NORWEGIAN ENVIRONMENT AGENCY

Tropenzorg B.V.
Postbus 1415
NL-1300 BK ALMERE
The Netherlands

Oslo, 30.09.2015

Your ref.:
[Your ref.]

Our ref. :
2015/6965

Contact person:
Kjetil Haugstad

Authorisation of Care Plus Anti-Insect DEET Roll-on 30% - NO-2015-0106

We refer to your application for mutual recognition of the product Care Plus Anti-Insect DEET Roll-on 30% (R4BP3 case no. BC-UV018263-12), and subsequent correspondence. Care Plus Anti-Insect DEET Roll-on 30% is an produkttype 19, containing the active substance N,N-diethyl-m-toluamide (DEET).

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation, Regulation of 10 April 2014 No. 548. The conditions for granting an approval of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

Decision
Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Care Plus Anti-Insect DEET Roll-on 30%.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. To facilitate the renewal procedure in accordance with the MR renewal Regulation, it is however agreed (CA-Sept14-Doc.5.7 -Final) that authorisations granted by the CMSs should have the same expiry date that the authorisation which is mutually recognised. Care Plus Anti-Insect DEET Roll-on 30% is thus authorised until 24.12.2024

According to Article 31(1) of the BPR, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

<u>The authorisation concerns:</u>

Product name: Care Plus Anti-Insect DEET Roll-on 30% (N,N-diethyl-m-toluamide (DEET) 30%)

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Authorisation number: NO-2015-0106

Authorisation date: 30.09.2015

Expiry date: 24.12.2024

Product type: 19

Authorisation holder in Norway: Primmed B.V.

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder come aware of such information, the Norwegian Environment Agency should be notified without delay.

Label

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the SPC. Furthermore, Article 69(2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above mentioned documents is accurate, and if relevant, translated correctly.

An electronic copy of the label with the Norwegian authorisation number shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) entered into force in Norway on 16 June 2012 and will apply for this product.

Phase-out of products with old labels:

According to Article 52 of the BPR, all products with old labels shall be phased out. This means that products with old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date. During this period, all advertising material related to products with old labels, should also be removed from the market. Any advertising for biocidal products must comply with Article 72 of the BPR and must include the sentences "Use biocides safely. Always read the label and product information before use.".

Changes to the authorisation

If it is desirable to amend the information submitted with the application, the authorisation holder must submit an application for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

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Yearly fee

For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. You will receive further information on this subject at a later stage.

Registration in the Norwegian Product Register

All biocidal products must be registered in the Product Register by using the biocide notification form. In addition, all biocidal products which are classified as hazardous must be fully declared, using the declaration form, if they are sold in amounts of 100 kg or more per year. Forms and further information can be found at http://www.miljodirektoratet.no/no/Tema/Kjemikalier/Produktregisteret/The_Product_Register/.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with § 7 of the Norwegian Biocide Regulation. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with § 28 of the Norwegian Public Administration Act.

Yours sincerely,
Norwegian Environment Agency

Eli Vike
Head of Section

Kjetil Haugstad
Senior Advisor