

Hygienix B.V.  
Koninginneweg 8, 1217 KX, Hilversum, Netherlands

Oslo, 03.03.2022

Your ref.:

Our ref.:  
2022/1652

Contact person:  
Tonje Danielsen Rongved

## Acceptance of notification – Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 – EU- 0018737-0000

We refer to your notification of placing on the market of the biocidal product Hygienix Light Duty Cleaning and Disinfection Liquid according to Article 27 of the Regulation (EU) No. 528/2012, R4BP 3 Case number BC-NK072645-25, containing the active substance(s) (+)-Tartaric acid and Sodium benzoate. 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.

### Evaluation

The Norwegian Environment Agency considers the conditions laid down in Article 25 of the BPR as fulfilled.

### 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 Netherlands 31.05.2019 until 31.05.2029.

### The authorisation concerns

Product name: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008

Trade name(s): Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008

Active substance(s): 87-69-4, 532-32-1

Product type: PT02 – PT04

Authorisation holder in Norway: The Norwegian Environment Agency

Authorisation number: EU-0018737-0000

Date of acceptance of notification: 14.02.2022

Expiry date: 31.05.2029

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 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 Norwegian authorisation number EU-0018737-0000 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address [biocides@miljodir.no](mailto:biocides@miljodir.no).

## Phase-out period of existing stocks, when relevant

The decision on renewal of product will repeal the previous authorisations for this product. The periods of grace in Article 52 applies. This means that products with old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date.

## 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](mailto: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 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*

Trine-Lise Torgersen  
Head of Section

Tonje D. Rongved  
Senior adviser