



Rīga

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Bayer A/S

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Denmark

On an authorisation of the biocidal product Harmonix Rodent Paste

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Bayer A/S** on 13 July 2021 concerning an authorisation of **Harmonix Rodent Paste** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Harmonix Rodent Paste** developed by the reference Member States – Germany.

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 (EU) No 528/2012), LEGMC authorises the **Harmonix Rodent Paste** on the basis of mutual recognition process.

The authorisation holder for **Harmonix Rodent Paste** in Latvia is:

Bayer A/S

Harmonix Rodent Paste contains **0.077 %** of *cholecalciferol* (CAS No. 67-97-0, EC No. 200-673-2) as an active substance.

LEGMC assigns the authorisation number for biocidal product Harmonix Rodent Paste:

LV/2021/MR/015

The authorisation is valid until 24 July 2025.

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

The authorisation of **Harmonix Rodent Paste** through mutual recognition is granted on the following terms:

- Product type: 14 – Rodenticides;
- Target organism: Norway rat (*Rattus norvegicus*) - adults and juveniles; Roof rat (*Rattus rattus*) – adults and juveniles; House mouse (*Mus musculus*) – adults and juveniles.
- Users: professional, trained professional;
- Product description: ready-to-use bait to be used in tamper-resistant bait stations;
- Product stability: 36 months;
- Field of use:
For professional: indoor; outdoor around buildings.

For trained professional: indoor; outdoor around buildings; outdoor open areas & waste dumps.

- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the product **Harmonix Rodent Paste** in the composition, form and packing for which the first authorisation is granted by reference Member State to **Harmonix Rodent Paste**.

The information on the label (and if applicable an enclosed instruction of use) of the **Harmonix Rodent Paste** should be as it is indicated in the first 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 reference Member State.

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.

Bayer A/S 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 **Harmonix Rodent Paste** through mutual recognition may be re-opened for review before 24 July 2025.

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 Bayer A/S is fully responsible of the content of the biocidal product **Harmonix Rodent Paste** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Bayer A/S to notify the above mentioned information down to supply chain.

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