

SOPURA  
rue de Trazegnies 199,  
6180 COURCELLES, HAINAUT,  
Belgium

Oslo, 20.09.2022

Your ref.:

Our ref.:  
2022/8094

Contact person:  
Marianne Stave Sekkenes

## Implementation of Union Authorisation – SOPUROXID – EU-0026179-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product family SOPUROXID - EU-0026179-0000 in Norway, R4BP 3 Case number BC-YU077710-00, containing the active substance peracetic acid. 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 Biocides Regulation of 18 April 2017 No. 480.

The Norwegian Environment Agency refers to Commission Implementing Regulation (EU) 2022/964 of 10 June 2022 granting a Union authorisation for the biocidal product family SOPUROXID.

When the Commission grants a Union authorisation or decides that a Union authorisation has not been granted, the EFTA states will, according to the EEA agreement Annex II Chapter XV point 12n (e), simultaneously and within 30 days of the Commission Act take corresponding decisions.

### Decision

The Norwegian Environment Agency hereby grants authorisation for the biocidal product family SOPUROXID, issued in accordance with the Commission Implementing Regulation (EU) 2022/964 of 10 June 2022, cf. the Norwegian Biocides Regulation § 3-1.

### The authorisation concerns

Product family name: SOPUROXID  
Active substance(s): Peracetic acid (CAS no. 79-21-0.)

Product type: PT 2 – Disinfectants and algacides not intended for direct application to humans or animals  
PT 3 – Veterinary hygiene  
PT 4 - Food and feed area

Authorisation holder in Norway: SOPURA

Family authorisation number: EU-0026179-0000

Authorisation date: 20.09.2022

Expiry date: 30.06.2032

Product family member(s):

Product name	Authorisation number	Trade name(s)
SOPUROXID 5	EU-0026179-0001 1-1	SOPUROXID 5 HyPro Biocide 5-22 AGRIOXID 5 TECMA CUAR HPA
SOPUROXID 5C	EU-0026179-0002 1-1	SOPUROXID 5C DEPTIL TR 5 DIS OXI-5+ ANTI-GERM DES OXI-50 TC Peracid ATR + FOR-Acid TR + X-CID TR 50 +
SOPUROXID 3.2	EU-0026179-0003 1-2	SOPUROXID 3.2 HyPro Biocide 3.2-23
ACIDOFOAM CF	EU-0026179-0004 1-3	ACIDOFOAM CF HyPro Biocide 3.2-23a TECHMA OXI PB
SOPUROXID 15	EU-0026179-0005 1-4	SOPUROXID 15 HORTICLEAN 15 FORT AGRIOXID 15 HyPro Biocide 15-22
Oxypur CS	EU-0026179-0006 1-4	Oxypur CS

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP 3.

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 European authorisation number EU-0026179-0000 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). In case of a biocidal product family, please submit an electronic copy of the label for one individual product in each meta-SPC.

## 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](mailto: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 Norwegian 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 Norwegian Public Administration Act.

Best regards  
Norwegian Environment Agency

*This document has been signed electronically*

Trine-Lise Torgersen  
Head of Section

Marianne Stave Sekkenes  
Senior Adviser