

Veltec Associates Inc. Europe
Rozengaard 1940
8212DT, Lelystad
Netherlands

Oslo, 15.06.2021

Your ref.:

Our ref.:
2021/6056

Contact person:
Karina Petersen

Norwegian Authorisation of the Union Authorised product family DEC-AHOL® Product Family - EU-0024324-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product family DEC-AHOL® Product Family – EU-0024324-0000 in Norway (R4BP3 case no BC-CN066591-33), containing the active substance propan-2-ol. 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) 2021/552 of 30 March 2021, granting a Union authorisation for the biocidal product family DEC-AHOL® Product Family.

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 DEC-AHOL® Product Family, issued in accordance with the Commission Implementing Regulation (EU) 2021/552 of 30 March 2021, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

Product family name: DEC-AHOL® Product Family
Active substance(s): Propan-2-ol (CAS no. 67-63-0)

Product-type: Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) – PT2

Authorisation holder in Norway: Veltek Associates Inc. Europe,

Family authorisation number: EU-0024324-0000

Authorisation date: 15.06.2021

Expiry date: 31.03.2031

Product family member(s):

Product name	Authorisation number	Trade name(s)
ALCOH-WIPE® PROCESS2WIPE® IPA70	EU-0024324-0001 1-1	ALCOH-WIPE® PROCESS2WIPE® IPA70
DEC-AHOL® AEROSOL WFI Formula	EU-0024324-0002 1-2	DEC-AHOL® AEROSOL WFI Formula
DEC-AHOL® WFI Formula DEC-AHOL® ASEPTI-CLEANSE	EU-0024324-0003 1-3	DEC-AHOL® WFI Formula DEC-AHOL® ASEPTI-CLEANSE
DEC-AHOL® AEROSOL WFI Formula Invertaspray	EU-0024324-0004 1-4	DEC-AHOL® AEROSOL WFI Formula Invertaspray

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3.

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.

For each meta-SPC an electronic copy of a representative label from one of the individual products belonging to that meta-SPC with the EU authorisation number EU-0024324-0000, shall be provided. The labels are to be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

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.

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/>

Best regards
Norwegian Environment Agency

This document has been signed electronically

Erlend Spikkerud
Head of Section, Biocides

Karina Petersen
Senior Adviser