

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2108**of 3 November 2022****granting a Union authorisation for the single biocidal product 'Ecolab UA Lactic acid single product dossier'****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first paragraph, thereof,

Whereas:

- (1) On 16 April 2019, Ecolab Deutschland GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a single biocidal product named 'Ecolab UA Lactic acid single product dossier' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Latvia had agreed to evaluate the application. The application was recorded under case number BC-XS050968-91 in the Register for Biocidal Products.
- (2) 'Ecolab UA Lactic acid single product dossier' contains L-(+)-lactic acid, as active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 24 March 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 4 November 2021, the Agency submitted to the Commission an opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'Ecolab UA Lactic acid single product dossier' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'Ecolab UA Lactic acid single product dossier' is a single biocidal product, that it is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 22 November 2021, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Ecolab UA Lactic acid single product dossier'.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 12 October 2021 on the Union authorisation of the biocidal product 'Ecolab UA Lactic acid single product dossier' (ECHA/BPC/294/2021), <https://echa.europa.eu/it/opinions-on-union-authorisation>.

- (8) In its opinion, the Agency recommends that the Commission request the authorisation holder to conduct a shelf-life study of 'Ecolab UA Lactic acid single product dossier' in commercial packaging in which the product is to be made available on the market, as a condition of the authorisation. The study should show relevant data demonstrating satisfactory chemical and physical properties prior to and after storage. The Commission agrees with that recommendation and considers that the submission of the results of that study should be a condition relating to the making available on the market and use of the single biocidal product pursuant to Article 22(1) of Regulation (EU) No 528/2012. Given the fact that that study is already being conducted, the authorisation holder should submit the results of that study to the Agency by 3 months after the date of entry into force of this Regulation. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of Regulation (EU) No 528/2012 on the basis of the existing data.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027463-0000 is granted to Ecolab Deutschland GmbH for the making available on the market and use of the single biocidal product 'Ecolab UA Lactic acid single product dossier' subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 24 November 2022 to 31 October 2032.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

TERMS AND CONDITIONS (EU-0027463-0000)

The authorisation holder shall conduct a shelf life study (24 months) of 'Ecolab UA Lactic acid single product dossier' in commercial packaging in which the product is to be made available on the market. The specification proposed and properties tested shall be in accordance with 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 2.1, March 2022, section 2.6.4 Storage stability, stability and shelf-life ⁽¹⁾. All relevant properties shall be determined prior to and after storage.

By 24 February 2023 the authorisation holder shall submit the results of the study to the Agency.

⁽¹⁾ https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b

ANNEX II

Summary of product characteristics for a biocidal product

Ecolab UA Lactic Acid single product dossier

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0027463-0000

R4BP asset number: EU-0027463-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	GEL NETTOYANT DESINFECTANT WC Maxx Into Des
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1, 40789 Monheim am Rhein Germany
Authorisation number	EU-0027463-0000	
R4BP asset number	EU-0027463-0000	
Date of the authorisation	24 November 2022	
Expiry date of the authorisation	31 October 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtstrasse 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 Saône Cedex, France

