

Sharda Europe B.V.B.A  
Jozef Mertensstraat 142  
1702 Dilbeek  
Belgium

Reykjavik 13 June 2018  
201710-0113/H.I.I.  
07.06.04

**Subject: Authorisation for placing the biocidal product, Deltasect, on the market in Iceland by mutual recognition**

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of Deltasect on 7<sup>th</sup> August 2014. The case was accepted by the agency on 27<sup>th</sup> September 2017 and validated on 12<sup>th</sup> of June 2018.

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

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 an authorisation for placing the biocidal product **Deltasect** on the market in Iceland, by mutual recognition of product authorisation UK-0004421-0000 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), 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 13<sup>th</sup> June 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 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 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.

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 30<sup>th</sup> March 2027, 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, cf. Article 4 of Regulation No 878/2014 on biocidal products.

Application for renewal of the authorisation shall be submitted at the latest 26<sup>th</sup> September 2025 according to Article 31 of Regulation (EU) No. 528/2012.

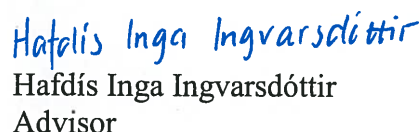
This administrative decision may be appealed before the Minister for the Environment and Natural Resources, in accordance with Article 26 of the Icelandic Administrative Act No 37/1993

Appeals should be directed, within three months from the receipt of this decision, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely



Gunnlaug H. Einarsdóttir  
Director



Hafdis Inga Ingvarsdóttir  
Hafdis Inga Ingvarsdóttir  
Advisor

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Confidential Biocidal Product Characteristics

Appendix 3: Conditions of Authorisation