatment plant (STP). Discharge of water from the STP to freshwater may occur, so the aquatic compartment and sediment compartment may be exposed. The soil compartment may also be exposed when sewage sludge is applied to the soil, and therefore risks to soil organisms and groundwater are also assessed.

Formulation of the products was not assessed as this emission is considered to be negligible in relation to the application phase. Service life was not assessed because it is limited to the shelf life of the end-product in the container. Finally, the waste stage was not assessed because it is assumed that cleaning product containers are disposed of as domestic waste and will usually be incinerated.

Emission to wastewater was calculated as described in the ESD PT 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector) (RIVM, 2001). Predicted environmental concentrations (PECs) were calculated according to the BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017). The fate and emission of chemicals in the STP was modelled using

SimpleTreat v4.0 (RIVM, 2014), with a concentration of suspended solids (Css) in the effluent of 30 mg/L set as described in ENV 9 of the Technical Agreements for Biocides (TAB) v2.1 (ECHA, 2019). Model parameter default values were used unless otherwise stated. Further calculations for groundwater were performed using FOCUS PEARL v4.4.4 and model input parameters selected as described in the TAB (v2.1).

L(+)-lactic acid

The active substance L(+)-lactic acid is approved for the product types PT1- 04 (Reg. (EU)2016/2291 and Reg (EU) 2017/2002 with approval dates 01/07/2017 and 01/05/2019).

L(+)-lactic acid is classified as readily biodegradable failing the 10 day window. The breakdown products for this active substance are water and CO2, or methane under anaerobic conditions. These metabolites are not considered relevant for the environmental risk assessment as natural occurring background concentrations are several orders of magnitude higher.

L(+)-lactic acid cannot be regarded as substance that is persistent, bio-accumulative, and toxic as the PBT-criteria are not fulfilled. The active substance does not sorb strongly to organic matter and is therefore mobile in soils.

Ethanol

The SoC ethanol is under review for the product types 1, 2, 4 and 6, according to the regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. No agreed list of endpoints is therefore available. As agreed by the WG ,a SoC which is also an active substance, is only assessed quantitively if an agreed list of endpoints is available.

Ethanol is stable in water (resistant to hydrolysis), but is readily biodegradable. The degradation products are water and carbon dioxide. These are not considered relevant for the environmental risk assessment as these are naturally occurring compounds. Adsorption of relevant amounts of ethanol on soils and sediments is not expected due to the low Koc (calculated to be 1 L/kg respectively). The active substance has a high vapour pressure and therefore easily evaporates to air.

Therefore, the assessment for SoC ethanol will be performed qualitatively.

General information on non-professional use

In ESD PT 2, two emission sub-scenarios are presented for use of disinfectants for sanitary purposes. The first one is based on the annual tonnage applied, the second on the average consumption. The emission rates of L(+) lactic acid to wastewater (in kg/d) were calculated for both scenarios, and the highest value used for further calculations of PECs in the different environmental compartments.

General information

Assessed PT	**PT 2** (Disinfectants and algaecides not intended for direct application to humans or animals)
Assessed scenarios	Scenario 1: Disinfectants used for sanitary purposes (Intended use: disinfection of surfaces that do not come into contact with food and feed by non-professionals)
ESD(s) used	ESD for PT 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), RIVM, 2001.
Approach	**Scenario 1a:** Release to wastewater calculated based on total EU tonnage **Scenario 1b:** Release to wastewater calculated based on aggregated exposure from all three non-professional uses. Only the scenario with the highest local release to STP is further assessed (worst case approach).
Distribution in the environment	Calculated based on: BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017). Technical Agreements for Biocides Environment (ENV). Version 2.1, December 2019. European Chemicals Agency, Helsinki, Finland.
Groundwater simulation	According to the guidance based on a Koc of 20 L/kg. Additional PEARL simulations were run for refinement of the PEC groundwater.

