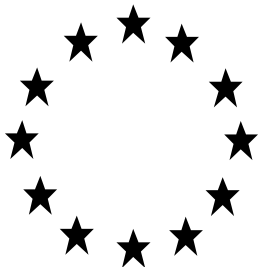
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Ecolab UA Lactic acid single product dossier

Product type 2

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

Case Number in R4BP: BC-XS050968-91

Evaluating Competent Authority: Latvia

Date: 2 September 2021

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1 CONCLUSION

The outcome of the assessment for the biocidal product "Ecolab UA Lactic acid single product dossier" is specified in the BPC opinion following discussions at the BPC-40 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Trade names	Country
Ecolab UA Lactic acid single product dossier	Maxx Into Des GEL NETTOYANT DESINFECTANT WC	European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1 40789 Monheim am Rhein Germany
Pre-submission phase started on	18th October 2018	
Pre-submission phase concluded on	26th November 2018	
Authorisation number	EU-0027463-0000	
Date of the authorisation	24 November 2022	
Expiry date of the authorisation	31 October 2032	

2.1.1.3 Manufacturers of the product

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	Afp Gmbh 21337 Lueneburg, Germany Acideka S.A. Capuchinos De Basurto 6, 4a Planta 48013 Bilbao, Bizkaia, Spain Adiego Hnos Adiego Ctra De Valencia 50410 Cuarte De Huerva, Spain Allied Products Allied Hygiene Unit 11, Belvedere Industrial Estate Fishers Way Da17 6bs Belvedere Kent, United Kingdom

	Arkema Gmbh Morschheimer Strasse 19, D-67292, Krichbeimbolanden, Germany Azelis Denmark Lundtoftegårdsvej 95 2800 Kgs. Lyngby, Denmark Belinka-Ljubljana Belinka Zasavska Cesta 95 1001 Ljubljana, Slovenia Bentus Laboratories Radio Street 24 Bld 1 105005, Moscow, Russian Federation Bio Productions Ltd 72 Victoria Road Rh15 9lh West Sussex, United Kingdom Bioxal Sa Route Des Varennes - Secteur A - Bp 30072 71103 Chalon Sur Saöne Cedex, France Bores S.R.L. Via Pioppa 179 44020 Pontegradella, Italy Brenntag Ardennes Route De Tournes Cd N 2 08090 Cliron, France Brenntag Cee – Guntramsdorf Blending Bahnstr 13a 2353 Guntramsdorf, Austria Brenntag Kleinkarlbach Humboldtring 15 45472 Muehlheim, Germany Brenntag Kaiserslautern Merkurstr. 47 67663 Kaiserslautern, Germany Brenntag Nordic – Haslev Høsten Teglværksvej 47 4690 Haslev, Denmark Brenntag Normandly 12 Sente Des Jumelles Bp 11 76710 Montville, France Brenntag Pl-Zgierz Ul. Kwasowa 5 95-100 Zgierz, Poland Brenntag Quimica Calle Gutemberg Nº 22, Poligono Industrial El Lomo 28906, Madrid, Spain

	Brenntag Schweizerhall Elsaesserstr. 231 Ch-4056 Basel Schweiz, Switzerland Budich International Gmbh Dieselstrasse 10 32120 Hiddenhause, Germany Caldic Deutschland Chemie B.V. Karlshof 10 D 40231, Deusseldorf, Germany Colep Bad Schmiedeberg, Kemberger Str. 3 06905 Bad Schmiedeberg, Germany Lana S.A. Condado De Trevino 46 09080 Burgos, Spain Comercial Godo França 13 08700, Barcelona, Spain Courtois Sarl Route De Pacy, 27730 Bueil, France Dan-Mor Natural Products And Chemicals Ltd Hailian Street 29 30600, Akiva, Israel Denteck BV Heliumstraat 8 2718 Sl Zoetermeer, Netherlands Detergents Burguera S.L. Joan Ballester, 50 07630 Campos (Illes Baleares), Spain ECL Biebesheim Justus-Von-Liebig-Straße 11 64584 Biebesheim Am Rhein, Germany ECL Celra Celra C/ Tramuntana S/N Poligona Industrial Celra 17460 Girona, Spain ECL Chalons Avenue Du General Patton 51000 Chalons En Champagne, France ECL Cisterna Via Ninfina Ii 04012 Cisterna Di Latina, Italy ECL Fawley Fawley Cadland Road, Hythe So45 3np Hampshire, South Hampton, United Kingdom

	ECL Leeds Lotherton Way Garforth Ls25 2jy Leeds, United Kingdom ECL Mandra 25th Km Old National Road Of Athens To Thiva, Gr 19600, 19600 Mandra, Greece ECL Maribor Vajngerlova 4 Si-2001 Maribor, Slovenia ECL Microtek B.V. Gesinkkampstraat 19 7051 Hr Varsseveld, Netherlands ECL Microtek Mosta F20 Mosta Technopark 3000 Mosta Mst, Malta ECL Mullingar Forest Park Zone C Mullingar Industrial Estate N91 Mullingar, Ireland ECL Niewegein Brugwal 11a 3432 Nz Nieuwegein, Netherlands ECL Rovigo Esoform Viale Del Lavoro 10 45100 Rovigo, Italy ECL Rozzano Via A. Grandi, 20089 Rozzano Mi, Italy ECL Tesjoki Nlc Tesjoki Kivikummuntie 1 07955 Tesjoki, Finland ECL Tessenderlo Industriezone Ravenshout 4 3980 Tessenderlo, Belgium ECL Weavergate Nlc Weavergate Northwich, Chheshire West And Chester Cw8, 4ee Weavergate, United Kingdom Ecolab Ltd Baglan/Swindon Plot 7a Baglan Energy Park, Baglan, Port Talbot Sa11 2hz Baglan, United Kingdom Ferdinand Eiermacher Westring 24 48356 Nordwalde, Germany F.E.L.T. B.P 64 10 Rue Du Vertuquet 59531 Neuville En Ferrain, France

	Gallows Green Services Ltd. Cod Beck Mill Industrial Estate Dalton Lane Thirsk North Yorkshire Yo7 3hr North Yorkshire, United Kingdom Gerdisa German Rguez Drogas Ind. Gerdisa Pol Industrial Miralcampo Parc.37 19200 Azuqueca De Henares Guadalajara, Spain Girasol Natural Products BV De Veldoven 12-14 3342 Gr Hendrik-Ido-Ambacht, Netherlands Henkel Engels 48 Pr. Stroitelei 413116 Saratov, Russian Federation Imeco GmbH & Co. Kg Boschstraße 5 D-63768 Hösbach, Germany Innovate GmbH Am Hohen Stein 11 06618 Naumburg, Germany Interfill Lcc-Tosno Moskovskoye Shosse 1 187000 Tosno - Leningradskaya Oblast, Russian Federation Jodel- Productos Quimicos Jodel Zona Inustrial 2050 Aveiras De Cima, Portugal Kleimann GmbH Am Trieb 13, 72820, Sonnenbühl, Germany La Antigua Lavandera S.L. Apartado De Correos, 58 41500, Sevilla, Spain Laboratoires Anios Pavé Du Moulin, 59260, Lille-Hellemmes, Spain Laboratoires Anios Rue De Lille 3330 59262, Sainghin-En-Mélantois, France Lichtenheldt GmbH Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt, Germany Lonza GmbH Morianstr. 32 42103 Wuppertal, Germany Multifill BV Constructieweg 25a 3641 Sb Mijdrecht, Netherlands

	Nopa Nordisk Parfumerivare Hvedevej 2-22 Dk-8900 Randers, Denmark Planol GmbH Maybachstr 17 63456 Hanau, Germany Plum A/S Frederik Plums Vej 2 Dk 5610 Assens, Denmark Productos La Corberana S.L. 46612 Corbera (Valencia), Spain The Proton Group Ltd Ripley Drive, Normanton Industrial Estate, Wakefield Wf6 1qt Wakefield, United Kingdom Quimicas Morales S.L. Misiones, 11 05005 Las Palmas De Fran Canaria, Spain Rnm Productos Quimicos Lda Rua Da Fabrica, 123 4765-080 Carreira Vila Nova De Famalicao Carreira Vila Nova De Famalicao Portugal Roquette & Barentz Route De La Gorgue F-62136 Lestrem, France Rutpen Ltd Membury Airfield Lambourn Berks Rg16 7tj, Membury, United Kingdom Solimix Montseny 17-19 Pol. Ind. Sant Pere Molanta 08799 Olerdola Barcelona, Spain Staub & Co Industriestraße 3 D-86456 Gablingen, Germany Stockmeier Chemie Eilenburg Gmbh & Co.Kg Gustav-Adolf-Ring 5 04838, Ellenburg, Germany Synerlogic BV L.J. Costerstraat 5 6827 Arnhem, Netherlands Univar Ltd Argyle House, Epsom Avenue, Sk9 3rn Wilmslow, United Kingdom Univar Spa Via Caldera 21 20-153 Milano, Italy

	Van Dam Bodegraven B.V, Beneluxweg 6-8 2410 Aa Bodegraven, Netherlands Pal International Ltd. Sandhurst Street – Leicester, United Kingdom Carbon Chemicals Group Ltd P43 R772 Ringaskiddy, County Cork, Ireland Brenntag Duisburg Am Röhrenwerk 4647529, Duisberg Germany Brenntag Glauchau Bochstrasse 08371 Glauchau, Germany Brenntag Hamburg Hannoversche Str 40 21079 Hamburg, Germany Brenntag Heilbronn Dieselstrasse 574076, Heilbronn, Germany Brenntag Lohfelden Am Fieseler Werk 934253, Lohfelden, Germany Brenntag Nordic – Vejle Strandgade 35 7100, Vejle, Denmark Kompak Nederland BV 433651 Bavel, Netherlands

2.1.1.4 Manufacturer of the active substance

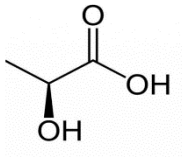
Active substance	L(+)-Lactic acid
Name of manufacturer	Purac Biochem BV
Address of manufacturer	Arkelsedijk 46 NL-4206 AC Gorinchem The Netherlands
Location of manufacturing sites	Arkelsedijk 46 NL-4206 AC Gorinchem The Netherlands

2.1.2 Product composition and formulation

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	Not available
Minimum purity / content	≥ 95.5% dry weight
Structural formula	

2.1.2.2 Candidate for substitution

L(+)-Lactic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+)-Lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	13.2%
D-Glucopyranose, oligomers, decyl octyl glycosides	D-Glucopyranose, oligomers, decyl octyl glycosides	Non-active substance	68515-73-1	500-220-1	3.25%
Alcohols, C8-10 (even numbered), ethoxylated (< 2,5-EO)	Alcohols, C8-10, ethoxylated		71060-57-6	-	1%

The substances listed in the table above are limited to substances identified as SoCs. See Section 3.5.1. of the Confidential Annex to PAR for full composition.

2.1.2.4 Information on technical equivalence

The active substance contained in the biocidal product is identical to the reference source (supplier is Purac Biochem bv).

2.1.2.5 Information on the substances of concern

Substances of concern are mentioned in the section above. For more information please refer to the Section 3.5.2 of the Confidential Annex to PAR.

The biocidal product is not considered to have endocrine disrupting properties. For further information, please see Section 3.5.5 of the Confidential Annex to PAR.

