

Primmed BV  
De Huchtstraat 14  
1327 EE Almere  
Netherlands

Oslo, 09.12.2022

Your ref.:

Our ref.:  
2015/6965

Contact person:  
Ingrid Ur Gjerde

## Acceptance of administrative change to the authorisation for Primmed BV – Care Plus Anti Insect DEET Roll-on 30% - NO-2015-0106

We refer to the notification dated 5 October 2022 for administrative change to the authorisation of the biocidal product Care Plus Anti Insect DEET Roll-on 30%, R4BP 3 case number BC-PQ080439-08.

### Decision

The Norwegian Environment Agency hereby accepts the notified administrative change(s) to the product authorisation for Care Plus Anti Insect DEET Roll-on 30% 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-0012787-0000 apply. 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](mailto: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 to the authorisation of Care Plus Anti Insect DEET Roll-on 30% on the Norwegian market. The notified change concerns addition of trade name Metode Mygg Roll-on DEET 30%, 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 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

Ingrid Ur Gjerde  
Adviser