LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

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Calvatis GmbH
Am Hafen 16
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Germany

On an authorisation of the biocidal product calgonit Des-H

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **SCC GmbH** on 16th July 2021 concerning an authorisation of **calgonit Des-H** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **calgonit Des-H** developed by the reference Member States – Germany.

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 **calgonit Des-H** on the basis of mutual recognition process.

The authorisation holder for **calgonit Des-H** in Latvia is:

Calvatis GmbH.

calgonit Des-H contains the following active substances:

- **30,151**% of ***propan-1-ol*** (CAS No.71-23-8, EC No.200-746-9)
- **45,455%** of ***propan-2-ol*** (CAS No.67-63-0, EC No.200-661-7).

LEGMC assigns the authorisation number for biocidal product calgonit Des-H:

LV/2024/MR/002

The authorisation is valid until 21st December 2033.

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

The authorisation of **calgonit Des-H** through mutual recognition is granted on the following terms:

- Product type: 1 – Human hygiene;
- Target organisms: bacteria, enveloped viruses, yeasts, fungi;
- Users: industrial, professional;
- Product description: RTU hand disinfectant for use in food industry;
- Application methods: hygienic hand rub;

- Product stability: up to 2 years;
- Field of use – indoor;
- Pack sizes and packaging material: 1L bottle (HDPE), 5L Jerrycan (HDPE).

The authorization through mutual recognition applies only to the product **calgonit Des-H** in the composition, form and packing for which the first authorization is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) of the **calgonit Des-H** 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.

Calvatis GmbH 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 **calgonit Des-H** through mutual recognition may be re-opened for review before 21st December 2033.

Additionally LEGMC would like to inform that *Calvatis GmbH* is fully responsible of the content of the biocidal product **calgonit Des-H** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask *Calvatis GmbH* to notify the above mentioned information down to supply chain.

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