



Rīga

08.06.2021 Nr. 4-6/847

**Bábolna Bioenvironmental
Centre Ltd.**

Szállás u. 6.
H-1107, Budapest
Hungary

On an authorisation of PROTECT PRO rodenticide fresh bait through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Bábolna Bioenvironmental Centre Ltd.** on 16th October 2020 concerning an authorisation of **PROTECT PRO rodenticide fresh bait** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **PROTECT PRO rodenticide fresh bait** developed by the reference Member State – Hungary.

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 **PROTECT PRO rodenticide fresh bait** on the basis of mutual recognition process.

The authorisation holder for **PROTECT PRO rodenticide fresh bait** in Latvia is:

Bábolna Bioenvironmental Centre Ltd.

PROTECT PRO rodenticide fresh bait contains **0.005 % (w/w)** of bromadiolone (CAS No. 28772-56-7; EC No. 249-205-9) as active substance.

LEGMC assigns the authorisation number for biocidal product PROTECT PRO rodenticide fresh bait:

LV/2021/MR/006

The authorisation is valid until 31st December 2024.

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

The authorisation of **PROTECT PRO rodenticide fresh bait** through mutual recognition is granted on the following terms:

- Product type: 14 – Rodenticides;
- Target organism – house mice (*Mus musculus*) and brown rat (*Rattus norvegicus*);
- Users: professionals and trained professionals;

- Product description: Ready-to-use bait - paste;
- Product stability: shelf life – 24 months;
- Use area: indoors and outdoors around buildings.

The authorisation through mutual recognition applies only to the biocidal product **PROTECT PRO rodenticide fresh bait** 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 **PROTECT PRO rodenticide fresh bait** 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.

Bábolna Bioenvironmental Centre Ltd. 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 **PROTECT PRO rodenticide fresh bait** through mutual recognition may be re-opened for review before the 31st December 2024.

Additionally, LEGMC would like to inform that Bábolna Bioenvironmental Centre Ltd. is fully responsible of the content of the biocidal product **PROTECT PRO rodenticide fresh bait** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Bábolna Bioenvironmental Centre Ltd. to notify the above mentioned information down to supply chain.

Head of Information Analysis Department



A. Jantone

biocides@lvgmc.lv

