LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

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ACP Solutions BV
Unit 30, Flight Forum 40
5657 DB, Eindhoven
Netherlands

On an authorisation of the same biocidal product Free Lotion Plus

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **ACP Solutions BV** on 3rd November 2023 concerning an authorisation of **Free Lotion Plus** according to *Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and the Council (Regulation (EU) No 414/2013)*.

The reference product is **Insect Repellent Lotion IR3535 10%** (authorisation number - **LV/2019/MR/015**) authorised through mutual recognition in Latvia on 28th November 2019. Authorisation holder is **Merck KGaA**, Frankfurter Strasse 250, 64293, Darmstadt, Germany.

ACP Solutions BV submitted application for authorisation of a same biocidal product *Free Lotion Plus* according to Article 2 and 3(1) of the Regulation (EU) No 414/2013.

LEGMC accepted and agreed with proposed differences between ***Free Lotion Plus*** and ***Insect Repellent Lotion IR3535 10%*** that are the subject on an administrative change in accordance with *Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Regulation (EU) No 354/2013).*

Therefore, in accordance with Article 5 of Regulation (EU) No 414/2013 LEGMC grants the authorisation of the same biocidal product *Free Lotion Plus*.

Additional trade name for *Free Lotion Plus* in Latvia is *Gurkha Protec Lotion*.

The biocidal product *Free Lotion Plus* 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 **LV/2024/SB/002** for the biocidal product *Free Lotion Plus*.

The authorisation is valid until 4th November 2029.

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

The authorisation of *Free Lotion Plus* 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;
- Product stability: shelf life - 18 months.

The authorisation applies only to the same product *Free Lotion Plus* in the form, composition and packing according to the reference product *Insect Repellent Lotion IR3535 10%* for which the first authorisation is granted by reference Member State – Belgium.

The information on the label (and if applicable an enclosed instruction of use) of the *Free Lotion Plus* should be as it is indicated in the first authorisation for *Insect Repellent Lotion IR3535 10%*, considering Product Assessment Report, summary of Product Characteristics and proposed differences for same product.

The information on the label shall be in Latvian.

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

- Article 69 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 (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.

ACP Solutions BV as the authorisation holder shall inform LEGMC about any changes in accordance with *Regulation (EU) No 354/2013.*

Additionally, LEGMC would like to inform that ACP Solutions BV is fully responsible of the content of the biocidal product *Free Lotion Plus* as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask ACP Solutions BV to notify the above-mentioned information down to supply chain.

Head of Information Analysis Department signature* L. Abele

biocides@lvgmc.lv

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