2.1.2.6 Type of formulation

AL – any other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Corr. 1C Eye Dam. 1
Hazard statement	H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage EUH071 - Corrosive to the respiratory tract
Labelling	
Signal words	Danger
Hazard statements	H314 - Causes severe skin burns and eye damage EUH071 - Corrosive to the respiratory tract
Precautionary statements	P260 – Do not breathe vapours. P264 - Wash hands thoroughly after handling. P280 – Wear protective gloves. P301 + P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 – Immediately call a POISON CENTER or doctor/physician. P321 - Specific treatment (see first aid instruction on this label). P363 – Wash contaminated clothing before reuse. P405 - Store locked up. P501 - Dispose of contents/container in accordance with national regulations.
GHS Pictogram	GHS05 
Note	N/A

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use 1 – Toilet bowl disinfectant

Product Type	PT02
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria and yeast
Field of use	Indoor – disinfection of hard surface on the inside of toilet bowl in institutional and healthcare area.
Application method(s)	Pouring directly onto surface
Application rate(s) and frequency	RTU - In an amount sufficient to cover the whole inner toilet bowl surface. Contact time – 15 minutes. Daily use.
Category(ies) of users	Professional
Pack sizes and packaging material	750, 1000 mL HDPE bottles with a dosing plug and PP/LDPE cap

2.1.4.2 Use-specific instructions for use

See general directions for use, section 2.1.5

2.1.4.3 Use-specific risk mitigation measures

See general directions for use, 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 general directions for use, 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 general directions for use, 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 general directions for use, section 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Lift up the toilet seat and carefully direct the nozzle under the toilet rim. Squeeze and apply slowly all around the inside of the bowl, allowing enough liquid to cover the whole inner toilet bowl surface. Leave for 15 minutes. Flush the toilet afterwards. May not be used with bleach or other cleaning agents. Inform the registration holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Do not breathe vapour. Avoid contact with eyes and skin. Do not brush the product in toilet bowl. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Wash hand thoroughly after handling.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a Poison Centre or a doctor. IF ON SKIN: Immediately wash with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: the eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid. IF SWALLOWED: Immediately rinse mouth. Do NOT induce vomiting. Give something to drink, if exposed person is able to swallow. Call 112/ambulance for medical assistance. When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose the product and its packaging in accordance with applicable national regulations.

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

Keep away from strong bases. Keep out of reach of children. Store in original container tightly closed. Store between + 5 °C and + 40 °C. Protect from frost. Shelf life: 24 months.

2.1.6 Other information

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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)
Bottle	750, 1000 mL	White opaque HDPE packaging with a dosing plug	PP/LDPE cap	professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list in Annex 1 for a list of studies for the biocidal product.

2.1.8.2 Access to documentation

A letter of access is available to the original dossier of the active substance from Purac Biochem bv, which is an approved substance supplier for PT2 according to Article 95 of Regulation (EU) No 528/2012.

2.1.8.3 Similar conditions of use

As stated in the letter from ECHA dated 26 November 2018, the biocidal product *Ecolab UA Lactic acid single product dossier* is deemed to be eligible for Union authorisation. This correspondence is submitted as part of the biocidal product dossier.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Table 2. Use 1 – Toilet bowl disinfectant

Product Type	PT02
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria and yeast
Field of use	Indoor – disinfection of hard surface on the inside of toilet bowl in institutional and healthcare area.
Application method(s)	Pouring directly onto surface
Application rate(s) and frequency	RTU - In an amount sufficient to cover the whole inner toilet bowl surface. Contact time – 15 minutes. Daily use.
Category(ies) of users	Professional
Pack sizes and packaging material	750, 1000 mL HDPE bottles with a dosing plug and PP/LDPE cap

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	Product: [redacted][redacted][1] Batch number: [redacted]	liquid	[redacted] (2019), Study No. 37613
Colour at 20 °C and 101.3 kPa	Visual assessment	Product: [redacted][redacted] Batch number: [redacted]	clear and colourless	[redacted] (2019), Study No. 37613
Odour at 20 °C and 101.3 kPa	Organoleptic examination	Product: [redacted] Batch number: [redacted]	sweetish	[redacted] (2019), Study No. 37613
Acidity / alkalinity	CIPAC MT 75.3	Product: [redacted]	pH 2.067 at 20°C	[redacted] (2019), Study No. 37613

[1] The composition is same with [redacted] and actual product Maxx Into Des. The relevant statements are included in IUCLID, Section 13.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	OECD Test guidance 122	Batch number: [redacted]	Acidity: 6.88% H_2SO_4 at 20°C	
Relative density / bulk density	OECD Test guidance 109	Product: [redacted] Batch number: [redacted]	1.040 at 20°C	[redacted] (2019), Study No. 37613
Storage stability test – **accelerated storage**	CIPAC MT46.3 The item is stored in commercial packaging: 750 ml HDPE bottle (white) with PP/LDPE cap	Product: [redacted] Batch number: [redacted]	Appearance: the physical state, colour and odour did not change during the storage for 3 months at 40±2°C. Weight variation (the weight of the item including packaging was observed): T_{0m}: 0.00% T_{1m}: -0.04% T_{2m}: -0.09% T_{3m}: -0.12% Density: T_{0m}: 1.040 T_{1m}: 1.040 T_{2m}: 1.041 T_{3m}: 1.041 Refractive index (measuring the angle of refraction of light at the interface between a prism and the liqud): T_{0m}: 1.3537 T_{1m}: 1.3537	[redacted] (2019), Study No. 37613

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T_{2m}: 1.3536 T_{3m}: 1.3537 pH: T_{0m}: 2.067 T_{1m}: 2.055 T_{2m}: 2.151 T_{3m}: 2.008 Acidity: T_{0m}: 6.88% H_2SO_4 T_{1m}: 7.09% H_2SO_4 T_{2m}: 7.14% H_2SO_4 T_{3m}: 7.15% H_2SO_4 Active substance content (chromatographical method): T_{0m}: 13.38% T_{1m}: 13.17% T_{2m}: 13.27% T_{3m}: 13.21% Variation of active substance is less than 10%. The test item is stable during storage for 3 months at 40°C ± 2°C.	
eCA remark: According to *Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0, May 2018, # 3.6.4 Storage stability and shelf-life*, accelerated storage data generated can be used to give an indication that the biocidal product will be stable for the two years at ambient temperature. According to the conditions for accelerated storage the test item should be stored for 8 weeks at temperature 40°C. As the product was stored during 3 months, eCA is in opinion that it is sufficient data to consider that a provisional shelf-life is 2 years.				
Storage stability test – **long term storage at**	The item is stored in commercial	Product: [redacted]	Appearance: the physical state, colour	[redacted] (2020), Study No. 38139

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
ambient temperature	packaging: 750 ml HDPE bottle (white) with PP/LDPE cap	Batch number: [redacted]	and odour did not change during the storage for 12 months at 22±3°C. Density: T_{0m}: 1.042 T_{3m}: 1.042 T_{6m}: 1.042 T_{12m}: 1.042 T_{24m}: on-going Refractive index: T_{0m}: 1.3542 T_{3m}: 1.3543 T_{6m}: 1.3543 T_{12m}: 1.3543 T_{24m}: on-going pH: T_{0m}: 1.96 T_{3m}: 2.00 T_{6m}: 2.00 T_{12m}: 1.98 T_{24m}: on-going Acidity: T_{0m}: 7.40% H_2SO_4 T_{3m}: 7.43% H_2SO_4 T_{6m}: 7.47% H_2SO_4 T_{12m}: 7.45% H_2SO_4 T_{24m}: on-going Active substance content: T_{0m}: 13.59% T_{3m}: 13.69% T_{6m}: 14.00% T_{12m}: 14.10% T_{24m}: on-going	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Variation of active substance is less than 10%. The test item is stable during storage for 12 months at ambient temperature. A GLP study is in progress to assess long term storage (24 months) at ambient temperature of the liquid product.	
eCA remark: Ongoing long-term storage stability for 24 months will be set as a post authorisation data requirement according to Technical Agreements for Biocides / Analytical Methods and Physicochemical Properties (APCP) Version 2.0, February 2020 #4.2.1.3. Shelf-life decision tree: "*A shelf life will be granted based on an accelerated storage stability test (variation < 10% of AS content). A provisional shelf-life up to 2 years could be granted*."				
Storage stability test – **low temperature stability test for liquids**	3 months storage at 4±2°C The item is stored in commercial packaging: 750 ml HDPE bottle (white) with PP/LDPE cap	Product: [redacted] Batch number: [redacted]	Appearance: the physical state, colour and odour did not change during the storage for 3 months at 4±2°C. Weight variation: T_{0m}: 0.00% T_{1m}: 0.00% T_{2m}: 0.00% T_{3m}: 0.00% Density: T_{0m}: 1.040 T_{1m}: 1.040 T_{2m}: 1.041 T_{3m}: 1.041	[redacted] (2019), Study No. 37613

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Refractive index: T_{0m}: 1.3537 T_{1m}: 1.3537 T_{2m}: 1.3537 T_{3m}: 1.3535 pH: T_{0m}: 2.067 T_{1m}: 2.051 T_{2m}: 2.123 T_{3m}: 2.004 Acidity: T_{0m}: 6.88% H_2SO_4 T_{1m}: 6.97% H_2SO_4 T_{2m}: 7.01% H_2SO_4 T_{3m}: 7.00% H_2SO_4 Active substance content (chromatographical method): T_{0m}: 13.38% T_{1m}: 12.77% T_{2m}: 12.97% T_{3m}: 12.93% Variation of active substance is less than 10%. The test item is stable during storage for 3 months at 4°C ± 2°C.	
eCA remark: The product tested is considered stable at 4°C. However, the tests should be performed at 0°C to negate the need of the storage restriction for low temperatures. The storage conditions require the restriction 'Protect from frost'.				
Effects on content of the active substance and technical characteristics of	Waiver: The white opaque HDPE packaging is used, so the product is not in contact with light. Label claim "Store in original container tightly closed."			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver: The effect of temperature is included in the stability studies. The humidity was not addressed as the product has a high water content.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver: An accelerated storage stability study was performed at 40°C for 3 months in 750 ml HDPE bottle closed by PP/LDPE cap. No variation was observed in the container material or product characteristics during accelerated storage. Furthermore, long-term storage stability study is performing in original packaging. No variations in either the container material or the product characteristics after 12 months. The results demonstrate that there is no reactivity of the product towards the container material.			
Wettability	Waiver: product is ready-to-use liquid formulation.			
Suspensibility, spontaneity and dispersion stability	Waiver: product is not suspension.			
Wet sieve analysis and dry sieve test	Waiver: product is ready-to-use liquid formulation.			
Emulsifiability, re-emulsifiability and emulsion stability	Waiver: product is ready-to-use liquid formulation.			
Disintegration time	Waiver: product is ready-to-use liquid formulation.			
Particle size distribution, content of dust/fines, attrition, friability	Waiver: (1) product is ready-to-use liquid formulation poured from the bottle; (2) MMAD is not necessary for the HH/EFF assessment and the product is not sold together with a trigger sprayer or other spraying equipment.			
Persistent foaming	Waiver: product is ready-to-use and not diluted with water prior to use.			
Flowability/Pourability/Dustability	Waiver: product is ready-to-use liquid formulation.			
Burning rate — smoke generators	Waiver: product is ready-to-use liquid formulation.			
Burning completeness — smoke generators	Waiver: product is ready-to-use liquid formulation.			
Composition of smoke — smoke generators	Waiver: product is ready-to-use liquid formulation.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols	Waiver: product is not aerosol and the product is not intended to be used via spraying.			
Physical compatibility	Waiver: product isn't to be used in combination with other substances, mixtures or biocidal or non-biocidal products.			
Chemical compatibility	Waiver: product isn't to be used in combination with other substances, mixtures or biocidal or non-biocidal products.			
Degree of dissolution and dilution stability	Waiver: product is ready-to-use liquid formulation.			
Surface tension	OECD Test guidance 115	Product: [redacted] Batch number: [redacted]	30.8 ± 1.6 mN/m at 20°C (mean value) The test item is surface active.	[redacted] (2019), Study No. 37613.18/397ANA
Viscosity	OECD Test guidance 114	Product: [redacted] Batch number: [redacted]	Dynamic viscosity at 20°C: 60 mPa s (250 rpm) – 438 mPa s (5 rpm) Dynamic viscosity at 40°C: 50 mPa s (250 rpm) – 288 mPa s (5 rpm) Non-Newtonian liquid	[redacted] (2019), Study No. 37613.18/397ANA

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

The product is clear and colourless gel liquid with a sweetish odour. pH around 2.00. The relative density is 1.040 g/cm^3.

