



W. Neudorff GmbH KG
An der Mühle 3
31860 Emmerthal
Germany

Oslo, 18.01.2019

Your ref.:
[Your ref.]

Our ref. :
2014/4868

Contact person:
Erlend Spikkerud

Renewal of authorisation - NEU 1262 I (NO-2014-0079)

The Biocidal Regulation (EU) No 528/2012 (BPR), concerning the making available on the market and use of biocidal products, is implemented in Norwegian law through the Norwegian Biocides Regulation 18 April 2017 No 480. In addition, Regulation (EU) No 492/2014 regarding the rules for renewal of authorisation of biocidal products subject to mutual recognition supplementing Regulation (EU) No 528/2012 applies.

NEU 1262 I (NO-2014-0079) was granted a mutual recognition in Norway 29.10.2014. An application for renewal was submitted to the Norwegian Environment Agency through R4BP within the stipulated deadline, cf. R4BP Case No BC-CH034018-57.

Decision

The Norwegian Environment Agency considers the conditions to grant an authorisation laid down in Article 19 of the BPR as fulfilled.

Subject to Article 19 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants a renewal of the authorisation of NEU 1262 I.

The product is mutual recognised in Norway under the terms and conditions as described in the Summary Product Characteristic (SPC). The decision is based on the evaluation of the refMS (DK).

The authorisation concerns:

Product name:	NEU 1262 I
Trade name(s):	Loxiran Lokkeboks Mot Maur, Raid Optimal Maurlokkeboks, Plantasjen Lokkeboks Mot Maur
Active substance:	Spinosad
Product-type:	Insecticides, acaricides and products to control other arthropods (PT18)
Authorisation holder in Norway:	W. Neudorff GmbH KG
Authorisation number:	NO-2014-0079
Authorisation date:	29.10.2014

Renewal of authorisation: 18.01.2019
Expiry date: 14.11.2023

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder become aware of such information, the Norwegian Environment Agency should be notified without delay.

According to Article 31(1) of the Biocidal Products Regulation, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

Label

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the attached SPC. Furthermore, Article 69(1), (2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above mentioned documents is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the updated label with the Norwegian authorisation number NO-2014-0079 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Grace period for products with old labels

The decision on renewal of NEU 1262 I will repeal the previous authorisations for this product. The periods of grace in Article 52 applies. This means that products with old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date.

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.

Yearly fee

For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B to the Norwegian Biocide Regulation.

Registration in the Norwegian Product Register

All biocidal products must be registered in the Norwegian Product Register. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Further information can be found at

<http://miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/>.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Best regards

Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Erlend Spikkerud
Senior Adviser