Confidential Annexes	Yes: In the confidential Annex to Part B the tonnage-based scenario (1a) is provided.
Life cycle steps assessed	Scenarios 1a and 1b: - Production: No - Formulation No - **Use: Yes** - Service life: No
Remarks	-

Emission estimation

Direct releases of the active substance from product use for sanitary purposes takes place only via wastewater to STP. The emissions rates to wastewater from scenarios 1a: tonnage-based (see confidential Annex), and scenario 1b: consumption-based (presented below) are calculated based on the respective calculation tables from ESD PT 2 (RIVM, 2001).

Scenario 1: Disinfectants used for sanitary purposes (Intended use: disinfection of surfaces that do not come into contact with food and feed by non-professionals)

Scenario 1a: Tonnage-based

Please refer to the confidential Annex.

Scenario 1b: Consumption-based

Input parameters for calculating the local emission				
Input	**Unit**	**Symbol**	**Value**	**Remarks**
Scenario 1b: Disinfectants used for sanitary purposes – consumption-based				
Number of inhabitants feeding one STP	cap	Nlocal	10,000	Default value
Consumption per capita	L/d	Vform	0.005 (general purpose: tiles, floors, sinks) 0.002 (lavatory)	Average consumption for general purpose according to ESD PT 2 (2011)

Concentration of active substance in the product	g/L	Cform	24	Highest in-use concentration *
Penetration factor of disinfectant	-	Fpenetr	0.5	Default value ESD PT 2 (2011)
Fraction of the product released to waste-water	-	Fwater	1	Default value ESD PT 2 (2011)
Output: Elocalwater = Nlocal · Vform · Cform · Fpenetr · (1 - Fdis) · Fwater				
Emission rate to wastewater (standard STP)	[kg/d]	**0.84**		

* The maximum concentration of L(+) lactic acid in the final use products is 2.4% w/w. Assuming a density of 1 kg/L, this is equivalent to 24 g a.s./L.

Calculations for Scenarios 1a and 1b:

The consumption-based scenario (scenario 1b) provides the highest emission rate to wastewater (see confidential Annex for comparison with scenario 1a). Therefore, as a worst case approach the emission rate of 0.84 kg/d is used as input for calculations of PEC values for the different environmental compartments.

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	Other
Scenario 1b	Yes	Yes	Yes[1]	Yes[1]	Yes	No	Yes	Yes	Not relevant

[1] *Emission to the marine environment is possible as some STP discharge to the open sea. Nevertheless, considering that the PEC:PNEC ratio for the marine environment is equal to the ratio for freshwater, no additional assessment for the marine compartment was made. The risk assessment for freshwater sufficiently covers the risks for seawater.*

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	90.08	g/mol	CAR, 2017
Melting point	53	°C	pure, crystalline solid L(+) lactic acid (CAR, 2017)
Vapour pressure (at 20 °C)	0.4	Pa	CAR, 2017
Water solubility (at 20 °C)	1E+06	mg/L	CAR, 2017
Log octanol/water partition coefficient	-0.74	log 10	Experimental (CAR, 2017)
Organic carbon/water partition coefficient (Koc)	20	L/kg	Experimental (CAR, 2017)
Henry's Law Constant (at 25 °C)	3.6E-05	$Pa/m^3/mol$	Calculated (CAR, 2017)
Biodegradability	Readily	[-]	Conclusion for lactic acid. *

* Please note that additional information on the biodegradation potential of the active substance L(+) lactic acid is used for assessment of this endpoint. Please refer to Annex 3.3 for more detail.

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 1b	
Air	1.09E-05	Simpletreat v4.0
Water	7.99	
Sludge	0.186	
Degraded in STP	91.8	

Note: Coupling of Simpletreat as described in TAB v2.1 (ENV9)

Calculated PEC values

The below listed PEC values were calculated using equations from the BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017). A refined PEC groundwater was calculated using FOCUS PEARL (v4.4.4).

The local emission rate of 0.84 kg/d as calculated using the consumption-based scenario (scenario 1b) is entered as input for calculation of the different PECs.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW} ***
	[mg/L]	[mg/L]	[mg/kg ww]	[mg/kg ww]	[µg/L]
Scenario 1b	3.35E-02	3.35E-03	4.08E-03	4.24E-03	6.97

* As the refined PEC_{GW} was calculated using the simulation tool FOCUS PEARL (v4.4.4.), the results for the refinement are provided in a separate table below.