The product in commercial packaging (HDPE bottle with PP/LDPE cap) is stable for 3 months at 40± 2°C and 4± 2°C. No changes in the appearance of the tested item occur. Furthermore, the product is expected to have the stability after a long-term storage stability procedure of 24 months at ambient temperature in its commercial packaging considering accelerated storage stability data and intermediate long term storage studies after 3-12 months. Therefore, a provisional shelf-life up to 2 years could be granted. A long-term storage stability test for 24 months is currently on-going and results will be provided when available (2021). Ongoing long-term storage stability will be set as a post authorisation data requirement or as a change request according to Technical Agreements for Biocides / Analytical Methods and Physico-chemical Properties (APCP) Version 2.0, February 2020

#4.2.1.3. Shelf life decision tree: "A shelf life will be granted based on an accelerated storage stability test (variation <10% of AS content). A shelf life up to 2 years could be granted."

The surface tension of the product is 30.8 ± 1.6 mN/m and it's considered as surface-active. The viscosity of the product at 20°C: 60 mPa s (250 rpm) – 438 mPa s (5 rpm) and at 40°C: 51 mPa s (250 rpm) – 288 mPa s (5 rpm). The product has Non-Newtonian liquid properties.

Label requirements:

- Store in original container tightly closed.
- Store between + 5 °C and + 40 °C.
- Protect from frost.

Shelf life: 24 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	CLP regulation	-	Waiver: (1) based on available data for all components. The screening procedure according to CLP regulation was followed; (2) the oxygen balance for each component was calculated. See Section 3.5.7.3 of the Confidential Annex to PAR for details; (3) exothermic decomposition energy (33.9 J/g) is less than 500 J/g and the onset of exothermic decomposition (160 °C) is below 500 °C.	[redacted] Study No. CSL-21-0687.01

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Therefore, no further testing is need.	
Flammable gases	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Flammable aerosols	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Oxidising gases	CLP regulation	-	Waiver: product is ready-to-use liquid formulation	-
Gases under pressure	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Flammable liquids	EN ISO 3679	-	The flash point of the product > 100 °C. The product is not flammable according to CLP criteria	[redacted] (2021), Study No. 40183.21/159ANA.
Flammable solids	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Self-reactive substances and mixtures	CLP regulation	-	Waiver: (1) based on available data for all components. The screening procedure according to CLP regulation was followed; (2) exothermic decomposition energy (33.9 J/g) is less than 300 J/g. Therefore, no further testing is need.	[redacted] Study No. CSL-21-0687.01
Pyrophoric liquids	CLP regulation	-	Waiver: None of the components in the formulation are pyrophoric. The liquid is stable at ambient temperature for prolonged of time.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Pyrophoric solids	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Self-heating substances and mixtures	CLP regulation	-	Waiver: According to CLP criteria, the surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating. Furthermore, product contains > 78% water and none of the components is classified as self-heating. Not expected that the product would be a self-heating mixture. This is also confirmed by the stability testing.	-
Substances and mixtures which in contact with water emit flammable gases	CLP regulation	-	Waiver: Since water is present (> 78%) in the product and the product is stable, no reaction can take place between the substances. This is also confirmed by the stability testing.	-
Oxidising liquids	CLP regulation	-	Waiver: None of the substances found in the formulation are classified for oxidizing properties. All organic substances present in the formulation only contain oxygen, that is chemically bonded to carbon or hydrogen and no other	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			inorganic substances are present that may contain oxidizing properties. Based on this, it can be concluded the formulation will not need to be classified as oxidizing liquid.	
Oxidising solids	CLP regulation	-	Waiver: product is ready-to-use liquid formulation.	-
Organic peroxides	CLP regulation	-	Waiver: product does not contain organic peroxides.	-
Corrosive to metals	UN Test C.1 as described in Section 37.4 of the UN-MTC	Product: Code [redacted] [redacted][2] Batch No. [redacted]	Uniform (criteria for mass loss 13.5%) and localised corrosion (criteria for corrosion attack 120 µm) were investigated. Maximum mass loss for aluminium plate: 0.8%. Maximum mass loss for steel plate: 6.1%. According to test results no localised corrosion attack (intrusions) was found at any of the plates at the end of the test. Not classified as corrosive to metals.	[redacted] (2019): Study No. 1901250G979 Amendment No. 1 of test report 19012502G979
Auto-ignition temperatures of products (liquids and gases)	-	-	Waiver: The product is known to be stable at room temperature and do not ignite spontaneously. The content of water is > 78% therefore auto-	-

[2] The composition is same with [redacted] and actual product Maxx Into Des. The relevant statements are included in IUCLID, Section 13.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			ignition is not expected. The flash point of the product > 100°C. Auto-ignition temperatures of the main co-formulants is > 300°C, for active substance > 400°C. It is therefore considered acceptable that no auto-ignition temperature study is available.	
Relative self-ignition temperature for solids	-	-	Waiver: product is ready-to-use liquid formulation.	-
Dust explosion hazard	-	-	Waiver: product is ready-to-use liquid formulation.	-

Conclusion on the physical hazards and respective characteristics of the product
The product is not classified with regard to physical hazards according to the CLP Regulation 1272/2008.

2.2.4 Methods for detection and identification

Determination of Lactic acid is performed by liquid chromatography equipped with a diode array detector, using an external standard calibration following standard operating procedure MON37 in use.

The method is applied for total Lactic acid determination. The stereochemical purity of active substance in solution > 99% L(+)-Lactic acid and < 1% D(-)-Lactic acid.

HPLC: NEXERA XR
Column: Hypurity C18 250 mm
Temperature: 30°C
Flow rate: 1.0 mL/min
Volume injected: 20 µL
UV detector wavelength: 210 nm
Run time: 8 minutes

1. Preparation of a stock standard at 0.5% w/w in into high pure water.
2. Preparation of the reference item solutions at the concentration 0.02-0.1% w/w into high pure water. The calibration curve was established on 2 injections of every standard.

3. Preparation of the test item: weight 0.2 g of test item in a single-use flask then complete in 50 g with high pure water. Every test item has been twice prepared and each specimen has been twice injected.
4. The test was performed during five different days. The results were calculated on the average of analyses.
5. The calculation of the concentration in the solution was done by measuring the area of the peak.

$$C_{Speci.} = (A_{Speci.} - b)/a$$

C_{Speci} – concentration of specimen expressed in % (w/w);

a – slope of the calibration function;

b – intercept of the calibration function;

A_{Speci} – area of the test item.

The content of L(+)-Lactic acid in the test item, expressed in % was therefore:

$$C_{EEtest} = (C_{Speci.} x\ Pt_{Speci.})/P_{EEtest}$$

C_{EEtest} – final concentration of the test item expressed in % (w/w);

C_{Speci} – concentration of specimen expressed in % (w/w);

Pt_{Speci}- weight of the specimen expressed in g;

Pt_{EEtest}- weight of the test item expressed in g.

6. The linearity of responses of the detector for determination of Lactic acid was validated within range 0.02% to 0.1%. The correlation coefficient R is higher than 0.99.
7. Study of specify was performed by analysis of formulation blank without Lactic acid. Specificity was also studied by analysis of recovery of spiked solution. Chromatograms obtained do not show significant interfering peak.
8. The accuracy and fidelity of the method was validated on the test item. Recovery of 99.81%. Relative standard deviation is 0.51% and $RAD_{Horwitz}$ 2.72%.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
[redacted][3] LOT: [redacted]	HPLC-DAD	10 independent preparations injected two times.	R=0.9986	Blank does not interfere with the peak of	99.14 - 100.6	99.8%	0.51	[redacted] Study No. 37646

[3] The composition is same with [redacted] and actual product Maxx Into Des. The relevant statements are included in IUCLID, Section 13.

				active ingredient.				
The analytical method provided is validated for the determination of the Lactic acid according to the SANCO/ 3030/99 rev 4.								

Analytical methods for soil								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
A letter of access for data on the complete active substance dossier has been granted to applicant. According to L(+)-Lactic acid Assessment report (2017) the residues in the environment compartments arising from the application of L(+)-Lactic acid are not expected. Therefore, residue analytical methods of L(+)-Lactic acid in soil are not required.								

Analytical methods for air								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
A letter of access for data on the complete active substance dossier has been granted to applicant. According to L(+)-Lactic acid Assessment report (2017) the residues in the environment compartments arising from the application of L(+)-Lactic acid are not expected. Therefore, residue analytical methods of L(+)-Lactic acid in soil are not required.								

Analytical methods for water								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
A letter of access for data on the complete active substance dossier has been granted to applicant. According to L(+)-Lactic acid Assessment report (2017) the residues in the environment compartments arising from the application of L(+)-Lactic acid are not expected. Therefore, residue analytical methods of L(+)-Lactic acid in soil are not required.								

Analytical methods for animal and human body fluids and tissues								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
Since L(+)-Lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.								

Analytical methods for monitoring of active substances and residues in food and feeding stuff								
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
Since the proposed use will not expose food & feeding stuff to the active substance, this analytical method is not required.								

Conclusion on the methods for detection and identification of the product

The validation of the analytical method for the quantitative determination of the active substance has been performed using a test formulation equal to actual product.

It has been concluded, that the method for the determination of Lactic acid is applicable for aqueous formulation with a suitable precision. The method of analysis of active substance lactic acid was validated according to the SANCO/ 3030/99 rev 4.

Methods for monitoring, the determination of residues in soil, air, water and food and feeding stuffs are not required according to the Assessment Report for L(+)-Lactic acid. Methods for the determination of residues in animal and human body fluids and tissues are not relevant as the active substance is not classified as toxic or very toxic.

No analytical methods have been provided for the SoCs as both non-ionic surfactants are considered chemically stable and widely used in cleaner industry. Due to its good wetting, dispersing and solubilizing properties both surfactants exhibit stability in acidic and alkali solution plus miscibility with other chemicals. Both substances do not have any "chemical potential" to react in formulation, that could create a decrease or increase of amount of SoCs. No variations in the product characteristics according to stability data that can be as indicator on non-reaction of components. In addition, for both SoCs only qualitative risk assessment is need, therefore LV CA accepts a non-submission of the methods.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product based on L(+)-Lactic acid to be used for the inner toilet bowl disinfection by professionals users. The ready-to-use biocidal product is applied directly from the bottle and is intended for institutional and healthcare area.

Details of the function and mode of control of L(+)-Lactic acid has been evaluated as part of the active substance approval. A letter of access is available for the active substance dossier.

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

Organisms to be controlled are bacteria and yeasts. The product is used for hygienic purposes to protect humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering

EN 13727, EN13624 and EN13697 studies are performed to cover efficacy requirements for non-porous surface disinfection use. The tests are conducted at 20±1°C for contact times 5 and 15 minutes under the dirty conditions with aim to reflect the instruction of use.

Application of the product leads to the irreversible inactivation of bacterial cells and yeast.

2.2.5.4 Mode of action, including time delay

According to Assessment report for L(+)-Lactic acid, 2017 the substance exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cells 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. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis is observed.

