

Streymi heildverslun ehf.
Goðanesi 4
603 Akureyri

Reykjavík 30. júní 2017
UST201706-184/E.P.
07.06.04

Authorisation for placing the biocidal Bromadiolone Wax Block (compressed) (Rode Holræsavaxkubbar), on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of Bromadiolone Wax Block (compressed) (Rode Holræsavaxkubbar) on 31st August 2013. The case was accepted by the agency on 2nd December 2014 and validated on 2nd December 2014.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as bromadiolone is, as of 01st July 2011, an approved active substance for product type 14 under Directive 2009/92/EC.

The Agency based the evaluation on the application documents as well as the original authorisation of the Swedish Chemicals Agency.

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product **Bromadiolone Wax Block (compressed) (Rode Holræsavaxkubbar)** on the market in Iceland, by mutual recognition of product authorisation SE-0001080-0000 issued by Swedish Chemicals Agency, in accordance with Article 5 of Icelandic Regulation No 878/2014 on biocidal products, that transposed Regulation (EU) No 528/2012 into Icelandic legislation.

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 30th June 2017 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 Appendices 1 and 2 – the

- relevant criteria for this biocidal, Bromadiolone Wax Block (compressed) (Rode Holræsavaxkubbar), authorisation applies as described therein.
2. Subject to compliance with the conditions as listed in Appendix 3, 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 31st August 2020, on the condition that the active substance is registered in EU list of approved active substances.

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

Application for renewal of the authorisation shall be submitted at the latest 28th February 2019 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 26 of the Icelandic Administrative Act No 37/1993

Appeals should be directed, within three months as of 30th June 2017, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland

Sincerely



Gunnlaug H. Einarsdóttir
Director



Elísabet Pálmadóttir
Advisor

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Confidential Biocidal Product Characteristics

Appendix 3: Conditions of Authorisation

Appendix 4: Product Assessment Report