

Hygienix B.V.
Rijksstraatweg 104B,
3632 AD, Loenen aan de Vecht,
Netherlands

Oslo, 28.05.2021

Netherlands
Your ref.:

Our ref.:
2021/3035

Contact person:
Marianne Stave Sekkenes

Acceptance of notification – Hygienix Disinfecting Foam Wash DFWS-L-09191_06 – EU-0018737-0045

We refer to your notification of placing on the market of the biocidal product Hygienix Disinfecting Foam Wash DFWS-L-09191_06 according to Article 27 of the Regulation (EU) No 528/2012, R4BP 3 Case no BC-PC064798-26, containing the active substances sodium benzoate and (+)-tartaric 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 placed on the market in that Member State.

Decision

Subject to Article 27(1) of the BPR, cf. § 1-1 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 the Netherlands 31.05.2019 until 31.05.2029.

The notification concerns:

Product name:	Hygienix Disinfecting Foam Wash DFWS-L-09191_06
Trade name(s):	Hygienix Disinfecting Foam Wash DFWS-L-09191_06 The Ritual of Ayurveda anti-bacterial hand foam
Active substance:	Sodium benzoate (CAS no. 532-32-1) (+)-Tartaric acid (CAS no. 87-69-4)
Product type:	PT 1 - Human hygiene
Authorisation holder in Norway:	Hygienix B.V.
Authorisation number:	EU-0018737-0045
Date of acceptance of notification:	28.05.2021
Expiry date:	31.05.2029

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

Label

The authorisation holder must ensure that information on the label is in accordance with the conditions specified in Article 69(1) and (2) of the BPR. This includes information on e.g., dispensing units or systems, if applicable, to enable the proper use of the biocidal product in accordance with Article 17(5).

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-0018737-0045 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

Marianne Stave Sekkenes
Senior Adviser