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 organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT2 Bactericidal	Toilet disinfectant	[redacted][4] L(+)-Lactic acid 13.2%	*Pseudomonas aeruginosa* CIP 103467 *Enterococcus hirae* CIP 5855 *Staphylococcus aureus* CIP 483	EN 13727 + A2 (2015)	- Quantitative suspension test (Phase 2 Step 1) - Test concentrations: 20% (v/v), 50% (v/v), 80% (v/v) - Interfering substance: 3g/L BSA + 3mL/ erythrocytes - Test method: dilution-neutralization - Diluent: distilled water - Test temperature: 20±1°C - Contact time: 5 min	The product when applied at 80% concentration for **5 minutes** contact time under dirty conditions and 20°C demonstrated acceptable efficacy (R > 5 log reduction) against all tested bacterial species	[redacted] (2019), Study number 37855
PT2 Yeasticidal	Toilet disinfectant	[redacted] L(+)-Lactic acid 13.2%	*Candida albicans* DSM 1386	EN 13624 (2013)	- Quantitative suspension test (Phase 2 Step 1) - Test concentrations: 10% (v/v), 20% (v/v), 50% (v/v), 80% (v/v) - Interfering substance: 3g/L BSA + 3mL/ erythrocytes - Test method: dilution-neutralization - Diluent: distilled water - Test temperature: 20±1°C - Contact time: 15 min	The product when applied at 80% concentration for **15 minutes** contact time under dirty conditions and 20°C demonstrated acceptable efficacy (R > 4 log reduction) against yeast *C. albicans*	[redacted] (2019), Study number 37854
PT2 Bactericidal	Toilet disinfectant	[redacted] L(+)-Lactic acid 13.2%	*Escherichia coli* CIP 54127 *Pseudomonas aeruginosa* CIP 103467 *Enterococcus hirae* CIP 5855 *Staphylococcus aureus* CIP 483	EN 13697 (2015)	- Quantitative non-porous surface test without mechanical action (Phase 2 Step 2) - Test concentrations: 20% (v/v), 50% (v/v), 80% (v/v) - Interfering substance: 3g/L BSA + 3mL/ erythrocytes - Test method: dilution-neutralization - Diluent: distilled water - Test temperature: 20±1°C - Contact time: 5 min	The product when applied at 50% and 80% concentrations for **5 minutes** contact time under dirty conditions and 20°C demonstrated acceptable efficacy (R > 4 log reduction) against all tested bacterial species	[redacted] (2019), Study number 37862

[4] The composition is same with [redacted] and actual product Maxx Into Des. The relevant statements are included in IUCLID, Section 13.

PT2 Yeasticidal	Toilet disinfectant	L(+)-Lactic acid 13.2%	*Candida albicans* DSM 1386	EN 13697 (2015)	- Quantitative non-porous surface test without mechanical action (Phase 2 Step 2) - Test concentrations: 20% (v/v), 50% (v/v), 80% (v/v) - Interfering substance: 3g/L BSA + 3mL/ erythrocytes - Test method: dilution-neutralization - Diluent: distilled water - Test temperature: 20±1°C - Contact time: 15 min	The product when applied at 50% and 80% concentrations for **15 minutes** contact time under dirty conditions and 20°C demonstrated acceptable efficacy (R ≥ 3 log reduction) against yeast *C. albicans*	(2020), Study number 37864
Additional studies							
PT2 Bactericidal	Dummy formulation	5 L(+)-Lactic acid 13.2%	6				
PT2 Yeasticidal	Dummy formulation	L(+)-Lactic acid 13.2%					
PT2 Bactericidal	Dummy formulation	7 L(+)-Lactic acid 0%					

5
6
7

					[redacted]	[redacted]	[redacted]

Conclusion on the efficacy of the product

Efficacy against target organisms

The biocidal product showed efficacy against tested bacteria species and yeast under the soiling conditions applicable for healthcare area (3 g/L BSA + 3ml/L erythrocytes):

- EN13727:2015 (Phase 2, Step 1) study has demonstrated acceptable efficacy (R > 5 log reduction) against all tested bacterial species with a contact time of 5 minutes;
- EN13624:2013 (Phase 2, Step 1) study has demonstrated acceptable efficacy (R > 4 log reduction) against yeast with a contact time of 15 minutes;
- EN13697:2015 (Phase 2, Step 2) study has demonstrated efficacy against bacterial species (R > 4 log reduction) and yeast (R ≥ 3 log reduction) with a contact time of 5 and 15 minutes, respectively.

As healthcare test conditions are worst case compared to institutional conditions, the product is also considered efficacious in the institutional sector. Although healthcare area application requires that surfaces that come into frequent contact with patients are tested with a maximum contact time of 5 minutes, this is not considered applicable as the product is used for disinfection of the inside of a toilet bowl which is normally not in contact with the patient or the medical staff, as well disinfection is usually performed during the general toilet room cleaning with the restricted enter.

Co-formulants

The biocidal product does not contain the co-formulants which are considered as a potential active substance according to CA-Jan18-Doc.4.2_final "Addressing concerns of co-formulants that contribute significantly to a product's efficacy".

Taking into account the non-variations of the co-formulants presented in biocidal product, it is considered that no bridging studies on impact of the co-formulants on the efficacy of the product are necessary. [redacted]

Contact time
The applicant proposed the following claims:

- 5 minutes contact time for bacteria and
- 15 minutes contact time for yeast.

However, based on the discussions of the Biocidal product Committee Working group on Efficacy (WGII2019, WGIV2019) and outcome of e-consultation *"Contact times for mandatory organisms in healthcare area (PT2) and veterinary area (PT3)"* at WG level in a scope of this application, it was agreed that one contact time for mandatory target organisms in healthcare area should be proposed. Therefore, eCA accepts the following claim:

- 15 minutes contact time for bacteria and yeast.

Decision
eCA considers that data sufficiently support the use of the product against bacteria and yeast on hard non-porous surfaces with a contact time of 15 minutes in dirty conditions.

2.2.5.6 Occurrence of resistance and resistance management

Resistance for lactic acid is not reported. As L(+)-Lactic acid is not specific for one cellular target and it will acidify the cell cytoplasm, interferes with membrane integrity, inhibits the cell functions and enzyme systems and lead to energy depletion, the development of true resistance is not to be expected.

2.2.5.7 Known limitations

No limitations have been observed during the studies on the efficacy against the target organisms.

2.2.5.8 Evaluation of the label claims

The biocidal product based to be used for the inner toilet bowl disinfection by professional users. The evaluation of efficacy demonstrates that the biocidal product meets agreed criteria for reduction of bacteria and yeast population in presence of organic soiling in healthcare and institutional area.

The following label claim can be used: Ready-to-use inner toilet disinfectant for healthcare and institutional area: bactericidal and yeasticidal activity at the contact time of 15 minutes under dirty conditions.

To ensure the efficacy of the product, the following use conditions have to be indicated on the product label:

- Squeeze and apply slowly all around the inside of the bowl, allowing enough liquid to cover the bowl completely.

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

The product is not intended to be used with any other products.

2.2.6 Risk assessment for human health

There are no studies with the biocidal product addressing the effects on human health. Classification of the product is addressed using available data on the individual components of the respective formulation.

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	Corrosive to skin, 1C
Justification for the value/conclusion	Based on the individual components' available data. pH ≤ 2.00.
Classification of the product according to CLP and DSD	H314 - Causes severe skin burns and eye damage

Data waiving	
Information requirement	Annex III of BPR, point 8.1, Skin corrosion or skin irritation
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected*." The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • in the absence of any other information, a mixture is considered corrosive to skin (Skin Corrosion Category 1) if it has a pH ≤ 2; • a mixture is considered corrosive to skin if the sum of all ingredients of a mixture classified as Skin Corrosion is ≥ 5 %. Both criteria are fulfilled. Therefore, the product is classified as Skin Corr. 1C. According to RAC Opinion on L(+)-Lactic acid (CLH-O-0000001412-86-191/F adopted 9 March 2018, Corrigendum 3 December 2019): the supplementary labelling element EUH071 "Corrosive to the respiratory tract" should be used.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damage, 1
Justification for the value/conclusion	H314 is already assigned. pH ≤ 2.00.
Classification of the product according to CLP and DSD	H318 - Causes serious eye damage

Data waiving	
Information requirement	Annex III of BPR, point 8.2, Eye irritation
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected*." The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • in the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2; • a mixture is classified skin corrosive, category 1; • a mixture is considered as Serious Eye Damage if the sum of all ingredients of a mixture classified as Serious Eye Damage is ≥ 3 %. All criteria are fulfilled. Therefore, the product is classified as Eye Dam. 1.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the conclusion	Biocidal product doesn't contain a co-formulants classified as STOT SE 3.
Classification of the product according to CLP and DSD	No classification

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, "other endpoints"
Justification	There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules of the Regulation (EC) No 1272/2008: • a generic concentration limit of 20%. None of the co-formulants is classified with respect to respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitizer
Justification for the value/conclusion	None of the co-formulants classified with H317 is present above the generic concentration limits limit of 1%.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Annex III of BPR, point 8.3, Skin sensitisation
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not*

	expected; the available information indicates that the product should be classified for skin sensitisation or corrosivity; or the substance is a strong acid (pH < 2.0) or base (pH > 11.5)". The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • all sensitising components of a mixture at or above their generic or specific concentration limit should be taken into consideration for the purpose of classification; • the additivity concept is not applicable for skin sensitisation. The biocidal product contains perfume which is classified Skin Sens. 1B. Six co-formulants of perfume's are classified Skin Sens. 1B. Taking into account the content of perfume in the biocidal product and maximal content of co-formulants in perfume themselves, none of the perfume's co-formulants are present at concentrations (≥ 1%) in final biocidal product. As well, the content of perfume's co-formulants in the product is below the concentration limit for elicitation of 0.1%.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to respiratory tract.
Justification for the value/conclusion	Biocidal product doesn't contain a co-formulants classified as respiratory sensitizer.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.4, Respiratory sensitisation
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected"*.

	The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • all sensitising components of a mixture at or above their generic or specific concentration limit should be taken into consideration for the purpose of classification; • the additivity concept is not applicable for respiratory sensitisation. None of the co-formulants is classified with respect to respiratory sensitization.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route
Justification for the selected value	Calculation from the ATE values for all relevant co-formulants according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1, Acute toxicity by oral route
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected*." The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • classification of mixture based on ingredients of the mixture (additivity formula). None of the perfume's ingredients are present above the generic cut-off limit of 1%.

	One co-formulant is classified Acute Tox. 4 (oral) and is present at ≥ 1%. The acute oral toxicity of the product has been determined using the converted acute toxicity point estimate according to the Guidance on the application of the CLP criteria and the calculation method. See Section 3.5.3. of the Confidential annex to PAR for further details. Based on this the product doesn't meet the criteria for classification as acutely toxic via the oral route.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route
Justification for the selected value	Biocidal product doesn't contain a component classified for acute toxicity via inhalation.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2, Acute toxicity by inhalation
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected*." The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • classification of mixture based on ingredients of the mixture (additivity formula). None of the co-formulants is classified with respect to acute inhalation toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route
Justification for the selected value	Biocidal product doesn't contain a component classified for acute toxicity via dermal route.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3, Acute toxicity by dermal route
Justification	According to Annex III of the BPR "*testing on the product/mixture does not need to be conducted if 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected*." The product's exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties is available through the safety data sheets. Classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008: • classification of mixture based on ingredients of the mixture (additivity formula). None of the co-formulants is classified with respect to acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	L(+)-Lactic acid
Value(s)	100%
Justification for the selected value(s)	Default value in the absence of data for the biocidal product containing ≥ 5% a.s. due to skin corrosive properties of the biocidal product.

Data waiving	
Information requirement	Annex III of BPR, point 8.6, Information on dermal absorption
Justification	Default values can be applied. No study needed.

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

The product's composition has been checked for any co-formulants which might qualify as substance of concern (SoC) according to the Guidance on the Biocidal Product Regulation, Volume III Human Health – Assessment & Evaluation (Parts B+C), version 4.0, December 2017.

The following co-formulants are considered as SoCs:

IUPAC name or other accepted chemical name	D-Glucopyranose, oligomers, decyl octyl glycosides
EC number	500-220-1
CAS number	68515-73-1
Classification:	H318

IUPAC name or other accepted chemical name	Alcohols, C8-10 (even numbered), ethoxylated (<2,5-EO)
EC number	615-247-5
CAS number	71060-57-6
Classification:	H318, H302

The above mentioned co-formulants are present in the biocidal product at concentrations sufficient to trigger the classification of the product by themselves (H318/H319) or together with other co-formulants/active substance (H318).

For none of the co-formulants EU OEL value is set.

According to the SoC guidance, a **Band B** assessment needs to be performed for these SoC, i.e. a qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H-statements are sufficient or whether other risk mitigation measures should be applied.

