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Drostenkamp 3  
8101 Raalte  
Netherlands

Oslo, 26.11.2021

Your ref.:

Our ref.:  
2015/3456

Contact person:  
Marianne Stave Sekkenes

## Amendment to the authorisation of MECDEET Solution - NO-2018-0151

We refer to the Norwegian authorisation of the biocidal product MECDEET Solution - NO-2018-0151, R4BP 3 asset no. NO-0019388-0000, containing the active substance N,N-diethyl-meta-toluamide and to the amendment notified by MSCA-France on 08.10.2021. The Norwegian Environment Agency hereby amends the current authorisation subject to Article 48(3) of the Biocidal Products Regulation.

### Background

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

On the 08.10.2021, the Member State France notified the other Member States, including Norway, that they have amended their authorisation for the biocidal product MECDEET Solution by adding "shake before use" as a mitigation measure under instructions for use in the SPC in accordance with Article 48 of the BPR. In line with Article 48(3) of the BPR, Competent Authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

### Evaluation

The Norwegian Environment Agency agrees to the amendment notified by the French Competent Authority as this mitigation measure also will apply in Norway.

### Decision

The Norwegian Environment Agency amends the authorisations for MECDEET Solution according to Article 48(3) of the BPR, cf. §1 of the Norwegian Biocide Regulation. The amendment concerns the addition of "share before use" as a mitigation measure under instructions for use in the Norwegian SPC.

Apart from the change(s) outlined above, the terms and conditions as stated in the authorisation letter dated 10.08.2018 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP3.

## Period of grace

In accordance with Article 52 of the BPR, ref. Biocide Regulation of 18 April 2017 No. 480 § 1, when an authorisation is amended, the Competent Authority shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned, with effect from the date of this letter.

## Label

In cases where the change(s) accepted in this letter have any consequences for the content on or the design of the product label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number to [biocides@miljodir.no](mailto:biocides@miljodir.no) within three months from the date of this letter.

## Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Best regards

Norwegian Environment Agency

*This document has been signed electronically*

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Head of Section

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