PEC groundwater refinement

For more detail on FOCUS PEARL (v4.4.4) model parameters, please refer to Annex 2.2.

Summary table on calculated PEC groundwater values (maximum 80th percentiles)		
Location	**PEC_{GW} (µg/L)**	
	grassland	**maize**
CHATEAUDUN	0.004	0.021
HAMBURG	0.011	0.066
JOKIOINEN	0.013	n.a.
KREMSMUENSTER	0.006	0.045
OKEHAMPTON	0.011	0.055

PIACENZA	0.007	0.017
PORTO	0.003	0.005
SEVILLA	< 0.001	< 0.001
THIVA	< 0.001	0.003

Primary and secondary poisoning

Primary poisoning

Not applicable as the final use products are intended for indoor use, and the products are not rodenticides or pesticides.

Secondary poisoning

The active substance L(+) lactic acid and the SoC ethanol are unlikely to bioaccumulate in aquatic or terrestrial environment according to the BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017), as their log Kow values are low. The substances are not highly adsorptive, do not belong to a class of substances known to have a potential to accumulate in living organisms and their structural features do not indicate accumulation and the substances are assessed to be readily biodegradable. The estimated bioconcentration factor for fish is 0.048 L/kg and the bioconcentration factor for earthworms is 6.78 L/kg for the active substance L(+) lactic acid. No further assessment of secondary poisoning via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Not a relevant receiving compartment.

Sewage treatment plant (STP)

Calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1b	0.003

Conclusion: The RCR, based on exposure from non-professional uses, is <1. The risk to micro-organisms in the STP is acceptable.

Aquatic compartment

Calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1b	< 0.001	< 0.001

Conclusion: The RCRs, based on exposure from non-professional uses, are <1. SoC ethanol may enter the aquatic environment due to deposition of airborne product. Considering that the SoC is diluted in the air and moreover degraded quickly once deposited, concentrations above environmental risks limits are not expected. The risk to aquatic organisms and sediment organisms is acceptable.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1b	0.002

Conclusion: The RCR, based on exposure from non-professional uses, is <1. For SoC, Airborne deposition of SoC ethanol on soils may occur. However, possible risks for terrestrial organisms are expected to be low as the SoC is highly diluted and quickly degraded in air, and quickly degraded once entering the soil compartment. The risk to terrestrial organisms is acceptable.

Groundwater

The foreseeable concentration (PEC) of the active substance in groundwater, does not exceed the maximum permissible concentration laid down by Directive 98/83/EC, i.e. is below 0.1 µg/L. For SoC ethanol, airborne deposition on soils may occur. However, considering that significant contamination of the soil compartment is not expected and ethanol is quickly degraded, transport to groundwater is expected to be negligible.

Primary and secondary poisoning

Primary poisoning

Not relevant (see justification above).

Secondary poisoning

Not relevant (see justification above).

Mixture toxicity

Method Anti-bac cleaner contains ethanol as a solvent. The BPR Guidance Volume IV Environment -Assessment and Evaluation (Part B+C), version 2.0 of October 2017 specifies that the following ground of concern is applicable for identification of Substances of Concern:
‘’Active substances (AS) from other product types (PTs) contained in the product (e.g. in-can preservatives) for which a draft final Competent Authority Report (CAR, with an agreed risk assessment) is available. This criterion identifies other active substances in the biocidal product that act as co-formulants. Those substances should be regarded as SoCs because they potentially affect environmental organisms due to their intrinsic biological activity. They should be considered as SoCs if they are present in the biocidal product at a concentration ≥ 0.1%. This concentration limit is not applicable to PBT- or vPvB- substances and endocrine disrupting chemicals (EDs), as safe concentration limits cannot be derived for those substances. No concentration limit applies to substances that are classified as such. It needs to be checked whether this concentration limit is valid for the respective substance as highly toxic substances may contribute to the overall toxicity of the product even when contained to very small amounts in the product, i.e a co-formulant should be regarded as SoC if the PNEC of the respective substance is lower than the PNEC of the a.s. even though its concentration in the product is below the 0.1% criterion.’’

