Norwegian Environment Agency

Elanco Animal Health Inc.
Mattenstrasse 24A
4058 Basel
Switzerland

Oslo, 27.06.2023

Your ref.:

Our ref.:
2015/414

Contact person:
Sabrina Auvray

Partial acceptance of administrative change to the authorisation for Elanco Animal Health Inc. – AGITA® 10WG NO-2018-0153

We refer to the notification dated 22 December 2022 for administrative change to the authorisation of the biocidal product AGITA® 10WG, R4BP 3 case number BC-JS083269-08.

The application is part of a group submission with Germany acting as the reference Member State, R4BP3 case number BC-BX083251-23.

Decision

The Norwegian Environment Agency hereby accepts the notified administrative change concerning the addition of the classification H361fd to the product authorisation for AGITA® 10WG on the Norwegian market. However, the classification H319 was not supported (see below).

Terms and conditions for the change to the authorisation

The revised terms and conditions are described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0013205-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu). The terms and conditions as stated in the authorisation letter dated 04 September 2018 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the product label, an electronic copy of the revised label(s) for the relevant products shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no). The electronic copy of the label(s) must be submitted within three months from the date of this letter. Please mark the email with the authorisation number.

The approval is given in accordance with Article 6(4) of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR).

Norwegian Environment Agency

Background

Regulation (EU) No. 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedure for applications for administrative notifications to authorisations are set out in Article 6 of Regulation (EU) No 354/2013.

The notification concerns

Elanco Animal Health Inc. has notified an administrative change to the authorisation of AGITA® 10WG on the Norwegian market as a part of a group submission. The notified change, as referred to in Section 1 of Title 2 to the Annex to Regulation (EU) No 354/2013, concerns the modification of the classification of the product. Following a change of classification of Thiamethoxam (Annex VI of Regulation (EC) No 1272/2008 (17th ATP) and of one of the coformulant in the product, the classifications Repr. 2 H361fd and Eye irrit. 2 H319 are notified. The Repr. 2 H361fd classification is supported as Thiamethoxams concentration in the product is above the generic concentration limit for this classification. The classification Eye irrit. 2 H319 is not supported as an animal study submitted in the initial application did not result in a corresponding classification.

Evaluation by the Norwegian Environment Agency

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

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment.

An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen	Sabrina Auvray
Head of section	Senior adviser