

Panzerglass
Delta 8,
DK-8382, Hinnerup,
Denmark

Oslo, 28.03.2022

Your ref.:

Our ref.:
2021/411

Contact person:
Lina Agneberg Dahl

Acceptance of major change – SPRAY Twice a Day – EU-0024114-0000

We refer to your notification for a major change to the biocidal product SPRAY Twice a Day – EU-0024114-0000 notified for placing on the market, R4BP 3 Case number BC-CM072540-44. The Norwegian Environment Agency hereby accepts the notification.

Background

According to Article 50 (2) in Regulation (EU) No. 528/2012 (Biocidal Product Regulation, BPR) concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be accepted by the Competent Authority. Changes to a product authorisation are further described in Regulation (EU) No. 354/2013.

Article 9 of Regulation (EU) No. 354/2013 states the following in case of an authorisation granted in accordance with Article 26 of the BPR. The authorisation holder or its representative shall notify each Member State, on the territory of which the biocidal product is made available, of notifications or applications made to the reference Member State in accordance with Article 6, 7 or 8 of this Regulation.

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. 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 Denmark will also apply to the notification in Norway.

Note that due to the current lack of option to register a SN-MAC task in R4BP 3, the major change is accepted as a SN-ADC task.

Decision

We hereby confirm that we accept the notification for a major change to SPRAY Twice a Day. The notification concerns inclusion of effect against enveloped virus, as referred to in Title 3 of the Annex to Regulation (EU) No 354/2013.

No other changes than the above mentioned is accepted with this letter. Apart from the changes outlined above, the terms and conditions as stated in the letter for acceptance of the notification dated 01.02.2021 apply.

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-00241 14-0000 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Lina Agneberg Dahl
Adviser