Currently, initial applications for approval of ethanol for PT1, PT2 and PT4 (Opinion development by BPC) and PT6 (CA evaluation) are in progress. The assessment reports are not published and thus are not available yet.
Ethanol is present in the biocidal product at 3.84 (4% as a mixture with propan-2-ol, in which 96% is ethanol), and thus ≥ 0.1%.
Ethanol is not identified as a PBT/vPvB substance, nor as an endocrine disrupting chemical (ED). Ethanol is not classified for the environment and thus cannot be identified as a highly toxic substance.
PNECs derived for L(+) lactic acid (CAR 2017) and ethanol (ECHA website) are shown in the tables below:

Hazard assessment conclusion of active substance L(+) lactic acid for the environment		
Compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	PNEC: 3.90 mg a.s./L	CAR (2017)
Sediments (freshwater)	PNEC: 4.8 mg a.s./kg ww * PNEC: 1.04 mg a.s./kg dw	CAR (2017)
Sewage treatment plant (STP)	PNEC: 10 mg a.s./L	CAR (2017)
Soil	PNEC: 1.90 mg a.s./kg ww * PNEC: 1.68 mg a.s./kg dw	CAR (2017)

* Please note that PNEC values for sediment and soil are presented as mg/kg wet weight (ww) and converted to mg/kg dry weight (dw) and are derived by applying the equilibrium partitioning method.

Hazard assessment conclusion of ethanol for the environment		
Compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	PNEC: 0.96 mg a.s./L	ECHA website
Sediments (freshwater)	PNEC: 3.6 mg a.s./kg dw *	ECHA website
Sewage treatment plant (STP)	PNEC: 580 mg a.s./L	ECHA website
Soil	PNEC: 0.63 mg a.s./kg dw *	ECHA website

* Please note that PNEC values for sediment and soil are presented as mg/kg dry weight (dw) and are derived by applying the equilibrium partitioning method.

The freshwater PNEC of L(+) lactic acid was based on the result of the algae being the most sensitive species of the 3 trophic levels (E_rC_{50} was 3,900 mg a.s./L). It should be noted that no long-term studies for L(+) lactic acid are available. The experimental studies on fish and invertebrates were considered to be invalid (RI = 3) and algae were identified to be the most sensitive organisms with the aid of the QSAR estimations (CAR 2017). The freshwater PNEC for ethanol was based on the NOEC of the daphnia reproduction test (9.6 mg/L), being the lowest NOEC from long-term studies for all 3 trophic levels.

For comparison, some phys-chem, fate and the ecotoxicological results for L(+) lactic acid and ethanol are summarized in the table below:

Parameter	L(+) lactic acid (CAR 2017)	Ethanol (ECHA website)
Water solubility	Completely miscible in water	789 g/L
$Log_{10}K_{OW}$	-0.74	-0.35
K_{OC}	20 L/kg	1
VP (Pa)	0.4	5726
Readily biodegradable	Yes, but 10-day window cannot be assessed	Yes
LC_{50} fish	130 mg a.s./L (96 h)* 177 g a.s./L (QSAR)	14.2 g/L (4-d)
EC_{50} daphnia	156 mg a.s./L (48 h)* 78.8 g a.s./L (QSAR)	10 g/L (48-h)
E_rC_{50} algae	3.9 g a.s./L (70.5 h)* 21.3 g a.s./L (QSAR)	275 mg/L (72-h)
NOEC Fish	-	250 mg/L (120 h)
NOEC Daphnia repro	-	9.6 mg/L (10 d)
NOErC/EC_{10} algae	1.1 g a.s./L (70.5 h-NOErC)*	11.5 mg/L (72 h EC_{10})
EC_{50} micro-organisms	> 100 mg/L (3 h)	5800 mg/L (4 h)

* Effect values are considered to be related to low pH.

