



1st March, 2018
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Riga

**Bábolna Bioenvironmental
Centre Ltd.**

Szállás u. 6., H-1107
Budapest
Hungary

On an authorisation of Protect Sensation through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Bábolna Bioenvironmental Centre Ltd.** on 8th January 2018 concerning an authorisation of **Protect Sensation** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Protect Sensation** developed by the reference Member State – United Kingdom.

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 Sensation** on the basis of mutual recognition process.

The authorisation holder for **Protect Sensation** in Latvia is:

Bábolna Bioenvironmental Centre Ltd.

Protect Sensation 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 Sensation through mutual recognition:

LV/2018/MR/004

The authorisation of Protect Sensation through mutual recognition is valid until 1st February 2021 based on reference Member State – United Kingdom decision.

The authorisation number of **Protect Sensation** through mutual recognition shall be indicated on the label of the biocidal product.

The authorisation of **Protect Sensation** through mutual recognition is granted on the following terms:

- Product type: 14 – Rodenticides;
- Target organisms: house mouse – juveniles and adults – *Mus musculus*, brown rat - juveniles and adults – *Rattus norvegicus*;
- Users: professional, trained professional;
- Product description: ready for use bait;
- Product stability: shelf life - 2 years;
- Use area: indoor and outdoor areas;

- Packaging size: packaging sizes and materials are indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the biocidal product **Protect Sensation** in the composition, form and packing material for which the first authorisation is granted by reference Member State to **Protect Sensation**.

The information on the label (and if applicable an enclosed instruction of use) of the **Protect Sensation** 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 (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.

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 Sensation** through mutual recognition may be re-opened for review before the 1st February 2021.

Additionally LEGMC would like to inform that Bábolna Bioenvironmental Centre Ltd. is fully responsible of the content of the biocidal product **Protect Sensation** 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.

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