LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

Riga

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Merck KGaA

Frankfurter Strasse,
64293,
Darmstadt,
Germany

On an authorisation of Insect Repellent Lotion IR3535 10% through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by Merck KGaA on 29th September 2015 concerning an authorisation of **Insect Repellent Lotion IR3535 10%** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Insect Repellent Lotion IR3535 10%** developed by the reference Member State – Belgium.

Therefore, in accordance with Article 34 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 **Insect Repellent Lotion IR3535 10%** on the basis of mutual recognition process.

The authorisation holder for **Insect Repellent Lotion IR3535 10%** in Latvia is:

Merck KGaA.

Insect Repellent Lotion IR3535 10% contains **10 % (w/w)** of ethyl 3-[N-acetyl-N-butyl] aminopropionate (CAS No. 52304-36-6; EC No. 257-835-0) as active substance.

LEGMC assigns the authorisation number for biocidal product Insect Repellent Lotion IR3535 10% through mutual recognition:

LV/2019/MR/015

The authorisation of Insect Repellent Lotion IR3535 10% through mutual recognition is valid until 4th November 2029 based on reference Member State – Belgium decision.

The authorisation number of **Insect Repellent Lotion IR3535 10%** through mutual recognition shall be indicated on the label of the biocidal product.

The authorisation of **Insect Repellent Lotion IR3535 10%** through mutual recognition is granted on the following terms:

- Product type: 19 – Repellents and attractants;
- Target organism – mosquitoes *(Culicidae)* and ticks *(Ixodidae)*;
- Users: general public;
- Product description: emulsion, oil in water;

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- Product stability: shelf life - 18 months.

The authorisation through mutual recognition applies only to the biocidal product **Insect Repellent Lotion IR3535 10%** 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 **Insect Repellent Lotion IR3535 10%** 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.

LEGMC would like to recommend to add following sentence on to the label: Use product for infants only when disease vectors are present, recommended by reference Member State (Product Assessment Report Section 2.2.6.1.) .

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.

Merck KGaA 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 **Insect Repellent Lotion IR3535 10%** through mutual recognition may be re-opened for review before the 4th November 2029.

Additionally LEGMC would like to inform that Merck KGaA is fully responsible of the content of the biocidal product **Insect Repellent Lotion IR3535 10%** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Merck KGaA to notify the above mentioned information down to supply chain.

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