



STERIS Ireland Limited

IDA Business and Technology Park,  
Tullamore,  
R35 X865 County Offaly,  
Ireland

Oslo, 29.11.2019

Your ref.:  
[Your ref.]

Our ref. :  
2019/10691

Contact person:  
Marianne Stave Sekkenes

## **Authorisation of Vaprox biocidal product family – NO-2019-0179**

We refer to your application for mutual recognition of the biocidal product family Vaprox biocidal product family (R4BP case no. BC-XS053382-10), containing the active substance hydrogen peroxide.

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. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. To facilitate the renewal procedure in accordance with the Mutual Recognition Renewal Regulation, it is agreed (CA-Sept14-Doc.5.7 -Final) that authorisations granted by the concerned member states should have the same expiry date as the authorisation which is granted by the reference Member State.

A derogation from mutual recognition is made for Vaprox biocidal product family in accordance with art 37(1) (b) of the BPR, adjusting the user category from trained professional to professional since Norway do not have any certification of trained professionals for PT02 biocidal products (Disinfectants and algicides not intended for direct application to humans or animals). The restrictions have been agreed upon by the applicant, earlier in the evaluation process.

### **Decision**

Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Vaprox biocidal product family until 14.04.2029.

**The authorisation concerns:**

Product name: Vaprox biocidal product family  
Trade names: Vaprox Hydrogen Peroxide Sterilant  
Vaprox 59 Hydrogen Peroxide Sterilant  
Active substance: Hydrogen peroxide  
Product type: 02  
Authorisation holder in Norway: STERIS Ireland Limited  
Authorisation numbers: NO-2019-0179-01-01  
NO-2019-0179-02-01  
Authorisation date: 29.11.2019  
Expiry date: 14.04.2029

Vaprox biocidal product family can only be made available to professional users with an occupational need. Regulation (EU) No 98/2013 concerning the marketing and use of explosives precursors is implemented in Norwegian law through "*forskrift om håndtering av utgangsstoffer for eksplosiver*" of 15 June 2015 No. 588. According to this regulation, products containing more than 12 %, by mass, of hydrogen peroxide can only be made available and handled by professional users with an occupational need.

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

According to Article 31(1) of the Biocidal Products Regulation, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

**Label**

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the attached SPC. Furthermore, Article 69(1), (2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above mentioned documents is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the label with the Norwegian authorisation number NO-2019-0179 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address [biocides@miljodir.no](mailto:biocides@miljodir.no).

**Phase-out period of existing stocks, when relevant**

In line with Article 89(4), existing products that do not comply with the conditions of this authorisation, 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 not comply with the new conditions, should also be removed from the market.

#### **Changes to the authorisation**

If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

#### **Yearly fee**

For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us using the e-mail address [biocides@miljodir.no](mailto:biocides@miljodir.no) if you do not intend to place the product family on the Norwegian market, and therefore should not be charged with the annual fee.

#### **Registration in the Norwegian Product Register**

All biocidal products must be registered in the Norwegian Product Register. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Further information can be found at

<https://tema.miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/>

#### **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 Advisor

A copy of this letter is sent to the Norwegian Directorate for Civil Protection (DSB).