



Rīga

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**EVANS VANODINE
INTERNATIONAL PLC**

Brierley Road, Walton Summit,
PR58AH Preston,
United Kingdom

On an authorisation of the biocidal product Handsan

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **EVANS VANODINE INTERNATIONAL PLC** on 28 June 2016 concerning an authorisation of **Handsan** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Handsan** developed by the reference Member States – United Kingdom.

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 (EU) No 528/2012), LEGMC authorises the **Handsan** on the basis of mutual recognition process.

The authorisation holder for **Handsan** in Latvia is:

EVANS VANODINE INTERNATIONAL PLC.

Handsan contains **69,75%** of *propan-2-ol* (CAS No.67-63-0, EC No.200-661-7) as an active substance.

LEGMC assigns the authorisation number for biocidal product Handsan:

LV/2019/MR/011

The authorisation is valid until 26th March 2029.

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

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

- Product type: 1 – Human hygiene;
- Target organism: bacteria, enveloped viruses, yeasts;
- Users: professional;
- Product description: hand disinfectant for use in food handling and preparation areas and in non-surgical medical care establishments;
- Product stability: up to 2 years;
- Field of use - indoor
- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the product **Handsan** 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 **Handsan** should be as it is indicated in the first authorisation of above mentioned 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 Regulation (EU) No 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.

EVANS VANODINE INTERNATIONAL PLC 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 **Handsan** through mutual recognition may be re-opened for review before 26th March 2029.

Application on renewal of an authorisation shall be submitted according to *Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition.*

Additionally LEGMC would like to inform that EVANS VANODINE INTERNATIONAL PLC is fully responsible of the content of the biocidal product **Handsan** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask EVANS VANODINE INTERNATIONAL PLC to notify the above mentioned information down to supply chain.

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