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Reykjavík, 30 November 2023
UST202308-026/H.I.I.
07.06.04

Authorisation for placing the biocidal product PROTEO EC on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of national authorisation for the biocidal product PROTEO EC on 29 September 2022, Case No BC-RH080179-26. The case was accepted by the Agency on 21 August 2023 and validated on 26 September 2023.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as deltamethrin (CAS No 52918-63-5) was as of 1 October 2013, an approved active substance for product type 18 under Commission Directive 2011/81/EU repealed with Regulation (EU) No 528/2012, and Commission Implementing Decision (EU) 2023/1088 postponing the expiry date to 31 March 2026.

The Agency based the evaluation on the application documents as well as the national authorisation (NA-APP) of the reference Member State Spain.

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product **PROTEO EC** on the market in Iceland, by mutual recognition of product authorisation ES-0002081-0000 issued by the Ministry of Health in Spain 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 reference authorisation in the R4BP database.

This authorisation is granted in exercise of the powers conferred by Articles 17(3), 19(1) and 33(3) 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 **30 November 2023** in the following terms:

1. The composition and formulation established for the biocidal product is detailed in the Summary of the Product Characteristics (SPC) - the relevant criteria for this biocidal product authorisation applies as described therein.

2. Subject to compliance with the conditions as listed in the Appendix, the authorisation holder is authorised to place on the market the biocidal product detailed in the SPC for the use(s) set out in that document.
3. This authorisation and associated documents outlined in the SPC may be amended in accordance with Articles 48 and 50 of Regulation (EU) No 528/2012.
4. This authorisation and associated documents outlined in the SPC may be cancelled in the circumstances set out in Articles 48 and 49 of Regulation (EU) No 528/2012.
5. Subject to paragraphs 3 and 4, this authorisation remains in force until midnight of **25 September 2028**, 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 classified as hazardous according to Regulation (EU) No 1272/2008 (CLP), such labelling shall be in Icelandic (enclosed in section 6 of the SPC), cf. Article 4 of Regulation No 878/2014 on biocidal products and Article 32 of the Chemicals Act No 61/2013.

The Authorisation holder is obliged to notify the national Poison Centre (Eitrunarmiðstöð Landspítala) on the composition and toxic effects of **PROTEO EC** to make that information available in case of suspected poisonous effects, according to Article 21(4) of the Chemicals Act No 61/2013. A poison centre notification (PCN) to the ECHA submission portal¹ is sufficient.

This administrative decision may be appealed to the Minister of the Environment, Energy and Climate, 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 receipt of this decision, to the Ministry of the Environment, Energy and Climate, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely,

Hafdís Inga Ingvarsdóttir
Advisor

Skúli Þórðarson
Director

Appendix: Conditions of Authorisation

¹ [ECHA PCN submission portal](#).

Appendix

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).