

Diversey Europe Operations B.V.
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Netherlands

Oslo, 06.12.2021

Your ref.:

Our ref.:
2017/8404

Contact person:
Marianne Stave Sekkenes

Acceptance of administrative change – Sure instant hand sanitizer – EU-0016940-0000

We refer to your notification for an administrative change to the biocidal product Sure instant hand sanitizer – EU-0016940-0000 notified for placing on the market, R4BP 3 Case number BC-UD071510-48. The Norwegian Environment Agency hereby accepts the notification.

Background

Regulation (EU) No. 528/2012 (Biocidal Product Regulation, BPR) concerning the making available on the market and use of biocidal product and Regulation (EU) No. 354/2013 concerning changes of biocidal products authorised under BPR are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

According to Article 27(1) of the 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. Since this biocidal product is placed on the Norwegian market under Article 27 of the BPR, the changes to the terms and conditions in the simplified product authorisation granted by Latvia will also apply to the notification in Norway.

Decision

We hereby confirm that we accept the notification of administrative changes to Sure instant hand sanitizer. The notification concerns addition of several product manufactures and an active substance manufacturer as referred to in Section 2 of Title 1 to the Annex to Regulation (EU) No 354/2013. No other changes than the above mentioned is accepted with this letter.

The revised Norwegian Summary of Product Characteristics (SPC) is uploaded to R4BP 3.

Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised

label with the Norwegian authorisation number EU-0016940-0000 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser