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Reykjavík, 27. september 2019
UST201907-133/E.Þ.B.
07.06.04

Major change on request of national authorisation for the biocidal product Protect rodenticide wax block is approved

The Environment Agency of Iceland (Umhverfisstofnun) received your application for major change on request of national authorisation for the biocidal product *Protect paraffinos blokk (Protect wax block extruded)* on 15 February 2018. The case was accepted and validated by the Agency on 25 September 2019.

The biocidal product, Protect wax block extruded, is authorised in Iceland with the authorisation number IS-0017862-0000. This major change on request of national authorisation is granted in exercise of the powers conferred by Articles 50(2) of Regulation (EU) No 528/2012 and Article 8(7) of Regulation (EU) No 354/2013 (on changes) in accordance with Article 1(1)(6) of Icelandic Regulation No 878/2014 on biocidal products, which implemented Regulation (EU) No 354/2013 into Icelandic legislation.

We hereby confirm that we approve the notifications for the decreased content of the active substance, change in the pack size range, changes of the name of the biocidal product and change to the classification and labelling.

The notification concerns

- Decreasing the content of the active substance bromadiolone from 50 ppm to 27 ppm.
- Changing in the pack size range.
- Changing of the biocidal product name to Protect rodenticide wax block.
- Changes to the classification and labelling to comply with requirements of Regulation (EC) No 1272/2008.

as referred to in Title 3, Title 2 and sections 1 and 2 of Title 1 of the Annex to Regulation (EU) No 354/2013.

Accordingly, the Environment Agency of Iceland has made the relevant changes to the Summary of Product Characteristics (SPC) under asset number IS-0017862-0000. The updated SPC is attached as Appendix 1 – the relevant criteria for the biocidal product authorisation apply as described therein.

Sincerely

Hafdís Inga Ingvarsdóttir
Hafdís Inga Ingvarsdóttir
Advisor

Skúli Þórðarson
Skúli Þórðarson
Director