Available toxicological data relating to a mixture

Not required.

Other

No other relevant information.

Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of co-formulants, please refer to the Section 3.5.5. of the Confidential annex to the PAR. Overall, none of the co-formulants are anticipated to have ED potential.

2.2.6.2 Exposure assessment

The biocidal product is intended to be used indoor for inner toilet bowl disinfection by professional uses.

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	Yes	No	No	Negligible	Negligible	No
Dermal	No	Yes	No	No	No	No	No
Oral	No	No	No	No	No	No	No

The Assessment Report for L(+)-Lactic acid in product types 2, 3 and 4 (Germany, June 2017) has been considered for the human health exposure and risk assessment.

The following available guidance documents and models were used:

- Guidance on the Biocidal Product Regulation, Volume III Human Health – Assessment and Evaluation (Parts B+C), version 4.0, December 2017;
- Technical Agreements for Biocides Human Health (version 2.0, November 2018);
- EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873);
- The exposure assessment is based on calculations using models and default values from the Cleaning Products Fact Sheet - Default parameters for estimating consumer exposure, updated version 2018 (RIVM Report 2016-0179), HEAdhoc Recommendations, HEEG opinions. ConsExpo Web is used for a calculation.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application / Pouring	**Primary exposure** The professional user cleans the interior of the toilet bowl by squeezing the bottle under the rim of the toilet bowl and covering the surface of the inside of the bowl. After a leave-on period, the toilet bowl is rinsed. Both dermal and inhalation exposure are considered. Oral exposure is not considered for professionals.	Professionals
2	Post-Application / flushing	**Secondary exposure** Secondary exposure after flushing the toilet is not considered, because it will be negligible	Professionals

		compared to the exposure during the disinfection task.	
3	Post-Application	**Secondary exposure** Inhalation exposure after toilet flushing is negligible. Dermal or oral contact with treated surfaces (inner toilet bowl surface) is not expected.	General public

Industrial exposure

Not relevant. The product is intended for professional users.

Professional exposure

Description of Scenario 1 - PT 2 – Inner surface disinfection of toilet bowl with poured liquid product.

The product is ready-to-use formulation containing 13.2% active substance that does not require mixing/loading actions.

The professional user cleans the inside of the toilet bowl by squeezing the bottle under the rim of the toilet bowl and covering the whole inner surface of the bowl with the product. Application rate is 60 ml (55 g) per one application. After 15 minutes the toilet bowl is rinsed. Toilet bowl is not brushed.

During application of the product, potential exposure may occur via inhalation route or via dermal contact with disinfection solution. However, exposure via inhalation during the task can be considered negligible because of very low potential to volatilization and the lack of aerosol formation. Oral exposure is considered not relevant, as this is unlikely for this type of application and only professional users are envisaged.

Exposure is estimated using ConsExpo Web, which contains a scenario covering the application of acid toilet cleaner for a consumer. Professional users will have a higher frequency of use. Therefore, the default parameters in the model are adjusted to better reflect the worst case. As a worst case, it is considered that the disinfection tasks are performed throughout the day (20 tasks per working day of 8 hours) by the same user. It is expected that the biocidal product is used daily. It is assumed that the user stays in maximum 15 minutes in the toilet room after toilet bowl treatment to perform other cleaning tasks and to rinse the bowl after the disinfection.

	Parameters	Value
Tier 1 (inhalation)	Model	Inhalation – exposure to vapour – evaporation - constant release area mode
	Exposure duration	15 min [1)]
	Product amount	55 g [1)]
	Room volume	2.5 m^3 [2)]
	Ventilation rate	2 per hour [2)]
	Inhalation rate	1.25 m^3/h [3)]
	Release area	0.175 m^2 [2)]
	Application duration	2 min [2)]
	Application temperature	20°C [2)]
	Vapour pressure	0.4 Pa [4)]
	Mass transfer coefficient	10 m/hr [2)]
	Molecular weight matrix	21 g/mol [2)]
	Absorption	100% [5)]
Tier 1 (dermal)	Model	Dermal-direct product contact-constant rate loading
	Exposed area	450 cm^2 [2)]

	Contact rate	193 mg/min [2)]
	Release duration	2 min [2)]
	Body weight (adult)	60 kg [3)]
	Absorption	100% [6)]
Tier 2 (dermal)	Use of gloves	10% (90% reduction) [7)]

1 Applicant value.
2 General Fact Sheet, General default parameters for estimating consumer exposure - Updated version 2018 / Toilet cleaner.
3 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure / Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017).
4 Assessment Report for L(+)-Lactic acid in product types 2, 3 and 4 (Germany, June 2017).
5 Not included in the Assessment Report, but assumed to be 100%.
6 Due to skin corrosive properties of the biocidal product.
7 HEEG opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario 1

ConsExpo input and outputs have been added in Annex 3.1.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake *)**
Scenario 1	1	0.0009 mg/kg bw/day	17 mg/kg bw/day	n.a.	17 mg/kg bw/day
	2 / gloves	0.0009 mg/kg bw/day	1.7 mg/kg bw/day	n.a.	1.7 mg/kg bw/day

*) systemic exposure values are rounded.

Further information and considerations on Scenario 1

The biocidal product is classified H314 (Causes severe skin burns and eye damage). When the product is poured from its original packaging that is designed for cleaning toilet bowls (section 3.5.7.1 of the Confidential annex to PAR), the direct contact with skin and eyes are not expected. In addition, the instruction of use includes general recommendation "*Avoid contact with eyes and skin*". As well, according to CLP regulation *P280 Wear protective gloves* statement is obligatory. With the proposed protection measures the reduction of dermal and eye contact minimizes the anticipated health risks to an acceptable level. Concerning corrosive properties in the respiratory tract, the eCA assesses inhalation exposure to be marginal so that no adverse effects are expected. No additional measures are need.

Combined scenarios

Only one scenario is presented. Combined scenario consideration is not relevant.

Non-professional exposure

The product is not intended for non-professional use.

Exposure of the general public

Once the toilet bowl is flushed, the 'source' of L(+)-Lactic acid is removed. Therefore, the L(+)-Lactic acid air concentration post application to be of a lower magnitude than the L(+)-Lactic acid air concentration during application. No further calculations are required. Dermal and oral contact with treated surface (inner toilet bowl surface) is not expected.

Monitoring data

No monitoring data are available.

Dietary exposure

Exposure via the diet is not expected for the proposed use of biocidal product in toilet room.

Information of non-biocidal use of the active substance

L(+)-Lactic acid has been approved in the EU as a food additive without an ADI or upper limit (*quantum satis*; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The use of product is intended to be carried out indoor and not in areas associated with the production, processing or storage of animal feed items. Furthermore, no direct application of product to livestock as anticipated.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

The product is not intended for disinfection of hard surfaces in food and feed areas.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

The product is not intended for non-professional users, as well for disinfection of hard surfaces in food and feed areas.

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

The product is supplied as ready-to-use formulated product. Once the formulated product has been used up, the empty container is disposed according to national legislation.

Aggregated exposure

The guidance is still under development.

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/d *)**
1.	Professional	1 / None	17
		2 / gloves	1.7

*) systemic exposure values are rounded.

2.2.6.3. Risk characterisation for human health

According to BPC opinion on L(+)-Lactic acid Product type 2, 2017 "*L(+)-Lactic acid is an endogenous alpha-hydroxy acid of generally low toxicity. Due to its acidity it is, however, considered to be a skin irritant and causing serious eye damage. Due to the very low systemic toxicity of L(+)-Lactic acid, the derivation of a systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD has been set. Likewise, L(+)-Lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)*."

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Not allocated				
$AEL_{medium\text{-}term}$					
$AEL_{long\text{-}term}$					
ARfD					
ADI					
NOAEC, dermal-acute, medium term, long term	Derived from rabbit irritation/corrosion studies: 88% and 50 % L(+) lactic acid were corrosive in rabbits (88	Not relevant			10%

	% were irritant in human patch tests); 10 % were non-irritant in rabbits and guinea pigs.		
Endogenous production	-	Not relevant	>100 g/person/day equivalent to > 1667 mg/kg bw/day *)
Food intake	-	Not relevant	>1 g/person/day equivalent to > 16.7 mg/kg bw/day *)

*) systemic exposure values will be compared with the endogenous production and food intake.

Maximum residue limits or equivalent

MRL is not required for L(+)-Lactic acid.

Specific reference value for groundwater

No specific reference value for groundwater was established. Therefore, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) applies.

Risk for industrial users

No use for industrial users.

Risk for professional users

The risk assessment is based on primary exposure of professional user. Secondary exposure will be negligible compared to the exposure during the disinfection task.

Systemic effects

The exposure data are given above. At the same time the estimated inhalation uptake and the estimated dermal uptake are added to result in the total internal body burden.

Because of very low systemic toxicity of L(+)-Lactic acid, derivation of any systemic toxicological reference dose was regarded not necessary, however, the exposure estimates are compared with endogenous production of L(+)-Lactic acid to carry out the risk characterisation for systemic effects. If the total internal body burden is lower than the reference dose (endogenous production or food intake), health risks leading to concern are not anticipated.

Task/ Scenario	Tier	Estimated total uptake, mg/kg bw/d	Endog. Production, mg/kg bw/d	Estimated total uptake/ Food intake, %	Acceptable (yes/no)
1	1	**17**	**> 1667**	**< 1.01**	**Yes**
	2	**1.7**	**> 1667**	**< 0.101**	**Yes**

Primary systemic exposure to this active substance is estimated to be clearly below endogenous production. Thus, it is concluded that exposure to L(+)-Lactic acid by professional use (considering the worst case of application) is acceptable. Secondary exposure after flushing the toilet is not considered, because it will be negligible compared to the exposure during the disinfection task.

Combined scenarios

Not applicable.

Local effects

The product is a ready-to-use liquid, so no mixing and loading step is involved. Exposure is only possible during the application step (disinfection and rinsing). Post-application exposure isn't relevant as the toilet bowl is flushed after the disinfection step.

The product warrants classification with respect to local effects on skin and eyes (H314 and H318, as well EUH071). According to Guidance on the Biocidal Product Regulation, Volume III Human Health – Assessment and Evaluation (Parts B+C), version 4.0, December 2017 a qualitative local risk assessment is triggered.

Hazards		Exposure				Risk
Hazard category	Classification assigned to the biocidal product	Task	Potential exposure	Frequency	Relevant RMM & PPE	Conclusion
High	H314 H318 EUH071	pouring	Skin	Daily, several times a day	**Product characteristics** - labelling according to CLP; - clear use description. **RMM:** - Do not breathe vapours.	**Acceptable** since: - packaging eliminating exposure; - low vapour pressure; - professionals using appropriate PPE; - proper instructions for use;

					- Avoid contact with eyes and skin. - Do not brush the product in toilet bowl. - Wash hand thoroughly after handling. **Packaging:** - specially constructed bottle excluding possibility for spillage or splashing. **PPE:** - Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).	- labelling according to CLP.

Dermal exposure to 13.2 % L(+)-Lactic acid in the product might result in skin corrosion and eye damage. However, the product is applied directly from the product container by squeezing the bottle equipped with a nozzle and directing the application under the rim of the toilet bowl. Toilet bowl is not brushed.
The contact with skin is minimised and contact with eye is excluded considering the following proposed protection measures:

- packaging design,
- PPE and
- RMMs: "Do not breathe vapours", "Avoid contact with eyes and skin", "Do not brush the product in toilet bowl", "Wash hand thoroughly after handling".

Concerning local respiratory effects due to properties of L(+)-Lactic acid, inhalation respiratory exposure is assessed to be marginal so that no adverse effects are expected.

Conclusion

According to the generally low toxicity of L(+)-Lactic acid, systemic effects after the handling and use of the active substance L(+)-Lactic acid are not expected for professionals.

Concerning the corrosive properties of L(+)-Lactic acid, exposure to the 13.2 % L(+)-Lactic acid during application phase should be minimized with protection measures (packaging

design, PPE). If the proposed safety protection measures are implemented, handling and use of the biocidal product does not lead to concern for professional users.

