ZAPI S.p.A.
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Oslo, 27.06.2018

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2018/4790	Erlend Spikkerud

Authorisation of BRODITEC P-29F (NO-2018-0148)

We refer to your application for mutual recognition of BRODITEC P-29F (R4BP3 case no. BC-GD038628-44), 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 18 April 2017 No. 480. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR.

Decision
Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocides Regulation, the Norwegian Environment Agency grants an authorisation of BRODITEC P-29F.

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 (UK), with some adjustments according to the national restrictions concerning rodenticides containing anticoagulant active substances, cf. Article 37 of the BPR.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. In addition, Article 23(6) of the BPR sets that notwithstanding Article 17(4), and without prejudice to Article 23(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five 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.

The authorisation concerns:

Product name:	BRODITEC P-29F
Trade name(s):	Klerat®Softpasta, Muskil Fluo BF, DEVILTOP SENSITIVE PASTA PLUS FLUO, ZED BF SENSITIVE PASTA FLUO-NP, BRODITOP NEXT PASTA FLUO-NP, Klerat® Mykpasta, Klerat® Mykblokk, Klerat®Softblokk, BRODITOP SENSITIVE PASTA FLUO-NP, BRODITEC P-29F, BRODITOP NEXT PASTA PLUS FLUO-NP, RODIBROD SENSITIVE PASTA FLUO, ZED BF SENSITIVE PASTA PLUS FLUO-NP, DEVILTOP SENSITIVE PASTA FLUO, BRODITOP SENSITIVE PASTA PLUS FLUO-NP
Active substance:	Brodifacoum
Product type:	Rodenticides – PT 14
Authorisation number:	NO-2018-0148
Authorisation date:	27.06.2018
Expiry date:	15.02.2023

Authorisation holder in Norway: ZAPI S.p.A.

The SPC is uploaded to R4BP3. Please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file may contain 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.

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 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 is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the label with the Norwegian authorisation number NO-2018-0148 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

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.

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, and the information shall at any time be correct. 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.

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	Erlend Spikkerud
Head of Section	Senior Adviser