

SALVECO S.A.S.
Avenue Pierre Mendès-France, Z.A. Hellioule 4, F 88100 SAINT DIE DES
VOSGES, France

Oslo, 24.03.2021

France
Your ref.:

Our ref.:
2021/3076

Contact person:
Marianne Stave Sekkenes

Acceptance of notification - Tork Hand Sanitizing Alcohol-Free Foam - EU-0025394-0000

We refer to your notification of placing on the market of the biocidal product Tork Hand Sanitizing Alcohol-Free Foam according to article 27 of the Regulation (EU) No 528/2012, R4BP 3 Case no BC-NS064891-08, containing the active substance lactic acid. The Norwegian Environment Agency hereby accepts your notification.

Background

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

According to Article 27(1) of Regulation (EU) No 528/2012 (BPR) the authorisation holder shall notify a product authorised under Article 26 of BPR to the Competent Authority in the member state at least 30 days before it is to be placed on the market in that member state.

Decision

Subject to Article 27(1) of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency hereby confirms that the product can be placed on the Norwegian market in accordance with the terms and conditions in the simplified product authorisation granted by MSCA Latvia 15.12.2020 until 07.06.2027.

The notification concerns:

Product name:	Tork Hand Sanitizing Alcohol-Free Foam
Trade name(s):	Tork Hand Sanitizing Alcohol-Free Foam
Active substance:	Lactic acid (CAS no. 200-018-0)
Product type:	PT 1 - Human hygiene
Authorisation holder in Norway:	Essity Hygiene and Health Aktiebolag
Authorisation number:	EU-0025394-0000
Date of acceptance of notification:	24.03.2021
Expiry date:	07.06.2027

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 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 label is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the label with the authorisation number EU-0025394-0000 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

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 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

Erlend Spikkerud
Head of Section Biocides

Marianne Stave Sekkenes
Senior Adviser