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Streymi ehf.
Goðanesi 4
603 Akureyri

Reykjavik 24th November 2017
UST201707-031/B.G.
07.06.04

Authorisation for placing a biocidal Protect wax block extruded, on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of Protect wax block extruded on 2nd October 2014. The case was accepted by the agency on 22nd January 2016 and validated on 29th September 2017.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as bromadiolone is, as of 1st 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 Health and Safety Executive, UK.

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal products listed in Appendix 2, belonging to **Protect wax block extruded** on the market in Iceland, by mutual recognition of product authorisation UK-2013-0772 issued by Health and Safety Executive, UK, 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 24th November 2017 in the following terms:

1 The composition and formulation established for the biocidal product is detailed in the Summary of the Product Characteristics in Appendices 1 and 2 – the relevant criteria for this biocidal product authorisation applies as described therein.

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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 24th November 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

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