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Reykjavík, 17 October 2023
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07.06.04

Administrative change of national authorisation for the biocidal product AGITA® 10WG is approved

The Environment Agency of Iceland (Umhverfisstofnun) received your application for administrative change of national authorisation for the biocidal product AGITA® 10WG on 22.12.2022. The case was accepted by the Agency on 10.10.2023.

The biocidal product, AGITA® 10WG, is authorised in Iceland with the authorisation number UST201808-134.

The applied administrative changes concerns addition of the classification Repr. 2, hazard statement H361fd and the relevant precautionary statements as referred to in Section 2 of Title 1 of the Annex to Regulation (EU) No 354/2013. The change is notified following a change of classification of the active substance Thiamethoxam as set out in Annex VI of Regulation (EC) No 1272/2008 (CLP).

The Environment Agency of Iceland approves the notification for change to the classification and labelling in exercise of the powers conferred by Articles 50(2) of Regulation (EU) No 528/2012 and Article 6(4) 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.

This decision is based on the evaluation of Germany as the reference Member State.

Accordingly, the Environment Agency of Iceland has made the relevant changes to the Summary of Product Characteristics (SPC) under asset number IS-0019891-0000. The updated SPC is uploaded under the asset - the relevant criteria for the biocidal product authorisation apply as described therein.

The terms and conditions as stated in the authorisation letter dated 11 December 2018 still apply.

The Authorisation holder is obliged to notify the national Poison Centre (Eitrunarmiðstöð Landspítala) on the composition and toxic effects of AGITA®10WG 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 for the Environment, Energy and Climate, 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, Energy and Climate, Skuggasundi 1,101 Reykjavík, Iceland.

Sincerely,

Hafdís Inga Ingvarsdóttir
Advisor

Helga Ösp Jónsdóttir
Advisor

¹ [ECHA PCN submission portal](#)