



Primmed BV
De Huchtstraat 14
1327 EE Almere
The Netherlands

Oslo, 14.10.2019

Your ref.:
[Your ref.]

Our ref. :
2015/6468

Contact person:
Marianne Stave Sekkenes

Amendment to the authorisation of Care Plus Anti Insect DEET Spray 20% - NO-2015-0105

We refer to your application for amendment to the authorisation of the biocidal product Care Plus Anti Insect DEET Spray 20% - NO-2015-0105], R4BP 3 Case no BC-LV051482-16, The Norwegian Environment Agency hereby amends the authorisation.

Background

According to Article 50(2) in Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products, the Competent Authority shall decide whether a change of an authorised biocidal product can be accepted with regard to ensuring compliance with Article 19 or, where relevant, Article 25, and whether terms and conditions of the authorisation need to be amended. Procedures for amendments to a product authorisation are further described in Regulation (EU) No. 354/2013.

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 amendment to the authorisation of Care Plus Anti Insect DEET Spray 20% concerns change in age restrictions and removal of the hazard statement H413 following the re-assessment by the reference member state, and is classified as a major change, in accordance with the criteria laid down in Title 3 of the Annex to Regulation (EU) No. 354/2013.

Decision

Subject to Articles 19 and 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency accepts the proposed changes to Care Plus Anti Insect DEET Spray 20% and amends the authorisation in conformity with these changes.

No other change(s) than the above mentioned is accepted with this letter. Apart from the changes outlined above, the terms and conditions as stated in the authorisation letter dated 30.09.2015 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP3.

Period of grace

In accordance with Article 52 of the BPR, when an authorisation is amended, the Competent Authority shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned, with effect from the date of this letter.

Label

In cases where the changes accepted 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 (final artwork) with the Norwegian authorisation number NO-2015-0105 to biocides@miljodir.no within three months from the date of this letter.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Best regards

Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of section

Marianne Stave Sekkenes
Senior adviser