

Primmed BV
De Huchtstraat 14
1327 EE Almere
Netherlands

Oslo, 18.04.2023

Your ref.:

Our ref.:
2015/7162

Contact person:
Karina Petersen

Acceptance of administrative change to the authorisation for Primmed BV – Care Plus Anti Insect DEET Spray 50% NO-2015-0108

With reference to the notification dated 20 February 2023 for administrative change(s) to the authorisation of the biocidal product Care Plus Anti Insect DEET Spray 50%, R4BP 3 case number BC- XD084657-20.

Decision

The Norwegian Environment Agency hereby accepts the notified administrative change to the product authorisation for Care Plus Anti Insect DEET Spray 50% 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-0012788-0000. 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 30 September 2015 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

Primmed BV has notified administrative change(s) to the authorisation of Care Plus Anti Insect DEET Spray 50% on the Norwegian market. The notified changes concerns addition of the trade name: METODEDE MYGG & Flåttmiddel, as referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013.

Evaluation by the Norwegian Environment Agency

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

Karina Petersen
Senior Adviser