

European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: **Lactic acid based products - CID LINES NV**

Opinion N° UAD-C-1646780-21-00/F

2 March 2023

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of Lactic acid based products - CID LINES NV

In accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013 of the European Commission 18 May 2013 on changes of biocidal products authorised in accordance with Biocidal Product Regulation (EU) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has prepared this opinion on the administrative changes to the Union authorisation of:

Name of the biocidal product family: Lactic acid based products - CID LINES NV

Authorisation holder: CID LINES NV

Target asset number: EU-0027740-0000

Active substance common name: L-(+)-lactic acid

Product types: 1, 2, 3 and 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on **3 February 2023**, and recorded in R4BP under case number **BC-RB084319-36**.

Following its acceptance by ECHA, the evaluation of the notification was initiated on **21 February 2023**.

The evaluation included a check that the proposed changes of an existing authorisation are of a purely administrative nature involving no change to the properties or efficacy of the biocidal product family in accordance with Article 3(1)aa of the BPR.

The scope of the assessment itself was based on and limited to the information provided by the authorisation holder in the supporting document for the notification for an administrative change of a Union or simplified authorisation under Regulation (EU) No 354/2013 supplied via R4BP 3.

ECHA prepared this opinion containing the conclusions of its assessment.

2. Detailed opinion and background

2.1. ECHA opinion

During the evaluation, ECHA has assessed whether the changes made in the SPC document provided by the applicant are administrative changes in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following changes to the biocidal product family sought by the authorisation holder are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **1** of the Annex to the Regulation (EU) No 354/2013 - *Name of the biocidal product* - change N° 2: *Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.*
- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - *Formulator(s) of the biocidal product* - change N° 4: *Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative changes to the biocidal product family sought by the authorisation holder.

2.2. ECHA assessment

2.2.1. Description of the changes as proposed by the authorisation holder

Changes as described by the authorisation holder in their supporting document supplied via R4BP 3.

