Norwegian Environment Agency

ZAPI S.p.A.
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Oslo, 09.06.2023

Your ref.:	Our ref.: 2020/8381	Contact person: Ingrid Ur Gjerde

Authorisation for ZAPI S.p.A. – HC6 EC – NO-2023-0245

With reference to your application for the biocidal product HC6 EC, R4BP 3 case number BC-HU059257-11. The application is a mutual recognition in parallel of the authorisation granted by the reference Member State France, R4BP3 case number BC-GV059252-20.

Decision

The Norwegian Environment Agency grants ZAPI S.p.A. an authorisation for the biocidal product HC6 EC on the Norwegian market. The authorisation is granted from 13 June 2023 to 11 February 2028 with the authorisation number NO-2023-0245.

The product is mutual recognised in Norway under the terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case NO-0030225-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu)

The decision is based on the evaluation of the reference Member State, with the following derogation concerning the removal of the professional user category in accordance with the Norwegian national restrictions for biocidal products in PT 18.

The authorisation is given in accordance with Article 34(6) and Article 37 of the BPR.

Terms and conditions for the authorisation

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in Norwegian and in accordance with the terms and conditions provided in the final Norwegian SPC. This is the responsibility of the authorisation holder. Further requirements are described in Article 69, Article 70 and 72 of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR). An electronic copy of the label(s) for each authorised product shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the authorisation date. Please mark the email with the authorisation number.

All biocidal products on the Norwegian market must be registered in the Norwegian Product Register in accordance with the Norwegian Biocide Regulation of 18 April 2017 No. 480 § 2-2, by using the biocide notification form. In addition, 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. The forms and further information can be found on our website https://www.environmentagency.no/areas-of-activity/product-register/

Background

Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedures for applications for mutual recognition in parallel of a national authorisation are set out in Article 34 of the BPR. These applications shall be authorised under the same terms and conditions as the national authorisation granted by the reference Member State, in line with Article 32 of the same regulation. 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.

In general, a biocidal product is authorised for a period not exceeding 10 years in line with Article 17(4) of the BPR. However, for authorisations that are mutual recognised, it is an agreement among the Member States that these authorisations shall have the same expiry date as the national authorisation granted by the reference Member State (c.f. CA-Sept14-Doc.5.7 –Final).

The application concerns

ZAPI S.p.A. has applied for an authorisation for the biocidal product HC6 EC on the Norwegian market as a mutual recognition. The biocidal product contains the active substances cypermethrin and imidacloprid and is for use in product type 18 (Insecticides, acaricides and products to control other arthropods). The authorisation holder in Norway is ZAPI S.p.A. The terms and conditions of the application are described in the submitted Norwegian SPC.

The reference Member State has identified the active substance imidacloprid to be a candidate for substitution according to the conditions in Article 10(1). They have performed a comparative assessment in line with Article 23(1) and concluded that the criteria of Article 23(3) of the same regulations are not met. The product can therefore be authorised for a period not exceeding five years.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency agrees with the reference Member State that the conditions to grant an authorisation laid down in Article 19 of the BPR are fulfilled for the biocidal product.

Derogation from mutual recognition

A derogation from the mutual recognition is made for the Norwegian authorisation in accordance with Article 37(1)(b) of the BPR. The derogation has been communicated to the applicant and agreed upon earlier in the evaluation process.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing stocks must be phased out in line with Article 89(4) of the BPR. The product shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the Norwegian Environment Agency (c.f., Article 47 of the BPR).

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.

Annual fee

For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us by email biocides@miljodir.no if you do not intend to place the product on the Norwegian market, and therefore should not be charged with the annual fee.

Renewal of application

An application for a renewal of the national authorisation must be submitted 550 days before the authorisation period expires, at the latest, according to Article 31(1) of the BPR.

Right to appeal

You can appeal this decision to the Ministry of Climate and Environment.

The complaint must be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Norwegian Environment Agency

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen	Ingrid Ur Gjerde
Head of Section	Adviser