

16th October 2018

Riga

Activa s.r.l.

Via Feltre, 32, 20132, Milano, Italy

On an authorisation of ACTIPASTA-BROD through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by Activa s.r.l. on 27th July 2018 concerning an authorisation of ACTIPASTA-BROD through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for ACTIPASTA-BROD developed by the reference Member State – Italy.

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 ACTIPASTA-**BROD** on the basis of mutual recognition process.

The authorisation holder for ACTIPASTA-BROD in Latvia is:

Activa s.r.l..

Additional trade name for ACTIPASTA-BROD in Latvia are:

- NEO-ACTIPASTA-BROD.

ACTIPASTA-BROD contains 0.0025 % (w/w) of brodifacoum (CAS No. 56073-10-0; EC No. 259-980-5) as active substance.

LEGMC assigns the authorisation number for biocidal product ACTIPASTA-BROD through mutual recognition:

LV/2018/MR/021

The authorisation of ACTIPASTA-BROD through mutual recognition is valid until 31st December 2022 based on reference Member State - Italy decision.

The authorisation number of ACTIPASTA-BROD through mutual recognition shall be indicated on the label of the biocidal product.

The authorisation of ACTIPASTA-BROD 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: professional and general public;
- Product description: Paste bait ready-to-use;
- Product stability: shelf life 2 years;
- Use area: indoor, outdoor around buildings;



The authorisation through mutual recognition applies only to the biocidal product **ACTIPASTA-BROD** 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 **ACTIPASTA-BROD** 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.

Activa s.r.l. 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 **ACTIPASTA-BROD** through mutual recognition may be re-opened for review before the 31st December 2022.

Additionally LEGMC would like to inform that Activa s.r.l. is fully responsible of the content of the biocidal product **ACTIPASTA-BROD** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Activa s.r.l. to notify the above mentioned information down to supply chain.

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