<u>Identification</u>	<u>Description</u>												
1.	Addition of tradenames for Kenolac SD (formula in metaSPC 9 of the Lactic acid based products BPF – CID LINES NV): - DESINTEC MH-Lactispray - UDDERgold EASY SPRAY												
2.	Addition of manufacturing locations The manufacturing sites to be added are: <table border="1"> <tr> <td>Name of manufacturer</td> <td>CID LINES NV</td> </tr> <tr> <td>Address of manufacturer</td> <td>Waterpoortstraat 2, 8900 Ieper Belgium</td> </tr> <tr> <td>Location of manufacturing sites</td> <td>Waterpoortstraat 2, 8900 Ieper Belgium</td> </tr> </table> <table border="1"> <tr> <td>Name of manufacturer</td> <td>Ecolab Europe GmbH</td> </tr> <tr> <td>Address of manufacturer</td> <td>Richtistrasse 7, 8304 Wallisellen Switzerland</td> </tr> <tr> <td>Location of manufacturing sites</td> <td>AFP GmbH, 21337 Lueneburg Germany ACIDEKA S.A. Edificio Feria. Capuchinos de Basurto 6, 4a planta, 48013 Bilbao. Bizkaia Spain Adiego CTRA DE VALENCIA, KM 5,900, 50410 CUARTE DE HUERVA (ZARAGOZA) Spain Allied Hygiene Unit 11, Belvedere Industrial Estate Fishers Way, DA17 6BS Belvedere Kent United Kingdom Arkema GmbH Morschheimer Strasse 19, D-67292 Krichheimbolanden Germany AZELIS DENMARK, Lundtoftegårdsvej 95, 2800 Kgs. Lyngby Denmark Belinka Zasavska Cesta 95, 1001 Ljubljana Slovenia BENTUS LABORATORIES LTD. RUSSIA, RADIO STREET, 24 BLD.1, 105005 MOSCOW Russian Federation BIO PRODUCTIONS 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, RH15 9LH WEST SUSSEX United Kingdom BIOXAL SA, Route des Varennes - Secteur A – BP 30072, 71103 Chalon sur Saône Cedex France</td> </tr> </table>	Name of manufacturer	CID LINES NV	Address of manufacturer	Waterpoortstraat 2, 8900 Ieper Belgium	Location of manufacturing sites	Waterpoortstraat 2, 8900 Ieper Belgium	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. Edificio Feria. Capuchinos de Basurto 6, 4a planta, 48013 Bilbao. Bizkaia Spain Adiego CTRA DE VALENCIA, KM 5,900, 50410 CUARTE DE HUERVA (ZARAGOZA) Spain Allied Hygiene Unit 11, Belvedere Industrial Estate Fishers Way, DA17 6BS Belvedere Kent United Kingdom Arkema GmbH Morschheimer Strasse 19, D-67292 Krichheimbolanden Germany AZELIS DENMARK, Lundtoftegårdsvej 95, 2800 Kgs. Lyngby Denmark Belinka Zasavska Cesta 95, 1001 Ljubljana Slovenia BENTUS LABORATORIES LTD. RUSSIA, RADIO STREET, 24 BLD.1, 105005 MOSCOW Russian Federation BIO PRODUCTIONS 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, RH15 9LH WEST SUSSEX United Kingdom BIOXAL SA, Route des Varennes - Secteur A – BP 30072, 71103 Chalon sur Saône Cedex France
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		<p>Bores Srl Via Pioppa, 179, 44030 Pontegradella (FE) Italy</p> <p>BRENNTAG ARDENNES Route de Tournes CD n 2, FR-08090 Cliron France</p> <p>Brenntag CEE GmbH Mixing / Blending Bahnstr. 13, A-2353 Guntramsdorf Austria</p> <p>Brenntag Duisburg GmbH Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Glauchau GmbH Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Hamburg GmbH Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Heilbronn GmbH Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Kaiserslautern, Merkurstr. 47, 67663 Kaiserslautern Germany</p> <p>Brenntag Kleinkarlbach GmbH, Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Lohfelden GmbH, Humboldttring 15, 45472 Muehlheim Germany</p> <p>Brenntag Nordic - Haslev, Høsten Teglværksvej 47, 4690 Haslev Denmark</p> <p>Brenntag Nordic Vivaa, Standgade 35,, 7100 Vejle Denmark</p> <p>Brenntag Normandie 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 S.A. - Madrid. Calle Gutemberg nº 22,.Poligono Industrial El Lomo. 28906 Getafe (Madrid) C/ Gutemberg, 22 Polig. Ind. El Lomo, 28906 Getafe (Madrid) Spain</p> <p>Brenntag Schweizerhall AG Elsaesserstr. 231, CH-4056 Basel Switzerland</p> <p>Budich International GmbH Dieselstrasse 10, 32120 Hiddenhause Germany</p> <p>Caldic Deutschland GmbH & Co.Kg Am Karlshof 10, D 40231 Duesseldorf Germany</p> <p>The Carbon Group Ltd, Ringaskiddy, P43 R772 County Cork Ireland</p> <p>ColepCCL Bad Schmiedeberg GmbH Kemberger Str. 3, 06905 Bad Schmiedeberg Germany</p> <p>COMERCIAL FARMACEUTICA CASTEL: LANA, S.A. "COFARCAS" Condado de Treviño, 46 P.I. Villalunquejar, 09080 BURGOS Spain</p> <p>COMERCIAL GODO França, 13, 08700 IGUALADA (BARCELONA) Spain</p> <p>COURTOIS SARL, ZA SOUS LE BEER Route de Pacy, 27730 BUEIL France</p> <p>DAN-MOR Natural Products and Chemicals Ltd. Or Akiva Industrial Zone, 30600 / Israel</p> <p>Dentek BV, Heliumstraat 8, 2718 SL Zoetermeer Netherlands</p> <p>DETERGENTS BURGUERA, S.L. Joan Ballester, 50, 07630 CAMPOS (ILLES BALEARES) Spain</p> <p>ECL Biebesheim, NLC Biebesheim Justus-von-Liebig-Straße 11, 64584 Biebesheim am Rhein Germany</p> <p>ECL Celra, NALCO - Celra C/ Tramuntana s/n Poligona Industrial Celra, 17460 Girona Spain</p> <p>ECL Châlons, AVENUE DU GENERAL PATTON, 51000 CHALONS EN CHAMPAGNE France</p> <p>ECL Cisterna, Nalco Italiana Manufacturing Srl. Via Ninfinia II, 04012 Cisterna di Latina Italy</p>
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2.2.2. Assessment of the changes as proposed by the authorisation holder

The assessment of the changes sought by the authorisation holder is presented in the following table:

<u>Identification</u>	<u>Corresponding reference in the Annex to Regulation (EU) No 354/2013</u>	<u>Evaluation</u>	<u>Result of the evaluation</u>	<u>Comments</u>
1.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	

Annex

Draft Summary of Product Characteristics