Norwegian Environment Agency

Jotun A/S
P.O.Box 2021,
NO-3202 Sandefjord,
Norway

21.09.2023

Your ref.:	Our ref.: 2017/13164	Contact person: Terje Haraldsen

Authorisation for Jotun A/S – Sea 1 – NO-2023-0253

We refer to your application for the biocidal product family Sea 1, R4BP 3 case number BC-SR036428-10. For this application, Norway has acted as the reference Member State.

Decision

The Norwegian Environment Agency grants Jotun A/S an authorisation for the biocidal product family Sea 1 on the Norwegian market. The authorisation is granted from 21.09.2023 to 21.09.2033 with the authorisation number NO-2023-0253.

The product family is authorised in Norway under the terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset no NO-0022018-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu).

Terms and conditions for the authorisation

For the products authorised under article 19(5) of the BPR, the authorisation holder must make sure that personal protective equipment is available at the point of sale and that information about the use of protective equipment is provided to the consumer.

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in Norwegian and in accordance with the terms and conditions provided in the final Norwegian SPC. This is the responsibility of the authorisation holder. Further requirements are described in Article 69, Article 70 and 72 of BPR. An electronic copy of the label(s) for each authorised product shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the authorisation date. Please mark the email with the authorisation number.

All biocidal products on the Norwegian market must be registered in the Norwegian Product Register in accordance with the Norwegian Biocide Regulation of 18 April 2017 No. 480 § 2-2, 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. The forms and further information can be found on our website https://www.environmentagency.no/areas-of-activity/product-register/

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Background

Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedures for applications for national authorisation are set out in Article 29 and 30 of the BPR. These applications shall be authorised under the same terms and conditions as the national authorisation granted by the reference Member State, in line with Article 32 of the same regulation. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

In general, a biocidal product is authorised for a period not exceeding 10 years in line with Article 17(4) of the BPR.

The application concerns

Jotun A/S has applied for an authorisation for the biocidal product family Sea 1 on the Norwegian market as a national authorisation. The Norwegian Environment Agency received the initial application for authorisation on December 20, 2017, and the application was validated on April 11, 2018. The biocidal product family contains the active substance dicopper oxide and is for use in product-type 21 - Antifouling products. The authorisation holder in Norway is Jotun A/S. The terms and conditions of the application are described in the submitted SPC.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency concludes that the conditions to grant an authorisation laid down in Article 19 of the BPR are fulfilled for the biocidal product family.

For use by non-professional users, there is an unacceptable effect on human health and, hence, Article 19(1)(iii) of the BPR is not fulfilled. However, not authorising for non-professionals would result in disproportionate negative impact for society when compared to the risk to human health. Therefore, use by non-professionals are authorised for the Norwegian market in line with Article 19(5) of the BPR. As a requirement, appropriate risk mitigation measures are set to ensure that the exposure to humans is minimised.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing stocks must be phased out in line with Article 89(4) 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.

Splitting of Biocidal Product families

There is an ongoing discussion with the EU Commission and the Competent Authorities on the splitting of biocidal product families that contain products both with approval in line with Articles 19(1) and 19(5) of the BPR. The outcome will probably be that such families must be split into separate families. At that time the Authorisation holder will be obliged to perform the necessary changes.

Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the Norwegian Environment Agency (c.f., Article 47 of the BPR).

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 by email 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.

Renewal of application

An application for a renewal of the national authorisation must be submitted 550 days before the authorisation period expires, at the latest, according to Article 31(1) of the BPR.

Right to appeal

You can appeal this decision to the Ministry of Climate and Environment.

The complaint must 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

Terje Haraldsen
Senior Adviser