



Bayer AB
c/o Bayer A/S
Arne Jacobsens Allé 13
2300 Köpenhamn S
Denmark

Oslo, 19.12.2017

Your ref.:
[Your ref.]

Our ref. :
2017/13008

Contact person:
Astrid Gaustad

Authorisation of K-Othrine SC 25 Family – NO-2017-0142

We refer to your application for mutual recognition of the product K-Othrine SC 25 (R4BP3 case no. BC-EN013318-42), containing the active substance deltamethrin.

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 of 18 April 2017 No. 480. 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.

The product application for K-Othrine SC 25 was submitted as a frame formulation under Directive 98/8/EC and has been evaluated as an application for a biocidal product family (K-Othrine SC 25 family), in accordance with the BPR and the transitional measures in Article 91. A notification according to article 17(6) of the BPR must be submitted to the Norwegian Environment Agency if more family members (products) are added to the family. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. The composition must be within the defined range of the product family as given in the authorisation of the reference Member state.

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 granted by the reference Member State.

According to national restrictions, non-bait products for use against bed bugs, cockroaches 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. A derogation from mutual recognition is proposed for the product family K-Othrine SC 25 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 restrictions have been communicated to the applicant earlier in the evaluation process.

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 the product family K-Othrine SC 25 until 28.06.2027.

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 family name: K-Othrine SC 25
Product within the family/trade name: K-Othrine SC 25 (NO-2017-0142-01-01)
Active substance: Deltamethrin
Authorisation number: NO-2017-0142
Authorisation date: 19.12.2017
Expiry date: 28.06.2027
Product type: Insecticides, acaricides and products to control other arthropods – PT18
Authorisation holder in Norway: Bayer AB

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) for the biocidal product family apply. The SPC is uploaded to R4BP3. In some cases a PDF-file of the SPC is automatically generated in R4BP3. In such cases, please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file generally seems to contain some errors.

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 be 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 for the product shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

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 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 of the Norwegian Biocide Regulation for details.

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 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 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.

Yours sincerely,
Norwegian Environment Agency



Eli Vike
Head of Section



Astrid Gaustad
Senior Adviser