In order to determine whether ethanol adds to the mixture toxicity together with L(+) lactic acid, the toxic units (TUi) of each of the two substances were calculated and the relative toxicity determined for each trophic level and based on the available data:

TUi = Ci/ECxi

rel TU*i* = (TU*i*/ΣTU)/100

	L(+) lactic acid				Ethanol			
	Ci (%)	EC_{50} * (g/L)	TUi	Relative TUi (%)	Ci (%)	EC_{50} (g/L)	TUi	Relative TUi (%)
Fish	2.4	177	0.014	4.8	3.84	14.2	0.27	95
Daphnia		78.8	0.03	7.3		10	0.38	93

Algae		21.3	0.11	0.8		0.275	14	99

*QSAR results were used

From the relative toxicity values, it can be concluded that ethanol drives the mixture toxicity. However, based on the high L(E)C_{50} and NOEC values of ethanol, this substance is of low toxicity.

A pragmatic approach for the environmental risk assessment of the mixture is further used to confirm no environmental concerns. Based on the phys-chem and e-fate properties of both substances, only the aquatic compartment is taken into consideration.

The mixture toxicity can be calculated from following equation:

$$EC_{x,mix} = \left(\sum_{i=1}^{n} \frac{p_i}{EC_{x,i}} \right)^{-1}$$

Where *p*i is the proportion of the compound *i* in the considered mixture (ranging between 0 and 1). It is calculated as the concentration of compound *i* in the mixture in relation to the summed concentrations of all compounds that are considered for the mixture assessment. Pi is 0.38 for L(+) lactic acid and 0.62 for ethanol.

The following ECx,mix were derived:

	Fish	daphnia	algae
ECx,mix (mg/L)	22E+03	15E+03	0.44E+03

Based on the similar phys-chem. and fate properties, predicted concentrations for L(+) lactic acid can be expected to be indicative of predicted concentrations of ethanol (PECs can be considered the same, taking into account the higher % of ethanol at one hand and some potential volatilization of ethanol on the other hand).

Aquatic PEC/PNEC values for the mixture are therefore calculated on 2 x PEC value for L(+) lactic acid and the PNEC of the mixture (lowest ECx,mix/1000).

With the PEC water of 0.00335 mg/L, PEC/PNECaquatic is calculated to be 0.015, which is approx. 17 times higher than the PEC/PNEC of L(+) lactic acid and still well below 1.

Conclusion: The environmental risk of the mixture L(+) lactic acid and ethanol is considered low as the pragmatic approach indicates that the PEC/PNEC of the mixture is approximately 17 times the aquatic PEC/PNEC of L(+) lactic acid and < 1.

Aggregated exposure (combined for relevant emmission sources)

In the CAR (2017) it was concluded that no aggregated exposure assessment for L(+) lactic acid needs to be performed because the biocidal use of L(+) lactic acid accounts for less than 10% of the total production and import volume in the EU. Based on the EU use volumes currently assessed for PT 2, this may be assumed to not have changed. Consequently, aggregated exposure assessment is not deemed necessary. Also note that the current product family only concerns disinfection of surfaces not contacted to food. Therefore, aggregated exposure assessment is not applicable.

Overall conclusion

Overall conclusion on the risk assessment for the environment of the product
Method Anti-Bac cleaner product family are PT2 disinfection products containing the active substance L(+) lactic acid. Following products use, discharge of water from the STP to freshwater may occur, therefore the aquatic compartment and sediment compartment were assessed. Furthermore, the soil compartment may also be exposed when sewage sludge is applied to the soil, and therefore risks to soil organisms and groundwater were also assessed. Acceptable risk was demonstrated for all relevant environmental compartments following product use under worst-case assumptions. One potential substance of concern was identified, ethanol. This substance was quantitatively assessed and demonstrated acceptable risk to potentially exposed compartments. Therefore, use of Method Anti-bac cleaner as ready to use products for the disinfection of non-porous surfaces without precleaning that do not come into contact with food and feed, can be considered as safe for the environment.

2.2.9 Measures to protect man, animals and the environment

Not applicable.

2.2.10 Assessment of a combination of biocidal products

Not applicable.

2.2.11 Comparative assessment

Not applicable.

