

Sumitomo Chemical Agro Europe SAS
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Oslo, 18.01.2023

Your ref.:

Our ref.:
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Implementation of Union Authorisation for Sumitomo Chemical Agro Europe SAS – Pesguard® Gel – EU- 0024951-0000

With reference to the Commission Implementing Regulation (EU) 2021/1044 of 22 June 2021 granting a Union Authorisation for the biocidal product Pesguard® Gel and Commission Implementing Regulation (EU) 2022/2405 of 7 December 2022 correcting Implementing Regulation (EU) 2021/1044 as regards the period of validity, R4BP 3 case number BC-RX071722-02. The union authorisation by the reference Member State Netherlands, R4BP3 asset number EU-0024951-0000 is implemented in Norway.

Decision

The Norwegian Environment Agency hereby provides Sumitomo Chemical Agro Europe SAS an implementation of the union authorisation for the biocidal product Pesguard® Gel on the Norwegian market. The authorisation is granted from 15 July 2021 to 30 June 2026 with the authorisation number EU-0024951-0000 (to be stated on the label). Due to the incorrect validity period given initially in Implementing Regulation (EU) 2021/1044, the implementation of the union authorisation in Norway was postponed until receiving the Implementing Regulation (EU) 2022/2405.

Terms and conditions for the authorisation

The product is authorised 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-0027610-0000. The final SPC can also be found on the website of the European Chemicals Agency here: [Information on biocides - ECHA \(europa.eu\)](https://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, 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 website <https://www.environmentagency.no/areas-of-activity/product-register/>

The authorisation is given in accordance with Article 44(5) of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR) and the EEA agreement (annex II, chapter XV, 12n).

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 union authorisations are set out in Article 42, 43 and 44 of the BPR. According to the EEA agreement (annex II, chapter XV, 12n) the union authorisations shall be authorised in the EFTA States under the same terms and conditions as granted by the reference Member State. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 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. However, for authorisations that are mutual recognised, it is an agreement among the Member States that these authorisations shall have the same expiry date as the national authorisation granted by the reference Member State (c.f. CA-Sept14-Doc.5.7 –Final).

The application concerns

Sumitomo Chemical Agro Europe SAS has applied for a union authorisation for the biocidal product Pesguard® Gel on the European market. The biocidal product contains the active substances clothianidin and pyriproxyfen and is for use in product type 18 – Insecticides, acaricides and products to control other arthropods. The authorisation holder in Norway is Sumitomo Chemical Agro Europe SAS. The terms and conditions of the application are described in the submitted Norwegian SPC.

The reference Member State has identified the active substance clothianidin to be a candidate for substitution according to the conditions in Article 10(1) of the BPR. They have performed a comparative assessment in line with Article 23(1) and concluded that the criteria of Article 23(3) of the same regulations are not met. The product can therefore be authorised for a period not exceeding five years.

Evaluation by the Norwegian Environment Agency

This 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 19 of the BPR are fulfilled for the biocidal product.

Candidate of substitution

Due to the identified candidate of substitution, the Norwegian Environment Agency has performed a comparative assessment for the Norwegian market and considered the criteria for substitution in Article 23(3) of the BPR. The Norwegian Environment Agency considers that if the biocidal product was substituted, the chemical diversity would be inadequate to minimise the occurrence of resistance in the target organisms. We also consider that there are no sufficient alternative methods available to substitute the biocidal product. The product can therefore be authorised according to Article 23(6) of the same regulation.

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.

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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