Risk for non-professional users

No use for non-professionals users.

Risk for the general public

Risk for general public is not expected.

Risk for consumers via residues in food

The product is not intended for disinfection of hard surfaces in food and feed areas.

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

Not applicable.

2.2.7. Risk assessment for animal health

No direct treatment of animals or indirect exposure of animals via feed, air or dinking water are anticipated.

2.2.8. Risk assessment for the environment

The biocidal product is intended to be used indoor for inner toilet bowl disinfection by professional uses.

All core data for L(+)-Lactic acid is addressed in the Assessment report (AR)[8], for which the Applicant has Letter of Access. There are valid available data on each of the components and synergistic effects between them are not expected. All components of the biocidal product do not meet neither criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, nor the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006. Furthermore, no substances of concern for environment have been identified and there are no indications of risk due to specific properties of the biocidal product. Consequently environmental risk assessment have been performed based on data that were agreed during the approval of the active substance L(+)-Lactic acid.

However a new study according to OECD TG 301B on ready biodegradability of L(+)-Lactic acid has been conducted and taking into account in the sections below.

8 Assessment report L(+)-Lactic acid, product type 2, 3 and 4, June 2017 (Germany)

The following available guidance documents and models were used:

- Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and Evaluation (Parts B+C), version 2.0, October 2017 (BPR, Vol. IV);
- Technical guidance document on risk assessment, Part II, 2003 (TGD)
- Emission Scenario Document for PT 2 (RIVM, 2001);
- Emission Scenario Document for PT 2 (JRC, 2011);
- Technical Agreements for Biocides Environment, version 2.0, August 2018 (TAB, ENV);
- EUSES 2.2.0;
- FOCUS Pearl 4.4.4.

2.2.8.1. Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No studies for biocidal product have been conducted. According to point 9.1 of Annex III to the BPR, classification of the biocidal product was done according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). The components classified as environmentally hazardous or that meets the criteria for classification as environmentally hazardous according to Regulation (EC) No 1272/2008, is well below concentration limit to lead the biocidal product to be regarded as environmentally hazardous within the meaning of this Regulation. Consequently, the biocidal product Ecolab UA Lactic acid single product dossier does not meet criteria for classification as hazardous for environment. Full composition of the biocidal product is available in Section 3.5.1 of the Confidential Annex to PAR.

The effect assessment of the biocidal product on the environment is conducted based on a data presented in the AR for L(+)-Lactic acid (June 2017).

According to AR only studies on the acute toxicity of L(+)-Lactic acid for aquatic organisms are available. Algae *(S. capricornutum)* were identified as most sensitive organisms with E_rC_{50} of 3.9 g/L for the inhibition of algal growth. Thus, the **$PNEC_{water}$ of 3.9 mg/L** was derived by applying an assessment factor of 1000 according to TGD on risk assessment.

Studies on sediment dwelling organisms are not available, therefore a **$PNEC_{sediment}$ of 4.8 mg a.s./kg** ww was derived by using equilibrium partitioning method according to TGD on risk assessment.

In an activated sludge respiration inhibition test the NOEC was assessed to be ≥ 100 mg a.s./L (nominal), the EC_{50} >100 mg a.s./L (nominal). As a worst case NOEC of 100 mg a.s./L with an assessment factor of 10 according to TGD on risk assessment was used. The **$PNEC_{STP}$ of 10 mg a.s./L** was derived.

Since direct exposure of the b. p. to the terrestrial compartment and adsorption of the a.s. occur to soil is not expected, the provision of experimentally derived data on the toxicity of the L(+)-Lactic acid to terrestrial organisms is not required. Instead the **$PNEC_{soil}$ of 1.9 mg**

a.s./kg ww was determined by applying equilibrium partitioning method according to TGD on risk assessment.

Available data indicate that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+)-Lactic acid to the atmosphere are unlikely to occur. Consequently, a risk assessment for air compartment is not necessary.

The PNECs for L(+)-Lactic acid are following:

Compartment	PNEC	
water	3.9	mg/L
sediment	4.8	mg/kg_{ww}
STP	10	mg/L
Soil	1.9	mg/kg_{ww}

Experimentally derived data on the bioaccumulation potential of the L(+)-Lactic acid are not available neither for the aquatic nor the terrestrial compartment, respectively. Hence, the bioconcentration factors (BCF) for the aquatic compartment (BCF_{fish} = 0.048 L/kg) and the terrestrial compartment ($BCF_{earthworm}$ = 6.78 L/kg) were assessed on the basis of the log KOW of -0.74 according to the standard equations given in the TGD on Risk Assessment (EU, 2003) / BPR guidance (Volume IV, parts B+C, 2017). Since both BCFs as well as other indicators (e.g. surface tension) indicate a low bioaccumulation potential of the L(+)-Lactic acid in the environment, experimental studies are not required.

Further Ecotoxicological studies

Data waiving	
Information requirement	Not required.
Justification	Sufficient data on the active substance is available to perform an environmental risk assessment. No relevant components such as substances of concerns or substances with synergistic effects have been identified. Therefore, no further ecological studies for the biocidal product are required.

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

Data waiving	
Information requirement	Not required.
Justification	According to the Guidance on the Biocidal Products Regulation, Volume IV Environment – Information Requirements (Part A), version 1.2, May 2018, data may be required for non-target organisms other than fish, microalgae and invertebrates if concerns are raised from the uses and emissions of the active substance, effects detected on other aquatic species, or a preliminary risk assessment. This may involve tests on sediment dwelling organisms

	and aquatic macrophytes, accumulation and elimination in shellfish, or tests with additional brackish or marine organisms. No additional test on other specific, non-target organisms is needed on the basis of intended uses. As well, a sufficient data on the active substance is available to perform an environmental risk assessment.

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

Data waiving	
Information requirement	Not required.
Justification	Not relevant for this biocidal product which is used indoor only and is not bait or granules.

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

Data waiving	
Information requirement	Not required.
Justification	Not relevant for this biocidal product which is used indoor only and is not bait or granules.

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

According to the Guidance on the Biocidal Products Regulation, Volume IV Environment – Information Requirements (Part A), version 1.2, May 2018, as a refinement higher tier field studies (soil and/or water-sediment compartment) may be required to identify secondary ecological effects when a habitat such as a water body, wetland, forest or field is treated.
The intended use does not cause any unacceptable risk to the environment. Therefore, an additional testing to evaluate possible effects at species, population or community and ecosystem level is not necessary.

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

The biocidal product containing L(+)-Lactic acid is used indoor for inner toilet bowl disinfection. The relevant release will occur via the Sewage Treatment Plant (STP) and the application of sewage sludge to agricultural areas. Indirect releases to surface water and sediment have to be considered according to emission pathway.

According to the ESD for PT 2 (RIVM, 2001) no exposure of the compartment air is foreseen and under consideration of the intrinsic properties of L(+)-Lactic acid it is scientifically justifiable that the exposure of the air compartment is assumed as negligible.

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

According AR of L(+)-Lactic acid (2017) degradation after 20 days was 60 and 67% at concentrations of 2 and 4 mg/l, respectively. However, the level of degradation within 10 days cannot be assessed. Therefore L(+) lactic acid were classified as readily biodegradable but failing 10-days window criterion. However additional information obtained via a literature search shows that the current assessment of the biodegradation behaviour of the of L(+)-Lactic acid in soil (default degradation half-live of 90-days) is overly conservative. Therefore for the product authorisation, new study on the ready biodegradability with appropriate test design in order to address the 10-day window of L(+)-Lactic acid was submitted by the applicant. The new study (done according OECD 301B, GLP) was considered to be valid, all criteria for acceptability of the test were met. Furthermore, average biodegradation of L(+)-Lactic Acid in vessel A and B reached ≥60% within a 10-day window.

Summary table on further studies on fate and behaviour in the environment							
Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentra-tion, C_0[mg/l]	Biodegradation, %	Re-marks	Reference
Determination of Ready Biodegradability: carbon dioxide (CO_2) Evolution test (Modified Sturm test), OECD TG 301B, GLP	Aerobic aqueous medium	7.6 – 7.8	22 - 23	37.5	Vessel A - 75 % (after 28 days) Vessel B - 76 % (after 28) Vessels A and B ≥ 60% at 10-days window	The validity criteria were met	Test facility study No. 20194906

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	The biodegradation of L(+)-Lactic Acid reached ≥60% within a 10-day window.
Justification for the value/conclusion	For the product authorisation a new study on the ready biodegradability according to OECD 301B with appropriate test design in order to address the 10-day window of L(+)-Lactic acid was submitted by the Applicant.

Leaching behaviour (ADS)

Not relevant for this product.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Not required.
Justification	No additional test on distribution and dissipation in the soil is needed on the basis of intended uses and available data on the L(+)-Lactic

	acid. Therefore, distribution and dissipation in soil is expected to be the same as for the active substance. A new ready biodegradability study demonstrating that L(+)-Lactic acid passes the 10-day window. This allows the use of a default DT_{50} of 30 days in soil for use in risk assessment.

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

Data waiving	
Information requirement	Not required.
Justification	No additional test on distribution and dissipation in water and sediment is needed on the basis of intended uses and available data on the L(+)-Lactic acid. Therefore, distribution and dissipation in water and sediment is expected to be the same as for the active substance. A new ready biodegradability study demonstrating that L(+)-Lactic acid is ready biodegradable and passes the 10-day window. This allows the use of a default DT_{50} of 15 days in water and sediment for use in risk assessment.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Not required.
Justification	Information on distribution and degradation for the active substance present in the biocidal product is sufficient.

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)

Data waiving	
Information requirement	Not required.
Justification	Product isn't used to be sprayed near surface water.

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)

Data waiving	
Information requirement	Not required.
Justification	Product isn't used to be sprayed outside.

2.2.8.2. Exposure assessment

The biocidal product to be used indoor for the inner toilet bowl disinfection by professionals. The content of L(+)-Lactic acid is 13.2% w/w (as pure).

For the environmental exposure assessment of the biocidal product the following life cycle stages are relevant:

- formulation of the biocidal product and
- professional use of the biocidal product as ready-to-use solution for toilet bowl disinfection.

However, in accordance with the Biocidal Products Regulation (Regulation (EU) 528/2012) the environmental release estimations and the PECs for the life cycle stage "formulation" was not taken into account for the environmental risk assessment.

Biocidal product is applied indoor and so exposure of the environmental compartments surface water and sediment will occur via the STP. The environmental compartments soil and groundwater may be affected by the field application of sewage sludge. According to the ESD for PT 2 (RIVM, 2001) no exposure of the atmosphere is foreseen and under the consideration of the intrinsic properties of L(+)-Lactic acid it is scientifically justifiable that the exposure of the air could be assumed as negligible.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Disinfection of the inner toilet bowl surface
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), RIVM, 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC, 2011
Approach	In the Emission Scenario Document for Product Type 2 (RIVM, 2001), two emission scenarios for disinfectants used in the sanitary sector are presented: (1) based on tonnage and (2) based on consumption. Based on the calculation of the break-even point the most suitable scenario should be used, which is the consumption-based approach for this product.
Distribution in the environment	Calculated based on TGD 2003 / Guidance BPR IV ENV B+C (2017)
Groundwater simulation	FOCUS Pearl model was used for higher tier groundwater simulation.

Confidential Annexes	Yes
Life cycle steps assessed	Scenario n: 1 Production: No Formulation: No Use: Yes Service life: Not applicable
Remarks	-

Emission estimation

The emissions can be calculated based on a tonnage or on the specific consumption. For completeness, both the emissions are detailed below according to the EU Workshop PT 1-6 Report (European Commission – Directorate General Environment, 2008). For the environmental exposure and risk assessment the worst-case emissions estimation is chosen to be relevant.

Tonnage based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas based on tonnage is described in Chapter 2.2 of the ESD for PT2 (RIVM, 2001). The resulting local emission of L(+)-Lactic acid to the wastewater from the application of a product is given in the Section 3.5.7.2 of the Confidential annex to PAR.

