



Vitax Limited
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Coalville, Leicestershire
LE67 3DE
United Kingdom

Oslo, 04.12.2015

Your ref.:
[Your ref.]

Our ref. :
2015/5844

Contact person:
Erlend Spikkerud

Authorisation of Nippon Maurmiddel - NO-2015-0109

We refer to your application for mutual recognition of the product Nippon Maurmiddel (case no. BC-YG012508-34 (2012/524/510/NO/AMR/8953)) containing the active substance spinosad.

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation 10 April 2014 No. 548. The conditions for granting an approval of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. To facilitate the renewal procedure in accordance with the Mutual Recognition Renewal Regulation, it is however agreed (CA-Sept14-Doc.5.7 -Final) that authorisations granted by the concerned member states should have the same expiry date as the authorisation which is mutually recognised.

Spinosad is, however, considered a candidate for substitution, since it meets two of the criteria for being a PBT (persistent and toxic, but not bioaccumulative). Under Article 23(1) of the BPR, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1), are required to perform a comparative assessment. The reference member state (UK) has performed a screening comparative assessment, and has concluded that the criteria of Article 23(3) of BPR are not met. The product can therefore be authorised for a period not exceeding 5 years.

Decision

Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Nippon Maurmiddel until 28 April 2020.

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.

The authorisation concerns:

Product name:	Nippon Maurmiddel
Active substance:	spinosad
Authorisation number:	NO-2015-0109
Authorisation date:	4 December 2015
Expiry date:	28 April 2020
Product type:	Insecticide - PT18
Authorisation holder in Norway:	Vitax Limited

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP. Please refer to the uploaded SPC in xml-format, as the automatically generated pdf-format seem generally to contain some mistakes.

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 come aware of such information, the Norwegian Environment Agency should be notified without delay.

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 SPC. Furthermore, Article 69(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 if relevant, translated correctly.

An electronic copy of the label with the Norwegian authorisation number NO-2015-0109 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) entered into force in Norway on 16 June 2012 and will apply for this product.

Phase-out of products with old labels:

According to Article 52 of the BPR, all products with old labels shall be phased out. 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. During this period, all advertising material related to products with old labels, should also be removed from the market. Any advertising for biocidal products must comply with Article 72 of the BPR and must include the sentences "Use biocides safely. Always read the label and product information before use."

Changes to the authorisation

If it is desirable to amend the information submitted with the application, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This 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 of the Norwegian Biocide Regulation for details. You will receive further information on this subject at a later stage.

Registration in the Norwegian Product Register

All biocidal products must be registered in the Product Register by using the biocide notification form. In addition, all biocidal products which are classified as hazardous must be fully declared, using the declaration form, if they are sold in amounts of 100 kg or more per year. Forms and 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 § 7 of the Norwegian Biocide Regulation. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with § 28 of the Norwegian Public Administration Act.

Yours sincerely,

Norwegian Environment Agency



Eli Vike
Head of Section



Erlend Spikkerud
Senior adviser