

Riga

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Primmed BV

De Huchtstraat 14, 1327 EE Almere, The Netherlands

On an authorisation of Care Plus Anti-Insect DEET Spray 40% through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by Tropenzorg BV on 20th February 2020 concerning an authorisation of Care Plus Anti-Insect DEET Spray 40% through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Care Plus Anti-Insect DEET Spray 40%** developed by the reference Member State – The Netherlands.

Therefore, in accordance with Article 33 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (regulation 528/2012) LEGMC authorises the Care Plus Anti-Insect DEET Spray 40% on the basis of mutual recognition process.

The authorisation holder for Care Plus Anti-Insect DEET Spray 40% in Latvia is:

Primmed BV.

Care Plus Anti-Insect DEET Spray 40% contains 40.0 % (w/w) of N,N-diethylmeta-toluamide (CAS No. 134-62-3; EC No. 205-149-7) as active substance.

LEGMC assigns the authorisation number for biocidal product Care Plus Anti-Insect DEET Spray 40%:

LV/2020/MR/013

The authorisation is valid until 24th December 2024.

The authorisation number shall be indicated on the label of the biocidal product.

The authorisation of Care Plus Anti-Insect DEET Spray 40% is granted on the following terms:

- Product type: 19 Repellents and attractants;
- Target organism: mosquitoes (Culicidae) and ticks (Ixodidae);
- Users: non-professionals;
- Product description: Ready-to-use spray;
- Product stability: shelf life 5 years.



The authorisation through mutual recognition applies only to the biocidal product Care Plus Anti-Insect DEET Spray 40% in the composition, form and packing material for which the first authorisation is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) of the Care Plus Anti-Insect DEET Spray 40% should be as it is indicated in the first authorisation of above mentioned biocidal product, taking into account also the information which is stated in the Product Assessment Report and Summary of Product Characteristics issued by reference Member State.

The information on the label shall be in Latvian.

Notwithstanding content of the label specified above, requirements stated in:

- Article 69 of regulation 528/2012,
- Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16
 December 2008 on classification, labelling and packaging of the substances and
 mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and
 amending Regulation (EC) No 1907/2006,
- all other relevant legislation shall be applied.

Primmed BV as the authorisation holder shall inform LEGMC about any changes in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18th April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

If the first authorisation issued by reference Member State is amended or revoked, the authorisation of **Care Plus Anti-Insect DEET Spray 40%** through mutual recognition may be re-opened for review before the 24th December 2024.

Additionally, LEGMC would like to inform that Primmed BV is fully responsible of the content of the biocidal product **Care Plus Anti-Insect DEET Spray 40%** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Primmed BV to notify the above mentioned information down to supply chain.

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