3 ANNEXES[6]

3.1 List of studies for the biocidal product (family)

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner

6 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner

Data point	Author(s)	Year	Title	Company Report No.	Source	GLP Y/N	Published Y/N	Vertebrate study Y/N	Data protection claimed Y/N	Owner
			method							

3.2 Output tables from exposure assessment tools

HUMAN TOXICOLOGICAL RISK ASSESSMENT

Report for assessment *Method Anti-bac cleaner (active substance)*
ConsExpo Web - Mon Jun 14 2021

Label	Value
Substance	
Name	L-(+)-lactic acid
CAS number	79-33-4
Molecular weight	90.1 g/mol
K_{OW}	-0.74 10Log
Product	
Name	Method Anti-bac cleaner
Weight fraction substance	0.024
Population	
Name	EU framework Biocides adult
Body weight	60 kg

Scenario *Spraying*

Label	Value
Frequency	365 per year
Description	

Inhalation

Label	Value
Exposure model	Exposure to spray - Spraying
Spray duration	2 minute
Exposure duration	60 minute
Weight fraction substance	0.024
Room volume	15 m^3
Room height	2.5 m
Ventilation rate	2.5 per hour

Label	Value
Inhalation rate	1.25 m^3/hr
Spraying towards person	No
Mass generation rate	0.8 g/s
Airborne fraction	0.008
Density non volatile	1.2 g/cm^3
Inhalation cut off diameter	15 µm
Aerosol diameter distribution	LogNormal
Median diameter	7.7 µm
Arithmetic coefficient of variation	1.9
Maximum diameter	50 µm
Include oral non-respirable material exposure	No
Absorption model	Fixed fraction
Absorption fraction	1

Dermal

Label	Value
Exposure model	Direct contact - Constant rate
Exposed area	–
Weight fraction substance	0.024
Contact rate	46 mg/min
Release duration	2 minute
Absorption model	Fixed fraction
Absorption fraction	0.5

Oral

Label	Value
Exposure model	n.a.
Absorption model	n.a.

Results for scenario *Spraying*

Inhalation

Mean event concentration	2.2×10^{-1} mg/m^3

(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)	
Peak concentration (TWA 15 min) (peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.)	5.2×10^{-1} mg/m³
Mean concentration on day of exposure (average air concentration over the day (accounts for the number of events on one day))	9.1×10^{-3} mg/m³
Year average concentration (mean daily air concentration averaged over a year)	9.1×10^{-3} mg/m³
External event dose (the amount that can potentially be absorbed per kg body weight during one event)	4.6×10^{-3} mg/kg bw
External dose on day of exposure (the amount that can potentially be absorbed per kg body weight during one day)	4.6×10^{-3} mg/kg bw
Internal event dose (absorbed dose per kg body weight during one exposure event)	4.6×10^{-3} mg/kg bw
Internal dose on day of exposure (absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)	4.6×10^{-3} mg/kg bw/day
Internal year average dose (daily absorbed dose per kg body weight averaged over a year.)	4.6×10^{-3} mg/kg bw/day
Dermal	
Dermal load (amount per cm² on the skin)	–
External event dose (the amount that can potentially be absorbed per kg body weight during one event)	3.7×10^{-2} mg/kg bw
External dose on day of exposure	3.7×10^{-2} mg/kg bw

(the amount that can potentially be absorbed per kg body weight during one day)	
Internal event dose (absorbed dose per kg body weight during one exposure event)	1.8×10^{-2} mg/kg bw
Internal dose on day of exposure (absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)	1.8×10^{-2} mg/kg bw/day
Internal year average dose (daily absorbed dose per kg body weight averaged over a year.)	1.8×10^{-2} mg/kg bw/day

Integrated

Internal event dose (absorbed dose per kg body weight during one exposure event)	2.3×10^{-2} mg/kg bw
Internal dose on day of exposure (absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)	2.3×10^{-2} mg/kg bw/day
Internal year average dose (daily absorbed dose per kg body weight averaged over a year.)	2.3×10^{-2} mg/kg bw/day

Scenario *Wiping*

Label	Value
Frequency	365 per year
Description	

Inhalation

Label	Value
Exposure model	n.a.
Absorption model	n.a.

