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Estko AS

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On an authorisation of the same biocidal product Oksoon

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Estko AS** on 17th July 2023 concerning an authorisation of **Oksoon** according to *Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and the Council (Regulation (EU) No 414/2013)*.

The reference product is **INTEROX FCC 35** (authorisation number – **EU-0027468-0012 1-6**) authorised with *Commission Implementing Regulation (EU) 2022/1232 of 13 July 2022 granting a Union authorisation for the biocidal product family 'INTEROX Biocidal Product Family 1' (Regulation (EU) 2022/1232)*. Authorisation holder for Union authorisation is **Solvay Chemicals International**, Address - Rue de Ransbeek 310, B-1120 Bruxelles, Belgium.

Estko AS submitted application for authorisation of a same biocidal product **Oksoon** according to Article 2 and 3(1a) of the Regulation (EU) No 414/2013.

LEGMC accepted and agreed with proposed differences between **Oksoon** and **INTEROX FCC 35**:

- trade name;
- authorisation holder;
- manufacturer of the active substance;
- manufacturer of the biocidal product.

The above mentioned differences are the subject of an administrative changes in accordance with *Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Regulation (EU) No 354/2013)*.

Therefore, in accordance with Article 5 of Regulation (EU) No 414/2013 LEGMC grants the authorisation of the same biocidal product the **Oksoon**.

The biocidal product **Oksoon** contains **35.7 % (w/w)** of hydrogen peroxide (CAS No. 7722-84-1; EC No. 231-765-0) as active substance.

LEGMC assigns the authorisation number for same biocidal product Oksoon:

LV/2023/SB/005

The authorisation of Oksoon is valid until 31st July 2032.

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

The authorisation of **Oksoon** is granted on the following terms:

- Product type: 4 – Food and feed area;
- Target organisms: bacteria, fungi/yeasts, viruses and bacterial spores;
- Users: professional;
- Product description: soluble concentrate;
- Product stability: 12 months in HDPE packs at ambient temperature.

The authorisation applies only to the same product **Oksoon** in the form and composition, form and packing according to the reference product **INTEROX FCC 35** for which the Union authorisation is granted by *Regulation (EU) 2022/1232*.

The information on the label (and if applicable an enclosed instruction of use) of the **Oksoon** should be as it is indicated in the first authorisation for **INTEROX FCC 35**, taking into account Product Assessment Report, summary of Product Characteristics and proposed differences for same product.

The information on the label shall be in Latvian.

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

- *Article 69 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 (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.

Estko AS as the authorisation holder shall inform LEGMC about any changes in accordance with *Regulation (EU) No 354/2013*.

Additionally, LEGMC would like to inform that **Estko AS** is fully responsible of the content of the biocidal product **Oksoon** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask **Estko AS** to notify the above mentioned information down to supply chain.

Head of Information Analysis Department

signature*

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* THIS DOCUMENT IS ELECTRONICALLY SIGNED WITH A SECURE ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP