



Rīga

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ACP Insect Repellents Ltd

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On an authorisation of the biocidal product Protec Active Insect Repellent

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **ACP Insect Repellents Ltd** on 29 October 2015 concerning an authorisation of **Protec Active Insect Repellent** through mutual recognition in parallel.

According to assessment made by reference Member States (rMS) – United Kingdom for **Protec Active Insect Repellent** all conditions according to Article 19(1) 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 (EU) No 528/2012) are met, except for Article 19(1)(b)(iii) where human health risk is unacceptable for children. However, rMS authorised **Protec Active Insect Repellent** for application on children according to Article 19 (5) of Regulation (EU) No 528/2012, with appropriate risk mitigation measures.

Article 19(5) of Regulation (EU) No 528/2012 assessment for the authorisation in Latvia shows that not authorising **Protec Active Insect Repellent** for application on children would result in disproportioned negative impact on society, therefore conditions of Article 19(5) are met and **Protec Active Insect Repellent** can be authorised for application on children with appropriate risk mitigation measures.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Protec Active Insect Repellent** developed by the rMS.

Therefore, in accordance with Article 34 of Regulation (EU) No 528/2012, LEGMC authorises the **Protec Active Insect Repellent** on the basis of mutual recognition process.

The authorisation holder for **Protec Active Insect Repellent** in Latvia is:

ACP Insect Repellents Ltd

Additional trade names for **Protec Active Insect Repellent**:

- FREE Repellent Active Spray
- Free Active Spray.

The biocidal product **Protec Active Insect Repellent** contains active substance *ethyl butylacetylaminopropionate* (CAS No 52304-36-6, EC No 257-835-0), concentration **20,0%**.

LEGMC assigns the authorisation number for biocidal product Protec Active Insect Repellent:

LV/2021/MR/017

The authorisation is valid until 26 January 2030.

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

The authorisation of **Protec Active Insect Repellent** through mutual recognition is granted on the following terms:

- Product type: 19 – Repellent;
- Target organisms: *Culicidae* - Mosquitos;
- Users: general public;
- Use conditions: The product is authorised according to Article 19 (1) of Regulation (EU) No 528/2012 for application on adults once a day and according to Article 19 (5) of Regulation (EU) No 528/2012 for application on children once a day. Applicable risk mitigation measures to minimize human exposure for application on children once a day:
 - An adult should apply the product to children below 12 years of age;
 - Do not use on children's hands;
 - Product can be used only on children older than 1 year.
- Product description: ready to use spray to repel mosquitos from human skin;
- Product stability: shelf life 24 months;
- Use area: indoor and outdoor areas;
- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the product **Protec Active Insect Repellent** in the composition, form and packing for which the authorisation for **Protec Active Insect Repellent** is granted by rMS.

The information on the label (and if applicable an enclosed instruction of use) of the **Protec Active Insect Repellent** should be as it is indicated in the authorisation of above-mentioned product, taking into account also the information which is stated in the Product Assessment Report and Summary of Product Characteristics issued by rMS.

The information on the label shall be in Latvian.

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

- *Article 69 Regulation (EU) No 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.

ACP Insect Repellents Ltd 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 rMS is amended or revoked, the authorisation of **Protec Active Insect Repellent** through mutual recognition may be re-opened for review before 26 January 2030.

Application on renewal of an authorisation shall be submitted according to *Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition.*

Additionally, LEGMC would like to inform that ACP Insect Repellents Ltd is fully responsible of the content of the biocidal product **Protec Active Insect Repellent** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask ACP Insect Repellents Ltd to notify the above-mentioned information down to supply chain.

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