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Authorisation for placing the biocidal product, SOMI, 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 SOMI on 11 March 2022. The case was accepted by the Agency on 1 June 2022 and validated on 15 September 2022.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as *deltamethrin* was as of *1 October 2013*, an approved active substance for product type 18 under Commission Directive 2011/81/EC

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

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product **SOMI** on the market in Iceland, by mutual recognition of product authorisation GR-0022120-0000 issued by Greece 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 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 **25 November 2022** 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.
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 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 Articles 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 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 **16 October 2027**, on the condition that the active substance is registered in the 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 Appendix 1), cf. Article 4 of Regulation No 878/2014 on biocidal products.

This administrative decision may be appealed before 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.

Conditions of Authorisation

A failure to comply with the conditions listed below 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).

Sincerely

Páll Jökull Þorsteinsson
advisor

Skúli Þórðarson
director