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c/o Bayer A/S
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2300 Köpenhamn S
Denmark

Oslo, 20.02.2019

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2017/13008	Astrid Gaustad

Amendment of biocidal product authorisation – K-Othrine SC 25 Family – NO-2017-0142

We refer to the biocidal product authorisation for K-Othrine SC 25 Family – NO-2017-0142, R4BP 3 Asset no NO-0019482-0000.

The Commission has adopted by means of an implementing act, a commission implementing decision on the terms and conditions of the authorisation of the biocidal product family in accordance with Article 36 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR). Regulation (EU) No 528/2012 is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

In accordance with Article 36(4) of the Regulation, the Member States Concerned and the reference Member State shall either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.

According to decision (EU) 2018/1305, the minimum and maximum percentage for the concentration of the active substance in the biocidal product family, as referred to in Article 22(2)(e) of Regulation (EU) No 528/2012 shall be expressed by considering the active substance as it was approved, which includes the main constituent of the active substance and any additives or impurities.

Decision
In accordance with Articles 36 (4) of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency amends the authorisation of the biocidal product family K-Othrine SC 25 Family, by adjusting the expression of the active substance content in the Summary of Product Characteristics (SPC) to comply with the commission implementing decision (EU) 2018/1305.
No other changes than the above mentioned is made. Apart from the change(s) outlined above, the authorisation conditions as stated in the authorisation letter dated 19.12.2017 are valid.

The authorisation holder is responsible for ensuring that the information on the label (cf. Article

69(1)), and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet is updated accordingly.

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

In line with Article 52, existing products that do not comply with the conditions of the amended authorisation, 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 360 days after the date of this letter.

An electronic copy of the revised label with the Norwegian authorisation number for the product shall be submitted to the Norwegian Environment Agency within three months from the date of this letter, using the email address biocides@miljodir.no.

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

Trine-Lise Torgersen
Head of Section

Astrid Gaustad
Senior Adviser