LATVIJAS VIDES, ĢEOLOĢIJAS
UN METEOROLOĢIJAS CENTRS

Riga

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STERIS Ireland Limited

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On an authorisation of Vaprox biocidal product family through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **STERIS Ireland Limited** on 19th August 2019 concerning an authorisation of **Vaprox biocidal product family** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Vaprox biocidal product family** developed by the reference Member State – United Kingdom.

Therefore, in accordance with Article 33 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (regulation 528/2012) LEGMC authorises the **Vaprox biocidal product family** on the basis of mutual recognition process.

The authorisation holder for **Vaprox biocidal product family** in Latvia is:

STERIS Ireland Limited.

Vaprox biocidal product family contains active substance **hydrogen peroxide** (CAS No 7722-84-1; EC No 231-765-0) at the concentration range **34.8-59.4 %**.

LEGMC assigns the authorisation number LV/2020/MR/004 for Vaprox biocidal product family.

The authorisation is valid until 14th April 2029.

The following members are authorised within family:

Biocidal product	Active substance concentration, %	Authorisation number
Vaprox® Hydrogen Peroxide Sterilant	35.0	**LV/2020/MR/004/01/001**
Vaprox® 59 Hydrogen Peroxide Sterilant	59.0	**LV/2020/MR/004/02/001**

The authorisation number of **Vaprox biocidal product family** shall be indicated on the label of the biocidal product.

The authorisation of **Vaprox biocidal product family** is granted on the following terms:

- Product type: 2 – Disinfectants and algaecides not intended for direct application to humans or animals;
- Target organism – bacteria, yeast, fungi, bacterial spores and viruses;
- Use area: disinfection on non-porous surfaces, materials, equipment and furniture;
- Users: trained professional;
- Product description: ready-to-use aqueous solution;
- Product stability: shelf life - 24 months.

The authorisation applies only to the **Vaprox biocidal product family** in the composition, form and packing for which the first authorisation is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) of the **Vaprox biocidal product family** should be as it is indicated in the first authorisation of above mentioned biocidal product, taking into account also the information which is stated in the Product Assessment Report and Summary of Product Characteristics issued by reference Member State.

The information on the label shall be in Latvian.

Notwithstanding content of the label specified above, requirements stated in:

- Article 69 of regulation 528/2012 (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of the biocidal products;
- Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of the substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006,
- all other relevant legislation shall be applied.

STERIS Ireland Limited as the authorisation holder shall inform LEGMC about any changes in accordance with *Commission Implementing Regulation (EU) No 354/2013 of 18th April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.*

If the first authorisation issued by reference Member State is amended or revoked, the authorisation of **Vaprox biocidal product family** through mutual recognition may be re-opened for review before the 14th April 2029.

Additionally, LEGMC would like to inform that **STERIS Ireland Limited** is fully responsible of the content of the biocidal products as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask **STERIS Ireland Limited** to notify the above mentioned information down to supply chain.

Head of Information Analysis Department A.Jantone

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