Norwegian Environment Agency

Thor GmbH
Landwehrstrasse 1
D-67346 Speye, Rheinland-Pfalz
Germany

Oslo, 28.01.2022

Your ref.:

Our ref.:
2018/10196

Contact person:
Lina Agneberg Dahl

Authorisation - Acticide C1 (NO-2022-0222)

We refer to your application for mutual recognition in parallel of the biocidal product Acticide C1, R4BP 3 case number BC-TD041729-32, containing the active substance 5-chloro-2-methyl-2h-isothiazol-3-one (C(M)IT). The Norwegian Environment Agency hereby grants authorisation.

Background

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.

According to Article 55(2) of the BPR, a derogation can be made from point (a) of Article 19(1), and until an active substance is approved. Competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance. To facilitate the renewal procedure, 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.

Evaluation

The evaluating competent authority (France) has submitted a recommendation for approval of the new active substance and consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

The Norwegian Environment Agency considers the conditions to grant an provisional authorisation laid down in Article 55(2) of the BPR as fulfilled.

Decision

Subject to Articles 55(2) of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Acticide C1 until 16.03.2024.

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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 evaluating competent authority (France).

The authorisation concerns

Product name:	ACTICIDE C 1
Trade name(s):	ACTICIDE(R) C 1
Active substance(s):	5-chloro-2-methyl-2h-isothiazol-3-one (C(M)IT) *(CAS no.* 26172-55-4*)*
Product type:	PT6
Authorisation holder in Norway:	THOR GmbH
Authorisation number:	NO-2022-0222
Authorisation date:	28.01.2022
Expiry date:	16.03.2024

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3.

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 attached SPC. Furthermore, Article 69(1), (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-2022-0222 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Phase-out period of existing stocks, when relevant

In line with Article 89(4), existing products that do not comply with the conditions of this authorisation, 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.

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 using the e-mail address 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.

Registration in the Norwegian Product Register

All biocidal products on the Norwegian market must be registered in the Product Register 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. Forms and further information can be found on our website https://www.environmentagency.no/areas-of-activity/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.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen	Lina Agneberg Dahl
Head of Section	Adviser