Dermal

Label	Value
Exposure model	Direct contact - Instant application
Exposed area	215 cm^2
Weight fraction substance	0.024
Product amount	0.1 g

Label	Value
Absorption model	Fixed fraction
Absorption fraction	0.5

Oral

Label	Value
Exposure model	n.a.
Absorption model	n.a.

Results for scenario *Wiping*

Dermal

Dermal load (amount per cm^2 on the skin)	2.2 × 10^{-3} mg/cm^2
External event dose (the amount that can potentially be absorbed per kg body weight during one event)	8.0 × 10^{-3} mg/kg bw
External dose on day of exposure (the amount that can potentially be absorbed per kg body weight during one day)	8.0 × 10^{-3} mg/kg bw
Internal event dose (absorbed dose per kg body weight during one exposure event)	4.0 × 10^{-3} mg/kg bw
Internal dose on day of exposure (absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)	4.0 × 10^{-3} mg/kg bw/day
Internal year average dose (daily absorbed dose per kg body weight averaged over a year.)	4.0 × 10^{-3} mg/kg bw/day

Integrated

Internal event dose (absorbed dose per kg body weight during one exposure event)	4.0 x 10^{-3} mg/kg bw
Internal dose on day of exposure (absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)	4.0 x 10^{-3} mg/kg bw/day

Internal year average dose (daily absorbed dose per kg body weight averaged over a year.)	4.0 x 10^{-3} mg/kg bw/day

Results for scenario 3: *Rubbing off*

Dermal

Parameter	Value	Unit
Exposed area	234	cm2
Film thickness on surface	0.01	cm
Fraction of substance in product	0.024	
Density of product	1004	mg/cm3
Transfer coefficient	100%	
Child weight	8	kg
Amount on skin	56.38464	mg
Dermal absorption	50%	
Absorbed via skin (50% of non-ingested amount)	3.171636	mg/kg bw/day

Oral

Transfer from skin to mouth	10%	
Ingestion absorption	100%	
Amount ingested	5.638464	mg
Absorbed via oral ingestion	0.704808	mg/kg bw/day

Total

Total internal exposure (dermal and oral)	3.876444	mg/kg bw/day

ENVIRONMENTAL RISK ASSESSMENT

FOCUS PEARL (v4.4.4): relevant input and output

FOCUS PEARL (v4.4.4) substance input parameters				
Parameter	**Value**	**Unit**	**at T**	**Remarks**
Physico-Chemical parameters				
Molecular weight	90.08	g/mol	-	
Vapour pressure	0.4	Pa	20 °C	CAR (2017)
Molar enthalpy of vaporization	95	kJ/mol		FOCUS recommendation
Water solubility	1.0E+06	mg/L	20 °C	CAR (2017)
Molar enthalpy of dissolution	27	kJ/mol		TAB v2.1 (ENV 23)
Diffusion coefficient in water	4.3E-05	m^2/d		TAB v2.1 (ENV 23)
Diffusion coefficient in gas	4.3E-01	m^2/d		TAB v2.1 (ENV 23)
Degradation in soil				
DT_{50} soil	30	d	12 °C	Based on conclusion 'readily biodegradable'
Temperature correction function: - Reference temperature - Activation energy - Q10-value	 - 65.4 2.58	 - J/mol -	 20 °C	 FOCUS recommendation TAB v2.1(ENV 23) TAB v2.1 (ENV 23)
Moisture correction function: - Reference moisture - Moisture exponent	 pF 2 0.7	 - -		 FOCUS recommendation FOCUS recommendation
Sorption to soil				
pH dependence	No	-		Although the substance is an acid (pKa = 3.86), in line with the available active substance data, no pH-dependence was taken into account.
Kf,oc	20	mL/g	-	CAR (2017); as no Kf,oc is available, the non-Freundlich Koc was used

Kf,om	11.60	mL/g		Calculated as: Koc / 1.724
Freundlich exponent (1/n)	1	-		TAB v2.1 (ENV 22)
Crop/ Management related parameters				
Plant uptake factor (PUF)	0	-		TAB v2.1 (ENV 23)

