



Pal Hygiene Products Limited
Unit 5B & Unit 5H,
Fingal Bay Business Park,
K32 NY57 Balbriggan, Co.Dublin,
Ireland

Oslo, 20.01.2020

Your ref.:
[Your ref.]

Our ref. :
2018/10832

Contact person:
Marianne Stave Sekkenes

Norwegian Authorisation of the Union Authorised product family Pal IPA Product Family - EU-0020463-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product family Pal IPA Product Family - EU-0020463-0000 in Norway (R4BP3 case no BC-VA056031-58), containing 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) 2019/2030 of 29 November 2019, granting a Union authorisation for the biocidal product family Pal IPA 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 Pal IPA Product Family, issued in accordance with the Commission Regulation (EU) 2019/2030 of 29 November 2019, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

Product family name:	Pal IPA Product Family
Active substances:	Propan-2-ol (CAS no 67-63-0)
Product type:	2, 4
Authorisation holder in Norway:	Pal Hygiene Products Limited
EU Authorisation family number:	EU-0020463-0000
Authorisation date:	20.01.2020
Expiry date:	30.11.2029
Product family member(s):	

Product name	EU Authorisation number	Trade name(s)
Alcohol Disinfectant Wipes	EU-0020463-0001	Medipal Alcohol Disinfectant Wipes Pal Tech Precision 70% IPA Wipes Pal TX IPA Surface Disinfectant Wipes

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-0020463-0000 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 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://tema.miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/>

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Marianne Stave Sekkenes
Senior Adviser