

KiiltoClean Oy
Tengströminkatu 6
20360 Turku
Finland

Oslo, 15.03.2023

Your ref.:

Our ref.:
2022/8280

Contact person:
Sanne Helene Kristensen

Acceptance of administrative change to the authorisation for KiiltoClean Oy – Kiilto IPA Produkt Familie – NO-2021-0205

With reference to the notification dated 6 July 2022 for administrative change to the authorisation of the biocidal product (family) Kiilto IPA Produkt Familie, R4BP 3 case number BC-MK078515-25.

Decision

The Norwegian Environment Agency hereby accepts the notified administrative change(s) to the product authorisation for Kiilto IPA Produkt Familie on the Norwegian market.

Terms and conditions for the change to the authorisation

The revised terms and conditions are described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0026115-0000. The final SPC can also be found on the website of the European Chemicals Agency here: [Information on biocides - ECHA \(europa.eu\)](#). The terms and conditions as stated in the authorisation letter dated 25 March 2021 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the product label, an electronic copy of the revised label(s) for the relevant products shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no). The electronic copy of the label(s) must be submitted within three months from the date of this letter. Please mark the email with the authorisation number.

The approval is given in accordance with Article 6(4) of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR).

Background

Regulation (EU) No. 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedure for applications for administrative notifications to authorisations are set out in Article 6 of Regulation (EU) No 354/2013.

The notification concerns

KiiltoClean Oy has notified administrative changes to the authorisation of Kiilto IPA Produkt Familie on the Norwegian market. The notified changes concern the following addition, removal, and amendment of trade names, as referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013:

- Meta SPC 1 – addition of the trade name DAX Handdesinfektion ipa.
- Meta SPC 2 – change of the trade names Antibac Overflatedesinfeksjon Extra and DAX Overflatedesinfeksjon Extra to Antibac Overflatedesinfektion Extra and DAX Overflatedesinfektion Extra, respectively, and addition of the trade name Kiilto Pro Overflatedesinfektion Extra.
- Meta SPC 3 – addition of the trade names Antibac Overflatedesinfeksjon 45% IPA, DAX Ytdesinfektion Plus, and Kiilto Pro Ytdesinfektion Plus.
- Meta SPC 4 - removal of the trade name Antibac Desinfeksjonsserviett for overflater and addition of the trade names Antibac Overflatedesinfeksjon Plus and Kiilto Pro Overflatedesinfektion Plus.
- Meta SPC 5 – removal of the trade name DAX Desinfeksjonsservietter for overflater and addition of the trade names Antibac Desinfeksjon for overflater, Antibac Desinfeksjonsserviett for overflater IPA, and Kiilto Pro Desinfeksjonsserviett for overflater IPA.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency considers the changes to meet the conditions in Title 1, Section 1 of Annex to Regulation (EU) no 354/2013 and therefore are acceptable.

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment.

An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Sanne Helene Kristensen
Adviser