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Riga

PelGar International Limited

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On an authorisation of Roban Control Whole Wheat Bait through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **PelGar International Limited** on 10th May 2018 concerning an authorisation of **Roban Control Whole Wheat Bait** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Roban Control Whole Wheat Bait** 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 **Roban Control Whole Wheat Bait** on the basis of mutual recognition process.

The authorisation holder for **Roban Control Whole Wheat Bait** in Latvia is:

PelGar International Limited.

Additional trade name for **Roban Control Whole Wheat Bait** in Latvia are:

– *Mumia.*

Roban Control Whole Wheat Bait contains 0.0025 % (w/w) of difenacoum (CAS No. 56073-07-5; EC No. 259-978-4) as active substance.

LEGMC assigns the authorisation number for biocidal product Roban Control Whole Wheat Bait through mutual recognition:

LV/2018/MR/013

The authorisation of Roban Control Whole Wheat Bait through mutual recognition is valid until 9th January 2023 based on reference Member State – United Kingdom decision.

The authorisation number of **Roban Control Whole Wheat Bait** through mutual recognition shall be indicated on the label of the biocidal product.

The authorisation of **Roban Control Whole Wheat 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: trained professional, professional and general public;
- Product description: Grain bait ready for use;

- Product stability: shelf life - 2 years;
- Use area: indoor, outdoor around buildings, outdoor open areas & waste dumps and sewers;

The authorisation through mutual recognition applies only to the biocidal product **Roban Control Whole Wheat 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 **Roban Control Whole Wheat 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.

PelGar International Limited 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 **Roban Control Whole Wheat Bait** through mutual recognition may be re-opened for review before the 9th January 2023.

Additionally LEGMC would like to inform that PelGar International Limited is fully responsible of the content of the biocidal product **Roban Control Whole Wheat Bait** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask PelGar International Limited to notify the above mentioned information down to supply chain.

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