

Rentokil Initial Limited
Hazel House, Millennium Park,
Naas, Co Kildare,
Ireland

Oslo, 16.06.2022

Your ref.:

Our ref.:
2019/10235

Contact person:
Marianne Stave Sekkenes

Godkjenning stor endring - Brodifacoum Family - PT14 - Rentokil Initial Limited

We refer to your application for major change to the authorisation of the biocidal product family Brodifacoum Family - PT14 – NO-2019-0180, R4BP 3 Case number BC-XB064638-28. The Norwegian Environment Agency hereby amends the authorisation.

Background

According to Article 50(2) in Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Product Regulation, BPR), the Competent Authority shall decide whether a change of an authorised biocidal product can be accepted with regard to ensuring compliance with Article 19 or, where relevant, Article 25, and whether terms and conditions of the authorisation need to be amended. Procedures for amendments to a product authorisation are further described in Regulation (EU) No. 354/2013.

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 amendment to the authorisation of Brodifacoum Family - PT14 concerns addition of claim against Black rats (*Rattus rattus*), change of shelf life for Brodifacoum Grain (24 months) and Brodifacoum 25 Paste (18 months) and removal of meta SPCs for Brodifacoum Blocks and Brodifacoum Paste. These amendments are classified as major changes, in accordance with the criteria laid down in Title 3 of the Annex to Regulation (EU) No. 354/2013. A correction was also made for the H & P statements in the Norwegian SPC by including "P260 - do not breath dust" in accordance with the approved PAR and master SPC.

Evaluation

The evaluation of the Norwegian Environment Agency is that the sought amendment to the authorisation of the biocidal product family Brodifacoum Family - PT14 is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

Derogations from mutual recognition

Black rats (*Rattus rattus*) are not present in harmful quantities in Norway and, hence, a derogation from mutual recognition is made for Brodifacoum Family - PT14 in accordance with Article 37(1) (e) of the BPR, removing black rats as a target organism. The derogation has been communicated to the applicant and agreed upon earlier in the evaluation process.

Decision

Subject to Articles 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency accepts the proposed change(s) to Brodifacoum Family - PT14 and amends the authorisation in conformity with the applied change(s).

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 13.12.2019 apply.

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

Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number to biocides@miljodir.no within three months from the date of this letter.

Phase-out period of existing stocks, when relevant

In accordance with Article 52 of the BPR, 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.

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

Marianne Stave Sekkenes
Senior Adviser