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**Intracare B.V.**

Voltaweg 4,  
5466 AZ Veghel  
Netherlands

### **On an authorisation of Intra Hydrocare through mutual recognition in Latvia**

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Intracare B.V.** on 25<sup>th</sup> January 2017 concerning an authorisation of **Intra Hydrocare** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Intra Hydrocare** developed by the reference Member State – Netherlands.

Therefore, in accordance with Article 34 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 **Intra Hydrocare** on the basis of mutual recognition process.

The authorisation holder for **Intra Hydrocare** in Latvia is:

**Intracare B.V.**

**Intra Hydrocare** contains **49.4 % (w/w)** of hydrogen peroxide (CAS No. 7722-84-1; EC No. 231-765-0) as active substance.

**LEGMC assigns the authorisation number for biocidal product Intra Hydrocare:**

**LV/2022/MR/007**

**The authorisation is valid until 1<sup>st</sup> July 2032.**

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

The authorisation of **Intra Hydrocare** through mutual recognition is granted on the following terms:

- Product types: 2 – Disinfectants and algacides not intended for direct application to humans or animals, 3 – Veterinary hygiene, 4 - Food and feed area and 5 – Drinking water;
- Target organism: bacteria, yeasts, fungi and biofilm;
- Users: professional;
- Product description: soluble concentrate;
- Product stability: 24 months;
- Pack sizes and packaging materials: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the biocidal product **Intra Hydrocare** in the composition, form and packing material 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 **Intra Hydrocare** 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*,
- *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.

Intracare B.V. as the authorisation holder shall inform LEGMC about any changes in accordance with *Commission Implementing Regulation (EU) No 354/2013 of 18<sup>th</sup> 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 **Intra Hydrocare** through mutual recognition may be re-opened for review before the 1<sup>st</sup> July 2032.

Additionally, LEGMC would like to inform that Intracare B.V. is fully responsible of the content of the biocidal product **Intra Hydrocare** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask **Intracare B.V.** to notify the above mentioned information down to supply chain.

Head of Information Analysis Department

A.Jantone

[biocides@lvgmc.lv](mailto:biocides@lvgmc.lv)