

DeLaval NV
Industriepark-Drongen 10
9031 Gent
Belgium

Reykjavík, 21 August 2019
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07.06.04

Authorisation for placing the biocidal product family DeLaval iodine-based teat disinfectant family on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of DeLaval iodine-based teat disinfectant family on 24 April 2015. The case was accepted by the Agency on 12 August 2019 and validated on 16 August 2019.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as iodine was as of 1 September 2015, an approved active substance for product type 3 under Commission Implementing Regulation (EU) No 94/2014.

The Agency based the evaluation on the application documents as well as the original authorisation of the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product family **DeLaval iodine-based teat disinfectant family** on the market in Iceland, by mutual recognition of product authorisation NL-0013188-0000 issued by the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) in accordance with Article 5 of Icelandic Regulation No 878/2014 on biocidal products, which implements Regulation (EU) No 528/2012 into Icelandic legislation. The Product Assessment Report and the Confidential Annex are accessible under the authorisation in the R4BP database.

This authorisation is granted in exercise of the powers conferred by Articles 17(3), 19(1) and 34(6) of Regulation (EU) No 528/2012.

The conditions in Article 19 of Regulation (EU) No 528/2012 have been met. The authorisation is granted according to Article 22 of Regulation (EU) No 528/2012. The authorisation comes into effect on 21 August 2019 in the following terms:

1. The composition and formulation established for the biocidal product family is detailed in the Summary of the Product Characteristics in Appendix 1 – the relevant criteria for this biocidal product family authorisation applies as described therein.

2. Subject to compliance with the conditions as listed in Appendix 2, the authorisation holder is authorised to place on the market the biocidal product(s) detailed in the Summary of the Product Characteristics (Appendix 1) for the use(s) set out in that document.
3. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be amended in accordance with Article 48 and 50 of Regulation (EU) No 528/2012.
4. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be cancelled in the circumstances set out in Article 48 and 49 of Regulation (EU) No 528/2012.
5. Subject to paragraphs 3 and 4, this authorisation remains in force until midnight of 1 August 2029, on the condition that the active substance is registered in the EU list of approved active substances


When placing the above-mentioned biocidal product family on the market in Iceland, the product(s) shall be labelled according to Article 69 of Regulation (EU) No 528/2012 and, if classified as hazardous according to Regulation (EU) No 1272/2008 (CLP), such labelling shall be in Icelandic (enclosed in section 6 of Appendix 1), cf. Article 4 of Regulation No 878/2014 on biocidal products.

Application for renewal of the authorisation shall be submitted at the latest 29 January 2028 according to Article 31 of Regulation (EU) No 528/2012.

This administrative decision may be appealed before the Minister for the Environment and Natural Resources, in accordance with Article 68 of the Chemicals Act No 61/2013 and Article 26 of the Icelandic Administrative Act No 37/1993. Appeals should be directed, within three months from the receipt of this decision, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely

Hafdís Inga Ingvarsdóttir
Hafdís Inga Ingvarsdóttir
Advisor


Skúli Þórðarson
Director

Appendix 1: Summary of Product Characteristics for a Biocidal Product Family
Appendix 2: Conditions of Authorisation