Consumption based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas based on tonnage is described in Chapter 2.2 of the ESD for PT2 (RIVM, 2001). As a worst case it can be assumed that disinfection takes place during all days. The default consumption per capita of the biocidal product for lavatory is 2 ml/d. The resulting local emission of L(+)-Lactic acid to the wastewater from the application of a product is given below.

Emission scenario for toilet bowl disinfection in institutional areas (professional users) (Chapter 2.2 of the ESD for PT2, RIVM, 2001)				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Number of inhabitants feeding one STP	N_{local}	10000	-	Default
Fraction released to wastewater	$F_{4,\ water}$	1	-	Default
Active substance in product	$C_{product}$	0.132	kg L^{-1}	Based on 13.2% content
Consumption per capita	$Q_{product}$	0.002	L cap^{-1} d^{-1}	Lavatory use
Penetration factor of disinfectant	F_{penetr}	0.5	-	
$E_{local_{4,water}} = N_{local} \cdot Q_{product} \cdot C_{product} \cdot F_{penetr} \cdot F_{4,water}$				
Emissions rate to wastewater	$E_{local_{4,water}}$	**1.32**	kg d^{-1}	

Break-even point

Based on the local emission from the consumption approach a regional tonnage equivalent can be calculated.

Calculation of the break-even point (Chapter 2.2 of the ESD for PT2, RIVM, 2001)				
Input	**Symbol**	**Value**	**Unit**	**Remarks**

Number of inhabitants feeding one STP	N_{local}	10000	-	Default
Active substance in product	$C_{product}$	0.132	kg L^{-1}	Based on 13.2% content
Consumption per capita	$Q_{product}$	0.002	L cap^{-1} d^{-1}	Lavatory use
Penetration factor of disinfectant	F_{penetr}	0.5	-	Default
Fraction of the main source (STP)	$F_{mainsource}$	0.002	-	Default
Number of emission days for life cycle stage 4 (private uses)	$T_{emission}$	365	d yr^{-1}	Default
$TONNAGEreg = (N_{local} \cdot Q_{product} \cdot C_{product} \cdot F_{penetr} \cdot T_{emission}) / (1\ 000 \cdot F_{mainsource})$				
Break-even point tonnage	TONNAGEreg	**240.9**	Tonnes yr^{-1}	

The break-even point is 240.9 t/y. Since this is more than the regional tonnage the consumption approach represents the worst-case situation. Therefore, for the environmental exposure and risk assessment the emission based on consumption is used.

Fate and distribution in exposed environmental compartments

The application of the biocidal product for toilet bowl disinfection results in exposure of the environmental compartments surface water and sediment via the Sewage Treatment Plant (STP). The environmental compartments soil and groundwater may be affected by the field application of sewage sludge. The exposure of the air compartment is assumed as negligible.

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 1	yes	yes	n.r.	n.r.	yes	negligible	yes	yes	n.r.

*n.r. – not relevant

From the structural formula of L(+)-Lactic acid it is clear that only hydrolysable group is present – the acid group. For the hydrolysis of the acid group, the dissociation constant (pK_a) of 3.86 should be taken into account. L(+)-Lactic acid cannot undergo direct photolysis in sunlight. Tropospherical half-life of L(+)-Lactic acid is 2.71 days. The Henry's law constant of $3.6 \cdot 10^{-5}$ Pa × m^3/mol at 20°C indicates low volatility from water. According to AR for L(+)-Lactic acid (June 2017) K_{OC} < 20.9 L/kg was estimated. However, a rounded value of KOC 20 L/kg can be used for environmental exposures calculations.

According to AR, 2017 L(+)-Lactic acid is considered to be readily biodegradable, but failing the 10-days window criterion. Therefore, according to the TGD on Risk Assessment further calculations for STP are performed with a rate constant of 0.3 h^{-1} and the half-life of L(+)-Lactic acid in soil was set 90 days.

However, within application for authorisation Applicant has provided a new study on the ready biodegradability according to OECD 301B with appropriate test design in order to address the 10-day window of L(+)-Lactic acid. LV CA accepted the submitted study and agreed to use a rate constant of 1.0 h-1 for STP and the half-life of L(+)-Lactic acid in soil 30 days according to the TGD on Risk Assessment (EU, 2003) / BPR guidance (Volume IV, parts B+C, 2017) for further environmental exposures calculations.

The input parameters used in risk assessment are listed in below:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	90.08	g mol^{-1}	AR, 2017 [9]
Melting point	53	°C	AR, 2017
Boiling point	204.2	°C	AR, 2017
Vapour pressure (at 20°C)	0.4	Pa	AR, 2017
Water solubility (at 20°C)	1000000	mg L^{-1}	AR, 2017
Log Octanol/water partition coefficient	-0.74	Log 10	AR, 2017
Organic carbon/water partition coefficient (K_{oc})	20	l/kg	AR, 2017
Henry's Law Constant	3.6 x 10^{-5}	$Pa/m^3/mol$	AR, 2017
Biodegradability	Ready biodegradable		Test facility study No. 20194906
DT_{50} for degradation in soil	30	days	Default based on ready biodegradability Section 2.3.6.5 of the Guidance on the BPR - Volume IV Environment[10]
Rate constant for STP	1	h^{-1}	Default based on ready biodegradability Section 2.3.6.4 of the Guidance on the BPR - Volume IV Environment
DT_{50} for degradation in air	2.71	days	AR, 2017

The distribution in the sewage treatment plants (STP) is calculated using Simple treat 4.0 version which is integrated in EUSES 2.2.0 version according to the TAB-ENV (Version 2, 2018) ENV #9. These results are present below:

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	8.26 x 10^{-6}	Calculated with EUSES 2.2.0
Water	8.00	
Sludge	0.27	
Degraded in STP	91.73	

Calculated PEC values

An overview of the predicted environmental concentrations of L(+)-Lactic acid of STP microorganisms, in surface water, sediment, soil and groundwater resulting from the application of biocidal product as toilet bowl disinfectant based on consumption approach is given below. Exposure of the groundwater occurs through the emissions of L(+)-Lactic acid via leaching from soil after the application of sewage sludge on agricultural land. The estimated concentration in the groundwater is defined by the concentration of L(+)-Lactic acid in pore water of agricultural soil. This is a conservative approach. As is stated in AR, 2017

[9] Assessment report L(+)-Lactic acid, product type 2, 3 and 4, June 2017 (Germany)

[10] Guidance on the BPR - Volume IV Environment – Assessment and Evaluation (Parts B + C), Version 2.0

the exposure of the atmosphere could be assumed as negligible (Henry's law constant indicates low volatility from water).

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Scenario 1	5.3×10^{-2}	5.28×10^{-3}	6.43×10^{-3}	4.42×10^{-3}	2.86×10^{-3}

Primary and secondary poisoning

Primary poisoning

The proposed uses of the biocidal product will not result indirect exposures to birds and mammals, as product is only used indoors.

Secondary poisoning

As indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg), the bioaccumulation potential of L(+)-Lactic acid and thus the risk of secondary poisoning is considered to be low.

2.2.8.3. Risk characterisation

The PNECs for L(+)-Lactic acid are presented in Section 2.2.8.1.

Atmosphere

Conclusion: Based on the low vapour pressures of L(+)-Lactic acid and correspondingly low Henry's law constant it can be assumed that exposure to the air compartment can be considered to be negligible.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	5.3×10^{-3}

Conclusion: The $PEC_{STP}/PNEC_{STP}$ ratio is < 1. The risk to microorganisms in sewage treatment plant is considered acceptable. Moreover, there are numerous natural resources L(+)-Lactic acid including human excretion (via urine and faeces). It may therefore be expected that microorganisms in the STP are adapted to relatively high loads of L(+)-Lactic acid and therefore the removal in the STP is highly effective. The concentrations of L(+)-Lactic acid in the STP's effluent are expected to be negligible. In view of this, a low risk for aquatic organisms, sediment organisms and micro-organisms in the STP is expected.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**

Scenario 1	1.35×10^{-3}	1.34×10^{-3}

Conclusion: The PEC and PNEC ratios are < 1. It indicated that the risk to the aquatic compartment and sediment can be considered to be acceptable. As emission of this biocidal product is via the STP the marine compartment has not been considered to be relevant and has not been assessed.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	2.32×10^{-3}

Conclusion: The PEC/PNEC ratio for soil remains well below the trigger value of 1, indicating no risk for the soil.

Groundwater

At the WGII2020[11] it was decided that Lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed, based on the following justification *"Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+)-Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD^+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic."*

Nevertheless, the Applicant has provided an assessment for the groundwater compartment according to a tiered approach:

- *Tier 1* – compare the PEC_{GW} obtained via EUSES 2.2.0 to the threshold value 0.1 µg/L for drinking water (Directive 98/83/EC);
- *Tier 2* – compare the refined PEC_{GW} obtained via model FOCUS PEARL to the threshold value 0.1 µg/L for drinking water (Directive 98/83/EC).

Tier 1

Comparison of PEC_{GW} to threshold value for drinking water

[11] Working Group - Environment

Scenario 1	2.86 x 10^{-3} mg/L (2.86 µg/L)	0.1 µg/L

The concentration in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 98/83/EC for drinking water (0.1 µg/L). Tier 1 assessment does not allow to conclude on an acceptable risk.

Tier 2

The groundwater assessment was refined at a second tier with the FOCUS PEARL model, which considers potential mobility of L(+)-Lactic acid in soils and the leaching behaviour to groundwater. The input parameters used for this refinement are the following:

Input parameters for calculating L(+)-Lactic acid concentrations in groundwater using FOCUS PEARL model			
Input	Value	Unit	Remarks
Molar mass	90.08	g mol^{-1}	AR, 2017[12]
Solubility in water (at test temperature)	1000 000 (at 20°C)	mg L^{-1}	AR, 2017
Molar enthalpy of dissolution	27	kJ mol^{-1}	TAB, 2018[13]
Saturated vapour pressure	0.4 (at 20°C)	Pa	AR, 2017
Molar enthalpy of vaporisation	95	kJ mol^{-1}	TAB, 2018
Reference temperature for diffusion	20	°C	TAB, 2018
Diffusion coefficient in water	4.3 x 10^{-5}	m^2 d^{-1}	TAB, 2018
Diffusion coefficient in air	0.43	m^2 d^{-1}	TAB, 2018
Sorption to soil organic carbon (K_{om})	11.6 (at 20°C)	L kg^{-1}	AR, 2017 K_{oc} = 20 L/kg K_{om} = K_{oc} / 1.724
Molar enthalpy of sorption	0	kJ mol^{-1}	Default value of FOCUS PEARL
Freundlich sorption exponent	0.9	-	TAB, 2018
DT_{50} (12°C)	30	days	Default based on ready biodegradability
Plant uptake factor	0		TAB, 2018
Molar activation energy	54	kJ mol^{-1}	TAB, 2018

In accordance with TAB, 2018 both grassland (alfalfa) and agricultural land (maize) should be modelled in FOCUS PEARL.
In case of grassland one sewage sludge application with a dosage of 0.00451 kg.ha^{-1} per year on 1st of March (absolute application) and 10 cm incorporation depth was considered. In case of agricultural land one sewage sludge application with a dosage of 0.02255 kg.ha^{-1} per year to maize 20 days before crop event "emergence" (relative application) and 20 cm incorporation depth was considered. The application rates have been calculated taking the following into account:

$$Application\ rate = App_{sewage\_sludge} \times C_{sludge} \times 10^{-6}$$

$$C_{sludge} = (Fstp_{sludge} \times Elocal_{water} \times 10^{6})/SLUDGERATE$$

$$SLUDGERATE = (2/3) \times SUSPCONC_{inf} \times Effluent_{stp} + SURPLUS_{sludge} \times CAPACITY_{stp}$$

