NORWEGIAN ENVIRONMENT AGENCY

Zapi S.p.A.
Via Terza Strada 12
35026 Conselve (Pd)
ITALY
Att: Laura Bombonato

Oslo, 25.01.2017

Your ref.:
[Your ref.]

Our ref. :
2016/9631

Contact person:
Solveig Aamodt

Authorisation of Broditop Gel – NO-2017-0127

We refer to your application for mutual recognition of Broditop Gel (R4BP3 case no. BC-UF004504-48), containing the active substance brodifacoum.

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 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.

National restrictions for rodenticides containing anticoagulant active substances apply in Norway. These national restrictions are currently being revised. The restrictions are as communicated earlier in the evaluation process, however there is a change of the minimum package size for rodenticides containing second generation anticoagulant active substances, which is lowered from 8 kg to 3 kg.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. However, Broditop pasta contains the anticoagulant active substance brodifacoum. Hence, the product meets the criteria for exclusion. Furthermore, to facilitate the renewal procedure in accordance with the Mutual Recognition Renewal Regulation, it is 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.

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 Broditop Gel until 18.11.2020.

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.

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The authorisation concerns:

Product name:	Broditop Gel
Active substance:	Brodifacoum
Authorisation number:	NO-2017-0127
Authorisation date:	25.01.2017
Expiry date:	18.11.2020
Product type:	Rodenticides – PT14
Authorisation holder in Norway:	Zapi S.p.A.

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The minimum package size given in the SPC is 3 kg, in accordance with the revised national restrictions which will apply shortly. The authorisation of package sizes down to 3 kg is issued subject to the entry into force of the revised national restrictions. The SPC is uploaded in 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 mistakes.

The Norwegian Environment Agency may, in accordance with article 47 or 48 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 NO-2017-0127 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

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.

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 § 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

Solveig Aamodt
Senior Adviser