



Unichem d.o.o.  
Sinja Gorika 2  
Vrhnika SI-1360  
Slovenia

Oslo, 09.10.2018

Your ref.:  
[Your ref.]

Our ref. :  
2015/3092

Contact person:  
Hilde Karin Midthaug

## **Renewal of authorisation – EFFECT RODENT PASTA BAIT - NO-2012-0021**

The Biocidal Regulation (EU) No 528/2012 (BPR), concerning the making available on the market and use of biocidal products, is implemented in Norwegian law through the Norwegian Biocides Regulation 18 April 2017 No 480. In addition, Regulation (EU) No 492/2014 regarding the rules for renewal of authorisation of biocidal products subject to mutual recognition supplementing Regulation (EU) No 528/2012 applies.

EFFECT RODENT PASTA BAIT - NO-2012-0021 was granted a mutual recognition in Norway 24.08.2012. An application for renewal was submitted to the Norwegian Environment Agency through R4BP 3 within the stipulated deadline, cf. Case No BC-DS030634-32.

### **Decision**

The Norwegian Environment Agency considers the conditions to grant an authorisation laid down in Article 19 of the BPR as fulfilled.

Subject to Article 19 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants a renewal of the authorisation of EFFECT RODENT PASTA BAIT.

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 refMS (UK), with some adjustments according to the national restrictions concerning rodenticides containing anticoagulant active substances, cf. Article 37 of the BPR.

### The authorisation concerns:

Product name:	EFFECT RODENT PASTA BAIT
Trade name(s):	Ratimor Dife pasta pose Profesjonell
Active substance:	Difenacoum
Product type:	Rodenticides – PT14
Authorisation holder in Norway:	Unichem d.o.o.
Authorisation number:	NO-2012-0021
Authorisation date:	24.08.2012

Renewal of authorisation: 09.10.2018

Expiry date: 17.07.2023

The SPC is uploaded to R4BP3. Please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file may contain errors.

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 become 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(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 updated label with the Norwegian authorisation number NO- 2012-0021 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address [biocides@miljodir.no](mailto:biocides@miljodir.no).

### Grace period for products with old labels:

The decision on renewal of EFFECT RODENT PASTA BAIT will repeal the previous authorisations for this product. The periods of grace in Article 52 applies. This means that products with old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date.

In addition, Commission Regulation (EU) 2016/1179 regarding the 9th Adaption to Technical and Scientific Progress (9<sup>th</sup> ATP) to the CLP regulation applies. The harmonised classification shall be adopted by 1 March 2018. The grace period indicated in Article 52 of the BPR cannot go beyond the date of implementation of the 9<sup>th</sup> ATP Regulation. It is the responsibility of the authorisation holder to ensure that the classification, labelling and packing of the product is in accordance with the CLP Regulation and Article 69 of the BPR.

Any advertising for biocidal products must comply with Article 72 of the BPR and must include the sentences "Use biocides safely. Always read the label and product information before use."

### **Changes to the authorisation**

The authorisation holder must submit an application/notification for any changes to the product authorisation 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 relevant fees for applications for change are given in appendix 1A to the Norwegian Biocide Regulation.

#### **Yearly fee**

For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B to the Norwegian Biocide Regulation.

#### **Registration in the Norwegian Product Register**

All biocidal products must be registered in the Product Register, and the information shall at any time be correct. In addition, all biocidal products which are classified as hazardous must be fully declared, if they are sold in amounts of 100 kg or more per year.

#### **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  
Head of Section

Hilde Karin Midthaug  
Senior Adviser