Norwegian Environment Agency

MYLVA S.A.
Via Augusta, 48
08006 Barcelona
Spain

Oslo, 28.11.2023

Your ref.:	Our ref.: 2023/8604	Contact person: Ingrid Ur Gjerde

Acceptance of notification for MYLVA S.A. –Magnet Gel Silverfish – EU-0030315-0000

With reference to the notification 25 October 2023 for placing the biocidal product Magnet Gel Silverfish on the Norwegian market, R4BP 3 case number BC-UW089689-73. The notification is based on the simplified authorisation granted by the reference Member State Greece, R4BP3 asset number EU-0030315-0000.

Decision

The Norwegian Environment Agency hereby accepts the notification for placing on the market from MYLVA S.A. for the biocidal product Magnet Gel Silverfish on the Norwegian market. The authorisation is granted from 24 November 2023 to 6 October 2033 with the authorisation number EU-0030315-0000 (to be stated on the label).

Terms and conditions for the authorisation

The product is accepted in Norway under the terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0031798-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu).

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in Norwegian and in accordance with the terms and conditions provided in the final Norwegian SPC. This is the responsibility of the authorisation holder. Further requirements are described in Article 69, Article 70 and 72 of the BPR. An electronic copy of the label(s) for each authorised product shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the authorisation date. Please mark the email with the authorisation number.

All biocidal products on the Norwegian market shall be registered in the Norwegian Product Register in accordance with the Norwegian Biocide Regulation of 18 April 2017 No. 480 § 2-2, by using the biocide notification form. In addition, biocidal products which are classified as

hazardous according to Regulation (EC) No 1272/2008 (the CLP Regulation) shall be fully declared if they are sold in amounts of 100 kg or more per year. The forms to be used and further information can be found on our websitehttps://www.environmentagency.no/areas-of-activity/product-register/
The product can be placed on the Norwegian market in accordance with Article 27 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR).

Background

Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedures for simplified authorisations are set out in Article 25 and 26 of the BPR and the notifications for making available on the market in accordance the simplified procedure is described in Article 27 of the same regulation. These notifications shall be accepted under the same terms and conditions, including the expiry date, as the national authorisation granted by the reference Member State. The conditions for granting an authorisation of a biocidal product are laid down in Article 25 of the BPR. Additionally, the transitional measures given in Article 91 apply.

In general, a biocidal product is authorised for a period not exceeding 10 years in line with Article 17(4) of the BPR.

The application concerns

MYLVA S.A. has notified placing on the market of the biocidal product Magnet Gel Silverfish with reference to a simplified authorisation granted by the reference Member State Greece. The biocidal product contains the active substance D-Fructose and is for use in product type 19 (repellents and attractants). The authorisation holder in Norway is MYLVA S.A. The terms and conditions of the application are described in the submitted Norwegian SPC.

Evaluation by the Norwegian Environment Agency

The decision is based on the evaluation of the reference Member State. The Norwegian Environment Agency agrees with the reference Member State that the conditions to grant an authorisation laid down in Article 25 of the BPR are fulfilled for the biocidal product.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing stocks must be phased out in line with Article 89(4) of the BPR. The product shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

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Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the Norwegian Environment Agency (c.f., Article 47 of the BPR).

Changes to the authorisation

If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

Annual fee

For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us by email (biocides@miljodir.no) if you do not intend to place the product on the Norwegian market, and therefore should not be charged with the annual fee.

Renewal of application

An application for a renewal of the national authorisation must be submitted 550 days before the authorisation period expires, at the latest, according to Article 31(1) of the BPR.

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

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Head of Section	Adviser