FOCUS PEARL (v4.4.4) application schemes			
Application schemes	**1**	**2**	**Remarks**
Crop *	alfalfa	maize	TAB v2.1 (ENV 36)
Csludge (mg/kg dw)	1.92	1.92	local STP
Application rate (kg/ha)	**0.00192** (= 1000 * C_{sludge} * 10^{-6})	**0.00192** (= 5000 * C_{sludge} * 10^{-6})	TAB v2.1 (ENV 36)
Number of applications (per year)	1	1	TAB v2.1 (ENV 36)
Application date - absolute	March 1	-	TAB v2.1 (ENV 36)
- relative	-	20 days pre-emergence	TAB v2.1 (ENV 36)
Application type	incorporation	incorporation	TAB v2.1 (ENV 36)
Depth (m)	0.1	0.2	TAB v2.1 (ENV 36)

* Alfalfa and maize are representative crops for grassland and arable land, respectively.

3.3 New information on the active substance

Further studies on fate and behaviour of L(+) lactic acid in the environment:

Biodegradation

In the CAR (2017), acceptable data from a BOD/COD study is available for L(+) lactic acid (The study was performed in accordance with test guidelines similar to EU C.5/C.6 and OECD 301D, and in compliance with GLP criteria. The BOD/COD ratio was determined after 5 days and 20 days inoculation to L(+) lactid acid at test concentrations of 2 and 4 mg/L. The percentages biodegradation were determined to be 48-50%, and 60-67% after 5 days and after 20 days inoculation, respectively. As a result of the study design, the 14-d window criterion could not be assessed, and therefore, L(+) lactic acid was assessed as 'readily biodegradable, but failing 14-d window'.

In the BPC opinion on the application for approval of the active substance L(+) lactic acid for PT 2 (ECHA, 2017), it was noted that not all groundwater scenarios for the representative product were safe on the basis of the default degradation half-live of 90 days for soil (as determined on the basis of the biodegradation conclusion). Furthermore, it was concluded that '*the current assessment of the biodegradation behaviour in soil of lactic acid is most likely too conservative: based on the information submitted in the application a default degradation half-live of 90 days was estimated*', and that '*additional information obtained via a literature search shows that in reality the degradation half-life may be lower.*'.

In the CLH report (BAuA, 2017) for L(+) lactic acid, QSAR calculations are presented by the eCA, and the results of all seven Biowin modules included in EPIWEP 4.1 indicate that the substance is readily biodegradable (Biowin1=0.94; Biowin2=0.97; Biowin3=3.52; Biowin4=4.23; Biowin5=0.74; Biowin6=0.88; Biowin6=0.91; Overall prediction: readily biodegradable). Based on these findings, the eCA concludes that the substance is rapidly degradable for the purpose of environmental classification which was taken over in the RAC Opinion for L(+) lactic acid (3 December 2019).

Additional data on the biodegradability of lactic acid and several alkyl lactate esters is available from a study by Bowmer et al. (1998) also included in the CLH report (BAuA, 2017) for L(+) lactic acid. In this study, a range of alkyl lactate esters were tested for their biodegradability in closed bottle screening tests. L(+) lactic acid and its esters were found to be >60% biodegraded within 28 days based on the ThOD of the esters, and were therefore assessed to be readily degradable in the designated test methods.

Unfortunately in this study also, percentages biodegradation were determined only at 5 days and 28 days after inoculation, and therefore provide insufficient detail to assess whether the 14-d window criterion was met.

In summary, lactic acid degrades readily in the designated test, and the potential for ready biodegradation is further confirmed by data available for longer-chain alkyl lactate esters as well as Biowin calculations for L(+) lactic acid.
Although, as a result of study design, it is not possible to assess whether or not the 14-d window criterion was met, based on the entire dataset it is considered too conservative to conclude that it was not. Therefore, for purpose of environmental exposure assessment, L(+) lactic acid is concluded to be 'readily biodegradable' instead of 'readily biodegradable, but failing 14-d window', and the associated default environmental half-lives of 15 days for surface water, and 30 days for soil are used in the assessment.

3.4 Residue behaviour

3.5 Summaries of the efficacy studies

Please refer to the IUCLID file of the biocidal product.