

Schuelke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany

Oslo, 13.04.2021

Your ref.:

Our ref.: 2021/3572 Contact person: Karina Petersen

Norwegian Authorisation of the Union Authorised product family perform-IPA - EU-0023656-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product family perform-IPA – EU-0023656-0000 in Norway (R4BP3 case no BC-JQ065162-30), 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) 2020/1991 of 27 November 2020, granting a Union authorisation for the biocidal product family perform-IPA.

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 perform-IPA, issued in accordance with the Commission Implementing Regulation (EU) 2020/1991 of 27 November 2020, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

| Product family name: | perform-IPA |
|---------------------------------|--|
| Active substance: | propan-2-ol (CAS no. 67-63-0) |
| Product type: | PT 2 – disinfectants and algicides not intended for direct |
| | application to humans or animals |
| | PT 4 – food and feed area |
| Authorisation holder in Norway: | Schülke and Mayr GmbH |
| Family authorisation number: | EU-0023656-0000 |
| Authorisation date: | 14.04.2021 |

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| Expiry date: Product family member(s): | 30.11.2030 | |
|---|----------------------|--|
| Product name | Authorisation number | Trade name(s) |
| Perform sterile alcohol IPA | EU-0023656-0001 1-1 | Perform® sterile alcohol IPA perform® classic alcohol IPA buraton® IPA perform® advanced alcohol IPA arcana® IPA clear IPA pure IPA disinfectant IPA Surface disinfection liquid classic sterile IPA mikozid® sterile liquid Surface disinfection liquid sterile |
| Perform® classic wipes IPA | EU-0023656-0002 1-2 | BTS 6000Perform classic wipes IPABuraton® wipes IPAPerform® advanced wipesIPAArcana® wipes IPAClear IPA wipesPure IPA wipesDisinfectant IPA wipesSurface disinfection wipesclassicPerform® sterile wipes IPASterile IPA wipesMikrozid® sterile wipesSurface disinfection wipessterile WipesSurface disinfection wipesSterile |
| Mikrozid® classic liquid | EU-0023656-0003 1-3 | Mikrozid® classic liquid Mikrozid® IPA liquid Surface Disinfection liquid pure |
| Mikrozid® classic wipes | EU-0023656-0004 1-4 | Mikrozid® classic wipes Mikrozid® IPA wipes Surface disinfection wipes classic |
| Kodan® wipes pure | EU-0023656-0005 1-5 | Kodan® wipes pure Schülke® classic wipes |
| Kodan® clean comfort wipes | EU-0023656-0006 1-6 | Schülke Hygiene-Tücher |



| | | SOS Desinfizierende |
|----------------|---------------------|------------------------------|
| | | Feuchttücher |
| | | SOS Hygiene-Tücher |
| | | Kodan® clean comfort wipes |
| | | Schülke clean comfort wipes |
| | | Hygiene-Tücher |
| | | Desinfizierende Feuchttücher |
| | | Desinfektionstücher |
| | | Clean comfort wipes |
| | | Disinfecting wipes |
| AntiLy 5 | EU-0023656-0007 1-7 | AntiLy 5 |
| AntiLy 6 | EU-0023656-0008 1-7 | AntiLy 6 |
| AntiLy 5 wipes | EU-0023656-0009 1-8 | AntiLy 5 wipes |
| AntiLy 6 wipes | EU-0023656-0010 1-8 | AntiLy 6 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-0023656-0000, 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 <u>biocides@miljodir.no</u>.

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 <u>biocides@miljodir.no</u> 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