Norwegian Environment Agency

Laboratorium Dr. Deppe GmbH
Hooghe Weg 35
47906 Kempen
Germany

Oslo, 06.11.2023

Your ref.:

Our ref.:
2023/8626

Contact person:
Hilde Karin Midthaug

Implementation of Union Authorisation for Laboratorium Dr. Deppe GmbH – Spray On – EU-0027669-0000

We refer to the Commission Implementing Regulation (EU) 2023/1161 of 2 June 2023 granting a Union Authorisation for the single biocidal product Spray On, R4BP 3 case number BC-UR051118-16. The product is a same biocidal product with Knieler & Team Propanol Family, R4BP 3 asset number EU-0027467-0000, evaluated by Reference Member State Switzerland, as the reference product. The union authorisation R4BP3 asset number EU-0027669-0000 is implemented in Norway.

Decision

The Norwegian Environment Agency hereby provides Laboratorium Dr. Deppe GmbH an implementation of the union authorisation for the same biocidal product Spray On, on the Norwegian market. The Union authorisation is valid from 5 July 2023 and implemented in Norway from the date of this letter. The authorisation is granted to 31 July 2032 with the authorisation number EU-0027669-0000 (to be stated on the label).

Terms and conditions for the authorisation

The product is authorised in Norway under the terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0031682-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu).

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in Norwegian and in accordance with the terms and conditions provided in the final Norwegian SPC. This is the responsibility of the authorisation holder. Further requirements are described in Article 69, 70 and 72 of the BPR. An electronic copy of the label(s) for each authorised 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.

All biocidal products on the Norwegian market shall be registered in the Norwegian Product Register in accordance with the Norwegian Biocide Regulation of 18 April 2017 No. 480 § 2-2, by using the biocide notification form. In addition, biocidal products which are classified as hazardous according to Regulation (EC) No 1272/2008 (the CLP Regulation) shall be fully declared if they are sold in amounts of 100 kg or more per year. The forms to be used and further information can be found on our website https://www.environmentagency.no/areas-of-activity/product-register/

The authorisation is given in accordance with Article 44(5) of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR) and the EEA agreement (annex II, chapter XV, 12n).

Background

Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedures for union authorisations are set out in Article 42, 43 and 44 of the BPR. According to the EEA agreement (annex II, chapter XV, 12n) the union authorisations shall be authorised in the EFTA States under the same terms and conditions as granted by the reference Member State. In general, a biocidal product is authorised for a period not exceeding 10 years in line with Article 17(4) of the BPR. Union authorisations shall have the same expiry date as stated in the corresponding Commission Implementing Regulation. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

The application concerns

Laboratorium Dr. Deppe GmbH has applied for a union authorisation for the same biocidal product Spray On on the European market. The biocidal product contains the active substances Propan-1-ol and Propan-2-ol and is for use in product types 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and product type 4 (Food and feed area). The authorisation holder in Norway is Laboratorium Dr. Deppe GmbH. The terms and conditions of the application are described in the submitted Norwegian SPC.

Evaluation by the Norwegian Environment Agency

This decision is based on the evaluation of the Agency, which is based on the reference biocidal product evaluation by the reference Member State Switzerland. The Norwegian Environment Agency agrees with the Agency that the conditions to grant an authorisation laid down in Article 19 of the BPR are fulfilled for the biocidal product.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing

stocks must be phased out in line with Article 89(4) 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.

Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the Norwegian Environment Agency (c.f., Article 47 of the BPR).

Changes to the authorisation

If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

Annual fee

For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us by email (biocides@miljodir.no) if you do not intend to place the product on the Norwegian market, and therefore should not be charged with the annual fee.

Renewal of application

An application for a renewal of the national authorisation must be submitted 550 days before the authorisation period expires, at the latest, according to Article 31(1) of the BPR.

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	Hilde Karin Midthaug
Head of Section	Senior Advisor