[12] Assessment report L(+)-Lactic acid, product type 2, 3 and 4, June 2017 (Germany)
[13] Technical Agreements for Biocides Environment (ENV), Version 2.0, August 2018

$$Effluent_{stp} = CAPACITY_{stp} \times Wastew_{inhab}$$

Input parameters for calculating of application rate			
Variable	Value	Unit	Reference
$App_{sewage\_sludge\_grass}$	1000	kg ha^{-1}	TAB, 2018
$App_{sewage\_sludge\_agr}$	5000	kg ha^{-1}	TAB, 2018
$Fstp_{sludge}$	0.0027	-	See calculated fate and distribution in STP with EUSES 2.2.0
$Elocal_{water}$	1.32	kg d^{-1}	Emission based on consumption approach
$SUSPCONC_{inf}$	0.45	kg m^{-3}	BPR guidance, Vol IV[14]
$SURPLUS_{sludge}$	0.019	kg d^{-1} eq^{-1}	BPR guidance, Vol IV
$CAPACITY_{stp}$	10 000	eq	BPR guidance, Vol IV
$Wastew_{inhab}$	200	L d^{-1} eq^{-1}	BPR guidance, Vol IV

The detailed results of the FOCUS PEARL calculations are presented in Annex 3.1. The average results of the PEC_{GW} refinement with the simulation model FOCUS PEARL are summarised below:

FOCUS PEARL modelled values (80th percentile annual average concentrations) for L(+)-Lactic acid via the application of sewage sludge		
Scenario	**Arable land [µg/L]**	**Grassland [µg/L]**
Châteaudun	0.0294	0.0019
Hamburg	0.0902	0.0050
Jokioinen	Not relevant	0.0030
Kremsmuenster	0.0535	0.0027
Okehampton	0.0964	0.0056
Piacenza	0.0325	0.0056
Porto	0.0056	0.0014
Sevilla	0.00037	0.00021
Thiva	0.0108	0.00023

It should be noted that maize isn't grown in Jokioinen (see table 1.3 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014). Therefore only 8 scenarios are simulated.

It is demonstrated that for all grassland scenarios and for all arable land scenarios the average concentration of L(+)-Lactic acid closest to the 80th percentile is below the trigger value of 0.1 µg/L. Therefore, the risk for the groundwater compartment is acceptable and there is no additional risk for the environment by the use of the product under evaluation as an toilet bowl disinfectant.

Primary and secondary poisoning

Primary poisoning

[14] Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and Evaluation (Parts B + C), version 2.0

The biocidal product is used be professional users indoor in line with the recommendations. Therefore, primary poisoning of non-target animals can be assumed as highly unlikely.

Secondary poisoning

As indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg) as well as by the surface tension (70.7 mN/m), the bioaccumulation potential of L(+)-Lactic acid and thus the risk of secondary poisoning is considered to be low.

Conclusion: The risk of primary or secondary poisoning can be considered as negligible.

Mixture toxicity

The product contains no substances of concern for the environment. For further detailed information, please refer to section 3.5.7.2 of the Confidential annex to PAR.

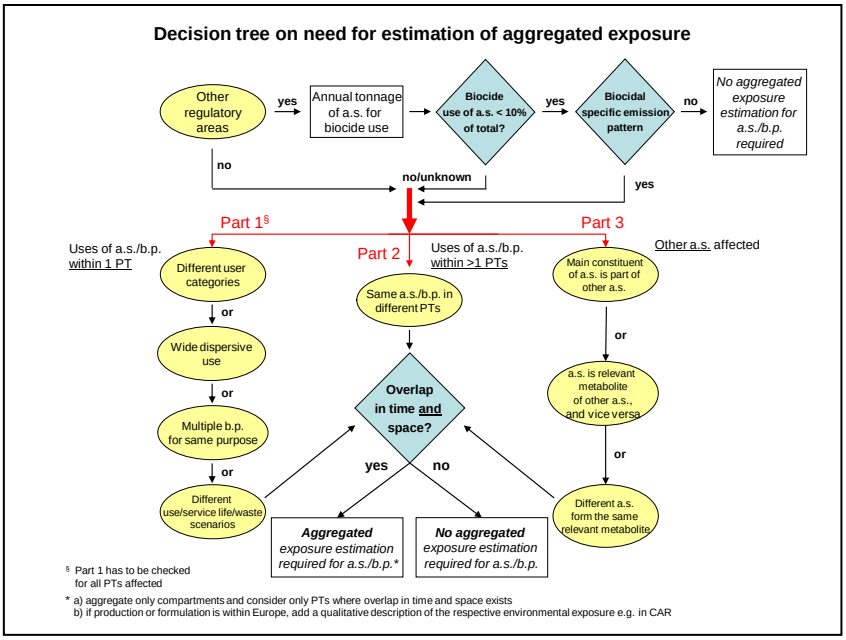
Conclusion: An assessment of mixture toxicity is not required since none of the non-active components are classified for ecotoxic effects and are not expected to enhance the toxicity of the active substance.

Aggregated exposure (combined for relevant emission sources)

The discussions regarding the necessity of the aggregated exposure for L(+)-Lactic acid were already included in the AR, 2017 (Germany). L(+)-Lactic acid is approved for use in biocidal products in PT 1, 2, 3, 4 and notified for PT 6. The intended uses under the mentioned PTs can lead to an overlap in time and space in different environmental compartments. However, L(+)-Lactic acid is also regulated in other regulatory areas:

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference**
1.	Veterinary use	Veterinary medicinal product	EMA Committee for veterinary medicinal products, Lactic acid, summary report, 1996 *No MRL set*
3.	Food additive	Lactic acid is an approved food additive (E270)	Commission Implementing Regulation (EC) No 1333/2008 of 16 December 2008 on food additives *No ADI or upper limit*
4.	Feed additive	Lactic acid is an approved feed additive	Commission Implementing Regulation (EU) 2017/56 of 14 December 2016 concerning the authorisation of lactic acid […] as feed additives for all animal species *Recommended maximum content of the active substance: 5 mg/kg of complete feedings tuff with a moisture content of 12%*

The amount of L(+)-Lactic acid that is used annually for biocidal purposes is less than 10% of the total production and import volume in the EU.



Decision tree on the need for estimation of aggregated exposure

Therefore, according to the "Decision tree on the need for estimation of aggregated exposure" the intended use does not represent a specific emission pattern. No aggregated exposure assessment has to be performed.

Overall conclusion on the risk assessment for the environment of the product
The biocidal product to be used indoor for the inner toilet bowl disinfection by professionals. The content of L(+)-Lactic acid is 13.2% w/w (as pure). A new ready biodegradation study has been carried out to show that L(+)-Lactic acid passes the 10-day window, so a DT_{50} of 30 days in soil can be applied for risk assessment. The resulting PEC/PNEC ratios confirm that no unacceptable risk is identified. In regards to groundwater, a higher Tier modelling with Focus Pearl was required, as PEC at Tier 1 exceed the threshold value of 0.1 µg/l. Further refinement of groundwater levels using Focus Pearl has shown that all scenarios give the acceptable levels of L(+)-Lactic acid in groundwater. Therefore, it can be concluded that the use of the biocidal product does not cause any unacceptable risk to the environment.

2.2.9. Measures to protect man, animals and the environment

Please see section 2.1.4 of this PAR and the SPC for information.

2.2.10. Assessment of a combination of biocidal products

The biocidal product is not intended to be used in combination with other biocidal products.

2.2.11. Comparative assessment

Not relevant

3. Annexes

3.1. Output tables from exposure assessment tools

Input - output parameters / ConsExpo / Exposure assessment / Primary exposure / Tier 1

[redacted]

Input - output parameters / EUSES 2.2.0 / Consumption based approach / Calculated fate and distribution in the STP / Calculated PEC values

[redacted]

Output parameters for calculating L(+)-lactic acid concentrations in groundwater using FOCUS PEARL MODEL

[redacted]

3.2. New information on the active substance

Not applicable

3.3. Residue behaviour

Not applicable

3.4. List of studies

Author	Year	Title	Testing laboratory	Report no.	Data Owner	Report date	Published/ Unpublished
[redacted]	2019	Stability study of the product [redacted]	[redacted]	37613	Ecolab Deutschland GmbH	14/02/2019	Unpublished
[redacted]	2020	Real time stability study of the product [redacted]	[redacted]	38139	Ecolab Deutschland GmbH	24/06/2020	Unpublished
[redacted]	2019	Physico-chemical parameters Viscosity and Surface Tension of the product [redacted]	[redacted]	37613.18/397 ANA	Ecolab Deutschland GmbH	05/02/2019	Unpublished
[redacted]	2019	Determination of the corrosion of metals by [redacted] following method 37.4 C.1 of the UN Handbook Amendment No. 1 of test report 19012502G979	[redacted]	19012502G979	Ecolab Deutschland GmbH	05/04/2019 23/07/2020	Unpublished
[redacted]	2019	Validation of the analytical method for the determination of lactic acid in the product [redacted]	[redacted]	37646	Ecolab Deutschland GmbH	01/04/2019	Unpublished
[redacted]	2019	Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the bactericidal activity of the [redacted]. Test method and prescriptions (phase 2 - step 1) according to NF EN 13727 + A2 (December 2015). Application to chemical disinfectants.	[redacted]	37855	Ecolab Deutschland GmbH	11/03/2019	Unpublished

Author	Year	Title	Testing laboratory	Report no.	Data Owner	Report date	Published/ Unpublished
[redacted]	2019	Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the yeasticidal activity of the [redacted]. Test method and prescriptions (phase 2 - step 1) according to NF EN 13624 (November 2013). Application to chemical disinfectants.	[redacted]	37854	Ecolab Deutschland GmbH	11/03/2019	Unpublished
[redacted]	2019	Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of yeasticidal activity of the [redacted]. Test method without mechanical action and requirements (phase 2 -step 2) according to the NF EN 13697 (June 2015). Quantitative carrier test for the evaluation of yeasticidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.	[redacted]	37864	Ecolab Deutschland GmbH	09/06/2019	Unpublished
[redacted]	2019	Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of bactericidal activity of the [redacted]. Test method without mechanical action and requirements (phase	[redacted]	37862	Ecolab Deutschland GmbH	11/03/2019	Unpublished

Author	Year	Title	Testing laboratory	Report no.	Data Owner	Report date	Published/ Unpublished
		2 -step 2) according to the NF EN 13697 (June 2015). Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.					
[redacted]	2019	Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the bactericidal activity of the formula [redacted]. Test method and prescriptions (phase 2 - step 1) according to NF EN 13727 + A2 (December 2015). Application to chemical disinfectants.	[redacted]	38170	Ecolab Deutschland GmbH	09/07/2019	Unpublished
[redacted]	2019	Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the yeasticidal activity of the formula [redacted]. Test method and prescriptions (phase 2 - step 1) according to NF EN 13624 (November 2013). Application to chemical disinfectants.	[redacted]	38168	Ecolab Deutschland GmbH	09/07/2019	Unpublished
[redacted]	2021	Chemical antiseptics and disinfectants. Quantitative suspension test for the	[redacted]	39936	Ecolab Deutschland GmbH	10/03/2021	Unpublished

Author	Year	Title	Testing laboratory	Report no.	Data Owner	Report date	Published/ Unpublished
		evaluation of the bactericidal activity of the formula [redacted]. Test method and prescriptions (phase 2 - step 1) according to NF EN 13727 + A2* (December 2015). Application to chemical disinfectants for the surface disinfection.					
[redacted]	2019	Determination of 'Ready' Biodegradability: Carbon Dioxide (CO2) Evolution Test (Modified Sturm Test) of [redacted]	[redacted]	20194906	Corbion NV	24/07/2019	Unpublished
[redacted]	2021	Determination the flash point of the product [redacted] according the NF ISO 3679	[redacted]	40183.21/159 ANA.	Ecolab Deutschland GmbH	19/05/2021	Unpublished
[redacted]	2021	Determination of thermal stability	[redacted]	CSL-21-0687.01	Ecolab Deutschland GmbH	21/06/2021	Unpublished

3.5. Confidential annex

The Confidential annex is included in the dossier as a separate file.