

PelGar International Limited
18 rue des Remparts d'Ainay
69002 Lyon
France

Oslo, 19.12.2023

Your ref.:

Our ref.:
2020/13924

Contact person:
Sanne Helene Kristensen

Approval of minor change to the authorisation for PelGar International Limited – Vertox 25 Oktablok NO- 2022-0221

With reference to the application dated 24 February 2022 for minor changes to the authorisation of the biocidal product Vertox 25 Oktablok, R4BP3 case number BC-CL073994-24.

The application is a part of a group submission with Ireland acting as the reference Member State, R4BP3 case number BC-WM073987-97.

Decision

The Norwegian Environment Agency hereby approves the application for the minor changes to the product authorisation for Vertox 25 Oktablok on the Norwegian market.

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 no. NO-0027540-0000. 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 11 January 2022 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).

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

PelGar International Limited has applied for minor changes to the authorisation of Vertox 25 Oktablok on the Norwegian market as a part of a group submission. The applied changes concern a reduction of the concentration of a filler which will not have an impact on any properties of the product and the addition of a formulator of the biocidal product, where the biocidal product composition and the formulating proves remain unchanged. The changes are classified as a minor and administrative change in accordance with the criteria laid down in Title 2 and Title 1, Section 2 of the Annex to Regulation (EU) No 354/2013, respectively.

A change has been made to the classification of the product in accordance with the evaluation performed by the reference Member State. Due to the reduction of the concentration of a filler ingredient, the changes to the classification which were notified in the administrative change recorded under R4BP3 case number BC-HD084855-36, have been amended to reflect the classification requirements for the updated concentration.

The Norwegian Environment Agency has updated the SPC for the Norwegian authorisation of Vertox 25 Oktablok to reflect the information stated in the SPC from the reference Member State. The change in the SPC includes an amendment of the address of the manufacturer of the product from Unit 13, Newman Lane, GU34 2QR Alton, Hants, United Kingdom to 18 rue des Remparts d'Ainay, 69002 Lyon, France.

Evaluation by the Norwegian Environment Agency

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

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