ENVIRONMENT AGENCY

Streymi heildverslun ehf.
Goðanesi 4
603 Akureyri

Reykjavík 14 December 2020
UST202008-250/H.I.I.
07.06.04

Renewal of National authorisation subject to mutual recognition for the biocidal product Bromadiolone Wax Block (compressed) (Rode holræsavaxkubbar)

The Environment Agency of Iceland (Umhverfisstofnun) received your application for renewal of National authorisation subject to mutual recognition for the biocidal product Bromadiolone Wax Block (compressed) on 12 July 2017. The case was accepted by the Agency on 28 August 2020 and validated on 11 December 2020, case no. BC-SL033097-28.

The Agency based the evaluation on the renewal decision and the Product Assessment Report (PAR) of the Hungarian Competent Authority acting as reference member state under the asset numer HU-0000903-0000.

The Environment Agency of Iceland hereby grants a renewal of National authorisation subject to mutual recognition for placing the biocidal product Bromadiolone Wax Block (compressed) under the trade name **Rode holræsavaxkubbar** on the market in Iceland 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 31(2) of Regulation (EU) No 528/2012 and Article 5(2) of Commission Delegated Regulation (EU) No 492/2014.

The Environment Agency of Iceland has determined that the conditions in Articles 19 and 32(2) of Regulation (EU) No 528/2012 are still met and renews this authorisation with the following terms:

1. This authorisation revokes the authorisation document reference number UST201706-184 (as supplemented or amended from time to time).
2. The composition and formulation established for the biocidal product is detailed in the Summary of the Product Characteristics in Appendix 1 – the relevant criteria for this biocidal product authorisation apply as described therein.
3. Subject to compliance with the conditions as listed in Appendix 2, the authorisation holder is authorised to place on the market the biocidal product detailed in the Summary of the Product Characteristics (Appendix 1) for the use(s) set out in that document.

Suðurlandsbraut 24
108 Reykjavík
Iceland
+354 591 2000
www.ust.is

4. 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.
5. 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.
6. Subject to paragraphs 4 and 5, this authorisation remains in force until midnight of **31 December 2022**, on the condition that the active substance is registered in the EU list of approved active substances.

When placing the above-mentioned biocidal product on the market in Iceland, the product 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.

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 receival of this decision, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely

Hafdís Inga Ingvarsdóttir
Advisor

Skúli Þórðarson
Director

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Conditions of Authorisation

Suðurlandsbraut 24
108 Reykjavík
Iceland

+354 591 2000
www.ust.is

ENVIRONMENT AGENCY

Appendix 2
Conditions of Authorisation

A failure to comply with any conditions contained in this Appendix may result in cancellation of the authorisation under Article 48 of Regulation (EU) No 528/2012.

1. Without prejudice to the duties imposed on the Authorisation holder of the biocidal product by Article 69 of Regulation (EU) No 528/2012, the authorisation holder must include on the product labels the information contained in the relevant meta summary of the product characteristics for the biocidal product, other than,
    - The list of all authorised product trade names and their relevant suffixes (however the relevant product name and suffix must be on the product label);
    - The name and address of the manufacturer(s) of the product(s) (including site details);
    - The name and address of the manufacturer(s) of the active substance(s) (including site details); and
    - The list of all authorised pack sizes and types (however the relevant pack size must be on the product label).

Suðurlandsbraut 24 +354 591 2000
108 Reykjavík www.ust.is
Iceland