

YOU Solutions Germany GmbH
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DE 30173 Hannover
Germany

Oslo, 12.01.2024

Your ref.:

Our ref.:
2015/956

Contact person:
Marianne Stave Sekkenes

Approval of major and minor change to the authorisation for YOU Solutions Germany GmbH – Tanalith E 8000 - NO-2018-0152

With reference to the application dated 22 December 2020 for major and minor changes to the authorisation of the biocidal product Tanalith E 8000, R4BP 3 case number BC-HP063641-30.

The application is a part of a group submission with France acting as the reference Member State, R4BP3 case number BC-MM063638-18.

Decision

The Norwegian Environment Agency hereby approves the application for the minor and major changes to the product authorisation for Tanalith E 8000 on the Norwegian market.

Terms and conditions for the authorisation

The revised terms and conditions as described in the final Norwegian Summary of Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0012779-0000. The final SPC can also be found on the website of the European Chemicals Agency here: [Information on biocides - ECHA \(europa.eu\)](#). The terms and conditions as stated in the authorisation letter dated 18 August 2018 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the label, an electronic copy of the revised label(s) for the relevant products shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the date of this letter. Please mark the email with the authorisation number.

The approval is given in accordance with Article 7(7) and Article 8(7) of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR).

Background

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No 480.

The procedure for applications for minor and major changes to authorisations are set out in Article 7(7) and Article 8(7) of Regulation (EU) No 354/2013.

The application concerns

YOU Solutions Germany GmbH has applied for minor and major changes to the authorisation of Tanalith E 8000 on the Norwegian market as a part of a group submission. The applied changes concerns exchanging the active substance copper carbonate (CAS no.: 12069-69-1) for granulated copper (CAS no. 7440-50-8) and addition of two new termite species (*Coptotermes* sp and *Heterotermes* sp) as target organisms. These changes are classified as major changes, in accordance with the criteria laid down in Title 3 of the Annex to Regulation (EU) No 354/2013. Additionally, a foaming agent (non-active substance) was changed, which is classified as a minor change, in accordance with the criteria laid down in Title 2 of the Annex to Regulation (EU) No 354/2013.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency considers the changes to be acceptable since Article 19 of the BPR still is fulfilled.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where an authorisation is changed, the existing stocks must be phased out in line with Article 52 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.

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment. An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Marianne Stave Sekkenes
Senior Adviser