

Unichem d.o.o.  
Sinja Gorica 2  
SI 1360 Vrhnika  
Slovenia

Oslo, 14.04.2023

Your ref.:

Our ref.:  
2015/3091

Contact person:  
Karina Petersen

## Acceptance of administrative change to the authorisation for Unichem d.o.o. – EFFECT RODENT WAX BLOCKS E NO-2012-0020

With reference to the notification dated 16 February 2023 for administrative change to the authorisation of the biocidal product EFFECT RODENT WAX BLOCKS E, R4BP 3 case number BC-KS084597-01.

### Decision

The Norwegian Environment Agency hereby accepts the notified administrative change to the product authorisation for EFFECT RODENT WAX BLOCKS E on the Norwegian market.

### Terms and conditions for the change to the authorisation

The revised terms and conditions are described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0002359-0000. 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 28 September 2018 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the product 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)). The electronic copy of the label(s) must be submitted 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 6(4) 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 administrative notifications to authorisations are set out in Article 6 of Regulation (EU) No 354/2013.

### **The notification concerns**

Unichem d.o.o. has notified administrative change to the authorisation of EFFECT RODENT WAX BLOCKS E on the Norwegian market. The notified changes concern a change in the classification of the product, as referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013. The change is the result of regulation (EU) 2020/1182 (15. ATP) which changed the harmonised classification of the substance octhilinone (CAS no.: 26530-20-1) and the product. The product must be additionally labelled with H317: May cause an allergic skin reaction,

## Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency considers the change to meet the conditions in Title 1, Section 1 of Annex to Regulation (EU) no 354/2013 and therefore is acceptable.

## 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*

Karina Petersen  
Senior Adviser