ENVIRONMENT AGENCY

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Reykjavík 19 June 2018
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07.06.04

Subject: Renewal of authorisation subject to mutual recognition for placing the biocidal product, Roban vaxkubbar, on the market in Iceland

The Environment Agency of Iceland (Umhverfisstofnun) received your application for renewal of national authorisation subject to mutual recognition of Roban vaxkubbar on 25th January 2017. The case was accepted by the agency on 13th June 2018 and validated on 18th June 2018.

The Agency based the evaluation on the application documents as well as the original authorisation of the United Kingdom, Health and Safety Executive.

The Environment Agency of Iceland hereby grants a renewal of authorisation for placing the biocidal product **Roban vaxkubbar** on the market in Iceland, by mutual recognition of product authorisation UK-2011-0065 issued by the United Kingdom, Health and Safety Executive, 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 is accessible under the authorisation in the R4BP 3 database.

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

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 UST20120300232 (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 Appendices 1 and 2 – the relevant criteria for this biocidal product authorisation apply as described therein.
3. Subject to compliance with the conditions as listed in Appendix 3, 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.

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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. 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
7. Subject to paragraphs 4 and 5, this authorisation remains in force until midnight of 17th April 2023, on the condition that the active substance is registered in EU list of approved active substances

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 19th June 2018, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland

Sincerely

Gunnlaug H. Einarsdóttir
Director

Hafdís Inga Ingvarsdóttir
Hafdís Inga Ingvarsdóttir
Advisor

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Confidential Biocidal Product Characteristics

Appendix 3: Conditions of Authorisation

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