

Lodi S.A.S.
Parc d'Activités des Quatre Routes
35390 Grand Fougeray
France

Oslo, 09.06.2023

Your ref.:

Our ref.:
2015/3482

Contact person:
Karina Petersen

Renewal of authorisation for LODI S.A.S. – DIGRAIN SPRAY – NO-2017-0138

With reference to the application dated 26 March 2021 for renewal of the biocidal product DIGRAIN SPRAY, R4BP 3 case number BC-CE065439-44. The application is a part of a group submission with France acting as the reference Member State, R4BP3 case number BC-QP065436-14.

Decision

The Norwegian Environment Agency hereby grants LODI S.A.S. a renewal of the authorisation for the biocidal product DIGRAIN SPRAY on the Norwegian market. The authorisation is renewed from 09 June 2023 to 11 January 2028 with the authorisation number NO-2017-0138.

Terms and conditions for the authorisation

The product is subject to mutual recognition 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-0017375-0000. 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/information-on-biocides).

The decision is based on the evaluation of the reference Member State, with the following derogations according to the national restrictions concerning use against certain target organisms. According to national restrictions, non-bait products for use against bed bugs, cockroaches, long-tailed silverfish, and pharaoh ants cannot be authorised for use by non-professionals. A derogation from mutual recognition is proposed for DIGRAIN SPRAY in accordance with art 37(1) (b) of the BPR, adjusting the terms and conditions of the authorisation by restricting the use area (target organisms to be controlled) in accordance with the national policy.

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 website <https://www.environmentagency.no/areas-of-activity/product-register/>

The authorisation is renewed in accordance with Article 31 and Article 37 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR) and Article 5 of Regulation (EU) No 492/2014 (renewal of authorisations of biocidal products).

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. In addition, Regulation (EU) No. 492/2014 regarding the rules and procedures for renewal of authorisation of biocidal products subject to mutual recognition supplements the Article 31 of the BPR.

These applications shall be renewed under the same terms and conditions as the national authorisation granted by the reference Member State.

The application concerns

LODI S.A.S. has applied for a renewal of authorisation for the biocidal product DIGRAIN SPRAY on the Norwegian market subject to mutual recognition. The biocidal product contains the active substance etofenprox and is for use in product type 18 – Insecticides, acaricides and products to control other arthropods. The authorisation holder in Norway is LODI S.A.S. The terms and conditions of the application are described in the submitted Norwegian SPC.

The reference Member State has identified the active substance etofenprox 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

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 organism(s). 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.

Derogation from mutual recognition

A derogation from the mutual recognition is made for the Norwegian authorisation in accordance with Article 37(1)(b) of the BPR, adjusting the terms and conditions of the authorisation by restricting the use area (target organisms to be controlled) in accordance with the national policy. According to national restrictions, non-bait products for use against bed bugs, cockroaches, long-tailed silverfish, and pharaoh ants are authorised for use by trained professionals only as these workers are considered to have the required knowledge, skills, and experience in handling of infestations of these especially challenging insects. The restrictions have been communicated to the applicant earlier in the evaluation process.

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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