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Oslo, 20.12.2023

Your ref.:

Our ref.:
2019/11360

Contact person:
Sanne Helene Kristensen

Approval of minor change to the authorisation for COMPO GmbH – COM 116 02 I AL – NO-2019-0176

With reference to the application dated 28 November 2022 for minor changes to the authorisation of the biocidal product COM 116 02 I AL, R4BP3 case number BC-QJ082196-25.

The application is a part of a group submission with Austria acting as the reference Member State, R4BP3 case number BC-WH082187-22.

Decision

The Norwegian Environment Agency hereby approves the application for the minor changes to the product authorisation for COM 116 02 I AL on the Norwegian market. The decision is based on the evaluation of the reference Member State, with the following derogation previously agreed upon prior to granting the product authorisation: Removal of cockroaches from the intended use of the indoor use (use no. 1) in line with the national restrictions in Norway.

Terms and conditions for the authorisation

The revised terms and conditions as described in the final Norwegian Summary of Product Characteristic (SPC) attached to the R4BP3 asset no. NO-0004523-0000. The final SPC can also be found on the website of the European Chemicals Agency here: [Information on biocides – ECHA \(europa.eu\)](#). The terms and conditions as stated in the authorisation letter dated 16 September 2019 also apply.

Where the changes approved in this letter have any consequences to the content on 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.

The approval is given in accordance with Article 7(7) of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR) and Article 37(1)(b) of the BPR.

Background

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No 480.

The procedure for applications for minor changes to authorisations are set out in Article 7(7) of Regulation (EU) No 354/2013.

The application concerns

COMPO GmbH has applied for minor changes to the authorisation of COM 116 02 I AL on the Norwegian market as a part of a group submission. The applied changes concern:

- a change in the composition of the biocidal product with respect to the deterrent (bittering agent).
- a change of the intended use for the indoor use (use no. 1) (change from the claim "garden ants, silverfishes, woodlice and cockroaches" to the claim "garden ants, crawling insects (incl. silverfishes and cockroaches), and woodlice")
- the addition of the packaging sizes 50 ml and 100 ml

All changes are in accordance with the criteria laid down in Title 2 of the Annex to Regulation (EU) No 354/2013.

Evaluation by the Norwegian Environment Agency

The decision is based on the evaluation of the reference Member State.

Derogation from mutual recognition

A derogation from the mutual recognition was made for the Norwegian authorisation in accordance with Article 37(1) (b) of the BPR for the application for the mutual recognition in parallel of COM 116 02 I AL, R4BP3 case number BC-JL002321-57. The derogation adjusted the terms and conditions of the authorisation by restricting the use area (target organisms to be controlled). This is according to national restrictions in Norway saying that non-bait products for use against bed bugs, cockroaches, long-tailed silverfish, and pharaoh ants are only authorised for use by trained professionals, as these workers are considered to have the required knowledge, skills, and experience in handling of infestations of these especially challenging insects. Hence, cockroaches are removed as a target organism for indoor use in the initial authorisation. The derogation was communicated to the applicant and agreed upon prior to granting the authorisation and is stated in the authorisation letter dated 16 September 2019.

The derogation will be applied for this application for a minor change, removing cockroaches from the intended use of the indoor use (use no. 1).

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

Sanne Helene Kristensen
Adviser