Norwegian Environment Agency

Ecolab Deutschland GmbH
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40789
Germany

Oslo, 07.10.2022

Your ref.:	Our ref.: 2022/11242	Contact person: Ingrid Ur Gjerde

Implementation of Union Authorisation – Bioquell HPV-AQ – EU-0027469-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product Bioquell HPV-AQ – EU-0027469-0000 in Norway, R4BP 3 Case number BC-HP078854-12, containing the active substance hydrogen peroxide. 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) 2022/1226 of 14 July 2022, granting a Union authorisation for the biocidal product Bioquell HPV-AQ.

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 Bioquell HPV-AQ, issued in accordance with the Commission Implementing Regulation (EU) 2022/1226 of 14 July 2022, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns

Product name:	Bioquell HPV-AQ
Trade name(s):	Bioquell HPV-AQ
Active substance(s):	Hydrogen peroxide *(CAS no. 7722-84-1)*

Product type:	PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals PT 3 – Veterinary hygiene PT 4 - Food and feed area
Authorisation holder in Norway:	Ecolab Deutschland GmbH
Authorisation number:	EU-0027469-0000
Authorisation date:	07 October 2022
Expiry date:	31 July 2032

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-0027469-0000 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address 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 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

Ingrid Ur Gjerde
Head engineer