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Oslo, 18.11.2022

Your ref.:

Our ref.:
2018/10837

Contact person:
Ingrid Ur Gjerde

Amendment to the Norwegian authorisation of the Union Authorised biocidal product – Contec IPA Product Family – EU-0020460-0000

We refer to the application dated 18 August 2022 for amendment of the implemented decision in EEA countries and Switzerland (EE-AAT) to the authorisation of the biocidal product family Contec IPA Product Family – EU-0020460-0000, R4BP 3 Case number BC-TN079319-07. The Norwegian Environment Agency hereby amends the Norwegian authorisation.

Terms and conditions for the authorisation

The revised terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0021978-0000. The final SPC can also be found on the website of the European Chemicals Agency here: [Information on biocides - ECHA \(europa.eu\)](https://echa.europa.eu). The terms and conditions as stated in the authorisation letter dated 20 January 2020 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 products 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 amendment of the implemented decision concerns addition of pack size and packaging material in Meta SPC 1 in the biocidal product family and is classified as a minor change, in accordance with the criteria laid down in Title 2 of the Annex to Regulation (EU) No 354/2013.

Evaluation

The evaluation of the Norwegian Environment Agency is that the applied for amendment to the authorisation of the biocidal product family Contec IPA Product Family is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

Decision

The Norwegian Environment Agency hereby accepts the amendment to the Norwegian authorisation of the Union Authorised biocidal product family Contec IPA Product Family.

No other change(s) than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the terms and conditions as stated in the authorisation letter dated 20 January 2020 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP 3.

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
Head of section

Ingrid Ur Gjerde
Adviser