

Certis Belchim BV  
Stadsplateau 16, 3521 AZ Utrecht,  
Netherlands

Oslo, 01.11.2023

Your ref.:

Our ref.:  
2019/5370

Contact person:  
Marianne Stave Sekkenes

## Approval of minor change to the authorisation for Certis Belchim BV – ENCLEAN RTU NO-2020-0195

With reference to the application dated 31 March 2022 for minor changes to the authorisation of the biocidal product ENCLEAN RTU, R4BP 3 case number BC-VS074822-03.

The application is a part of a group submission with France acting as the reference Member State, R4BP3 case number BC-NG074811-38.

### Decision

The Norwegian Environment Agency hereby approves the application for the minor changes to the product authorisation for ENCLEAN RTU on the Norwegian market.

### Terms and conditions for the authorisation

The revised terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0024535-0000. 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 11 September 2020 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](mailto: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) 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/major] changes to authorisations are set out in Article 7(7) of Regulation (EU) No 354/2013.

### **The application concerns**

Certis Belchim BV has applied for minor changes to the authorisation of ENCLEAN RTU on the Norwegian market as a part of a group submission. The applied changes concerns change in shelf life to three years, addition of new packaging and addition of an active substance supplier, and 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 decision is based on the evaluation of the reference Member State.

### 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