

CID LINES NV Waterpoortstraat 2 8900 leper Belgium

Oslo, 07.11.2023

Your ref.:

Our ref.: 2022/12200 Contact person: Sanne Helene Kristensen

Amendment to the Norwegian implementation of the Union Authorised biocidal product Lactic acid based products - CID LINES NV – EU-0027740-0000

We refer to the application dated 3 May 2023 for amendment of the implemented decision in EEA countries and Switzerland (EE-AAT) to the authorisation of the biocidal product Lactic acid based products - CID LINES NV – EU-0027740-0000, R4BP3 Case number BC-VL086100-33.

Decision

The Norwegian Environment Agency hereby accepts the amendment to the Norwegian implementation of the Union Authorised biocidal product family Lactic acid based products - CID LINES NV.

Terms and conditions for the authorisation

The revised terms and conditions are described in the final Norwegian Summary of Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0029945-0000. The final SPC can also be found on the website of the European Chemicals Agency here: <u>Information on biocides - ECHA (europa.eu)</u>. The terms and conditions as stated in the implemented decision letter dated 19 January 2023 also apply.

Where the changes approved in this letter have any consequences to the content or the design of the label, an electronic copy of the revised label(s) for the relevant product shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the date of this letter. Please mark the email with the authorisation number.

Background

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.



According to Article 50(2) of the BPR, the authorisation holder of a Union Authorisation seeking to change any of the information submitted in relation to the initial application of the authorisation, shall apply to the Agency. The Agency shall examine, and the Commission decide whether the conditions of Article 19 or, where relevant, Article 25, are still met and whether the terms and conditions of the authorisations need to be amended. The procedure on changes of biocidal products authorisations is described in detail in Regulation (EU) No. 354/2013.

According to Article 17(6) of the BPR the authorisation holder shall notify a product authorised under Article 44(5) of BPR to the Agency and the Commission at least 30 days before it is placed on the market.

The application concerns

The amendment of the implemented decision concerns amendment of pack size in meta SPC 7 in the biocidal product family and a notification of placing on the market the product VALIANT ULTRA EVERYDAY, added to meta SPC 9. The changes are classified as a minor change in accordance with the criteria laid down in Title 2 of the Annex to Regulation (EU) No 354/2012 and a notification of placing on the marked according to Article 17(6) of the Regulation (EU) 528/2012, respectively. The amendment of the packaging included in meta SPC 7 is in accordance with the post authorisation requirements stated in the BPC opinion on the evaluation of post authorisation conditions (ECHA/BPC/384/2023) adopted 7 June 2023.

Evaluation

The evaluation of the Norwegian Environment Agency is that the applied for amendment to the authorisation of the biocidal product family Lactic acid based products - CID LINES NV is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where an authorisation is changed, the existing stocks must be phased out in line with Article 52 of the BPR. The product shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment. An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards Norwegian Environment Agency



This document has been signed electronically

Trine-Lise Torgersen Sanne Helene Kristensen Head of section Adviser