

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

Oslo, 18.04.2023

Your ref.:

Our ref.:  
2020/13924

Contact person:  
Karina Petersen

## Acceptance of administrative change to the authorisation for PelGar International Limited – Vertox 25 Oktablok NO-2022-0221

With reference to the notification dated 1 March 2023 for administrative changes to the authorisation of the biocidal product Vertox 25 Oktablok, R4BP 3 case number BC-HD084855-36.

### Decision

The Norwegian Environment Agency hereby accepts the notified administrative changes to the product authorisation for Vertox 25 Oktablok on the Norwegian market.

### Terms and conditions for the change to the authorisation

The revised terms and conditions are described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case 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 product 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](mailto:biocides@miljodir.no)). The electronic copy of the label(s) must be submitted 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 6(4) 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 administrative notifications to authorisations are set out in Article 6 of Regulation (EU) No 354/2013.

### The notification concerns

PelGar International Limited has notified administrative change to the authorisation of Vertox 25 Oktablok on the Norwegian market. The notified changes concerns change to the classification and labelling, where the change is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council, as referred to in Section 2 of Title 1 to the Annex to Regulation (EU) No 354/2013.

The changes concern addition of the following GHS pictogram, hazard phrase and EUH 208 phrase, due to the re-classification of OIT (which is present at 0.0016875%), following the entry into force of the 15th ATP to the CLP.

- GHS07
- H317 May cause an allergic reaction
- EUH 208 Contains 1,2-benzisothiazol-3-one and 2-octyl-2H-isothiazol-3-one. May produce an

## Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency considers the changes to meet the conditions in Title 1, Section 2 of Annex to Regulation (EU) no 354/2013 and therefore are acceptable.

## 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*

Karina Petersen  
Senior Adviser