

Brynsløkken Delitoppen 3 1540

1540 Oslo, 15.08.2022

Your ref.: Our ref.: Contact person: 2022/6833 Marit Espevik Randall

Authorisation of biocidal product family - Brynsløkken AS - CuO - family - NO-2022-0227

We refer to your application for authorisation of the biocidal product family Brynsløkken AS - CuO - family (R4BP3 case no. BC-RT036764-05), where Norway has acted as the reference Member State. The Norwegian Environment Agency hereby grants authorisation to the biocidal product family.

Background

The Biocidal Regulation (EU) No 528/2012 (Biocidal Products Regulation, BPR), concerning the making available on the market and use of biocidal products, is implemented in Norwegian law through the Norwegian Biocides Regulation 18th April 2017 No 480.

On December 23, 2017, the Norwegian Environment Agency received the initial application for authorisation of the biocidal product family "Brynsløkken AS - CuO - family". The biocidal product family consists of products for antifouling treatment of aquaculture fish nets (Product type 21, Antifouling products). The application was validated on April 20, 2018.

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 an authorisation for the biocidal product family "Brynsløkken AS - CuO - family".

The products may be placed on the marked under the terms and conditions as described in the Summary Product Characteristic (SPC). The decision is based on the evaluation of Norway acting as the reference Member State.

The authorisation concerns:

Product family name: Brynsløkken AS - CuO - family

Trade name(s): See table below

Active substances: Dicopper oxide (CAS no. 1317-39-1)

Product type: Antifouling products – PT21

Authorisation holder in Norway: Brynsløkken AS

Family authorisation number: NO-2022-0227



Authorisation date: 03.06.2022

Expiry date: 03.06.2032

Product family member(s):

| Product name | Authorisation number | Trade name(s) |
|-------------------------------|----------------------|-------------------------------|
| Notorius A12 (Red; Conc.) | NO-2022-0227-01-01 | Notorius A12 (Red; Conc.) |
| Notorius A12 (Black; Conc.) | NO-2022-0227-01-02 | Notorius A12 (Black; Conc.) |
| Alpha Net Gard (Red; Conc.) | NO-2022-0227-01-03 | Alpha Net Gard (Red; Conc.) |
| Alpha Net Gard (Black; Conc.) | NO-2022-0227-01-04 | Alpha Net Gard (Black; Conc.) |
| Notorius A (Yellow; Conc.) | NO-2022-0227-02-01 | Notorius A (Yellow; Conc) |
| Notorius A (Black; Conc.) | NO-2022-0227-02-02 | Notorius A (Black; Conc) |
| Notorius A15 (Red; Conc.) | NO-2022-0227-02-03 | Notorius A15 (Red; Conc) |
| Notorius A15 (Black; Conc.) | NO-2022-0227-02-04 | Notorius A15 (Black; Conc) |
| Notorius A12 (Red; RTU) | NO-2022-0227-03-01 | Notorius A12 (Red; RTU) |
| Notorius A12 (Black; RTU) | NO-2022-0227-03-02 | Notorius A12 (Black; RTU) |
| Alpha Net Gard (Red; RTU) | NO-2022-0227-03-03 | Alpha Net Gard (Red; RTU) |
| Alpha Net Gard (Black; RTU) | NO-2022-0227-03-04 | Alpha Net Gard (Black; RTU) |
| Notorius A (Yellow; RTU) | NO-2022-0227-04-01 | Notorius A (Yellow; RTU) |
| Notorius A (Black; RTU) | NO-2022-0227-04-02 | Notorius A (Black; RTU) |
| Notorius A15 (Red; RTU) | NO-2022-0227-04-03 | Notorius A15 (Red; RTU) |
| Notorius A15 (Black; RTU) | NO-2022-0227-04-04 | Notorius A15 (Black; RTU) |

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The agreed English SPC has been uploaded to R4BP. A translated version of this SPC to Norwegian language must be submitted within 3 weeks from the date of this letter.

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 BPR, 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 apply.

The authorisation holder is responsible for ensuring that the information given in the above-mentioned documents is accurate, and that the biocidal products are labelled in Norwegian, cf. Article 69(3) of the BPR.



An electronic copy of the updated label with the Norwegian authorisation number NO-2022-0227 shall be submitted to the Norwegian Environment Agency within three months from the acceptance of the translated SPC, using the email address biocides@miljodir.no.

Phase-out period of existing stocks, when relevant

In line with Article 89(4) of the BPR, 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 changes 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 if you do not intend to place the product (family) on the Norwegian market, and therefore should not be charged with the annual fee.

Registration in the Norwegian Product Register

All biocidal products must be registered in the Norwegian Product Register. 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. Further information can be found at 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 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 Marit Espevik Randall Head of section Senior adviser

