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> Reykjavík 19 December 2018 UST201809-120/H.I.I. 07.06.04

National authorisation of same biocidal product for the product Protect wax block extruded/Rode vaxkubbar/Músabaninn

The Environment Agency of Iceland (Umhverfisstofnun) received your application for national authorisation of the same biocidal product for Protect wax block extruded/Rode vaxkubbar/Músabaninn on 21st July 2017. The case was accepted by the agency on 3rd September 2018 and validated on 17th December 2018.

The Environment Agency of Iceland granted authorisation for mutual recognition in sequence to Protect wax block extruded, with authorisation number UST201707-031, on 24th November 2017 in accordance with the Icelandic Regulation No 878/2014 on biocidal products. The Agency has based the authorisation for same biocidal product on that authorisation as well as the application documents.

This authorisation is granted in exercise of the powers conferred by Articles 19(1) of Regulation (EU) No 528/2012 and Article 5 of Regulation (EU) No 414/2013 in accordance with Article 1(7) of Icelandic Regulation No 878/2014 on biocidal products, that implements Regulation (EU) No 414/2013 into Icelandic legislation.

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 19 December 2018 in the following terms:

- 1. 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 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 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 product 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 (enclosed in section 6, Other information, of Appendix 2), 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 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

Sigrún Ágústsdóttir

Director

Hafdis Inga Ingvarsdóttir Hafdís Inga Ingvarsdóttir Advisor

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Conditions of Authorisation