	<p>BORES S.R.L., Bores Srl Via Pioppa 179, 44020 Pontegradella, Italy</p> <p>BRENNTAG ARDENNES, Route de Tournes CD n 2, 08090 Cliron, France</p> <p>BRENNTAG CEE – GUNTRAMSDORF, Blending Bahnstr 13A, 2353 Guntramsdorf, Austria</p> <p>BRENNTAG Kleinkarlbach, Humboldttring 15, 45472 Muehlheim, Germany</p> <p>BRENNTAG KAISERSLAUTERN, Merkurstr. 47, 67663 Kaiserslautern, Germany</p> <p>BRENNTAG NORDIC – HASLEV, Høsten Teglværksvej 47, 4690 Haslev, Denmark</p> <p>BRENNTAG NORMANDLY, 12 Sente des Jumelles BP 11, 76710 Montville, France</p> <p>BRENNTAG PL-ZGIERZ, ul. Kwasowa 5, 95-100 Zgierz, Poland</p> <p>BRENNTAG QUIMICA – Calle Gutemberg n° 22., Poligono Industrial El Lomo, 28906 Madrid, Spain</p> <p>BRENNTAG SCHWEIZERHALL, Elsaesserstr. 231, CH-4056 Basel, Switzerland</p> <p>BUDICH INTERNATIONAL GmbH, Dieselstrasse 10, 32120 Hiddenhausen, Germany</p> <p>CALDIC DEUTSCHLAND CHEMIE B.V., Karlshof 10 D, 40231 Deusseldorf, Germany</p> <p>COLEP BAD SCHMIEDEBERG, Kemberger Str. 3, 06905 Bad Schmiedeberg, Germany</p> <p>LANA S.A. Condado de Trevino 46, 09080 Burgos, Spain</p> <p>COMERCIAL GODO, França 13, 08700 Barcelona, Spain</p> <p>COURTOIS SARL, Route de Pacy, 27730 Bueil, France</p> <p>DAN-MOR Natural products and Chemicals Ltd, Hailian street 29, 30600 Akiva, Israel</p> <p>DENTECK BV, Heliumstraat 8, 2718 SL Zoetermeer, Netherlands</p> <p>DETERGENTS BURGUERA S.L., Joan Ballester, 50, 07630 Campos (illes Balears), Spain</p> <p>ECL BIBESHEIM, Justus-von-Liebig-Straße 11, 64584 Biebesheim am Rhein, Germany</p> <p>ECL CELRA, Celra C/Tramuntana s/n Poligona Industrial Celra, 17460 Girona, Spain</p> <p>ECL CHALONS, AVENUE DU GENERAL PATTON, 51000 Chalons en Champagne, France</p> <p>ECL CISTERNA, Via Ninfina II, 04012 Cisterna di Latina, Italy</p> <p>ECL FAWLEY, Fawley Cadland Road, Hythe, SO45 3NP Hampshire, South Hampton, United Kingdom</p> <p>ECL LEEDS, Lotherton Way Garforth, LS25 2JY Leeds, United Kingdom</p> <p>ECL MANDRA, 25TH KM OLD NATIONAL ROAD OF ATHENS TO THIVA, GR 19600, 19600 Mandra, Greece</p> <p>ECL MARIBOR, Vajngerlova 4, SI-2001 Maribor, Slovenia</p> <p>ECL MICROTEK B.V. – Gesinkkampstraat 19, 7051 HR Varsseveld, Netherlands</p> <p>ECL MICROTEK MOSTA, F20 MOSTA TECHNOPARK, 3000 MOSTA MST, Malta</p> <p>ECL MULLINGAR, Forest Park Zone C Mullingar Industrial Estate, N91 Mullingar, Ireland</p> <p>ECL NIEWEGEIN, Brugwal 11A, 3432 NZ Nieuwegein, Netherlands</p> <p>ECL ROVIGO ESOFORM, Viale del Lavoro 10, 45100 Rovigo, Italy</p> <p>ECL ROZZANO, Via A. Grandi,, 20089 Rozzano MI, Italy</p> <p>ECL TESJOKI, NLC Tesjoki Kivikumuntie 1, 07955 Tesjoki, Finland</p>
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ECL TESSENDERLO, Industriezone Ravenshout 4, 3980 Tessenderlo, Belgium

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ECOLAB LTD BAGLAN/SWINDON, Plot 7a Baglan Energy Park, Baglan, Port Talbot, SA11 2HZ Baglan, United Kingdom

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Gallows Green Services Ltd. Cod Beck Mill Industrial Estate Dalton Lane Thirsk North Yorkshire, YO7 3HR North Yorkshire, United Kingdom

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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 Industrial, 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

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LICHTENHELDT GmbH, Lichtenheldt Industriestrasse 7-9, 23812 Wahlstedt, Germany

LONZA GmbH, Morianstr.32, 42103 Wuppertal, Germany

MULTIFILL BV, Constructieweg 25A, 3641 SB Mijdrecht, Netherlands

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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

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Solimix, Montseny 17-19 Pol. Ind. Sant Pere Molanta, 08799 Olerdola Barcelona, Spain

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1.4. Manufacturer(s) of the active substance(s)

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkensedijk 46, 4206 AC Gorinchem, Netherlands
Location of manufacturing sites	Arkensedijk 46, 4206 AC Gorinchem, Netherlands

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic 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	Non-active substance	71060-57-6	615-247-5	1,0

2.2. **Type of formulation**

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Causes severe skin burns and eye damage. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe vapours. Wash hands thoroughly after handling. Wear protective gloves. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician. Specific treatment (see first aid instruction on this label). Wash contaminated clothing before reuse. Store locked up. Dispose of contents according to national regulations. Dispose of container according to national regulations.

4. AUTHORISED USE(S)

4.1. **Use description**

Table 1.

Use # 1 – Toilet bowl disinfectant

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor Indoor – disinfection of hard surface on the inside of toilet bowl in institutional and healthcare area.
Application method(s)	Method: Pouring Detailed description: Pouring directly onto surface
Application rate(s) and frequency	Application Rate: Ready to use (RTU) – in an amount sufficient to cover the whole inner toilet bowl surface. Contact time – 15 minutes. Dilution (%): Ready-to-use Number and timing of application: 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.

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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

See general directions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

4.1.5. *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

5. GENERAL DIRECTIONS FOR USE ⁽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.

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 hands thoroughly after handling.

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.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

5.4. **Instructions for safe disposal of the product and its packaging**

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

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.

6. OTHER INFORMATION

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