



Rīga

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ZAPI S.p.A.

via Terza Strada 12
35026, Conselve,
Padova, Italy

On an authorisation of BRODITEC P-17F through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **ZAPI S.p.A.** on 29th April 2020 concerning an authorisation of **BRODITEC P-17F** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **BRODITEC P-17F** developed by the reference Member State – France.

Therefore, in accordance with Article 34 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 **BRODITEC P-17F** on the basis of mutual recognition process.

The authorisation holder for **BRODITEC P-17F** in Latvia is:

ZAPI S.p.A.

BRODITEC P-17F contains **0.0017 % (w/w)** of 3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin (**Brodifacoum**) (CAS No. 56073-10-0; EK Nr. 259-980-5) as active substance.

The additional trade names of **BRODITEC P-17F** in Latvia are: Broditop Strike PF, Broditop Matrix PF, Broditop LC PF, Zed Strike PF, Zed Matrix PF, Zed LC PF, Rodibrod Strike PF, Rodibrod Matrix PF, Rodibrod LC PF, Protemax Strike PF, Protemax Matrix PF, Protemax LC PF, Deviltop Strike PF, Deviltop Matrix PF, Deviltop LC PF, ZAPI-TOP Strike PF, ZAPI-TOP Matrix PF, ZAPI-TOP LC PF, ZAPI-RAT Strike PF, ZAPI-RAT Matrix PF, ZAPI-RAT LC PF, Muskil PR, Deviltop PR, Broditop PR, Rodibrod PR.

LEGMC assigns the authorisation number for biocidal product BRODITEC P-17F:

LV/2023/MR/006

The authorisation is valid until 16th February 2028.

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

The authorisation of **BRODITEC P-17F** through mutual recognition is granted on the following terms:

- Product type: 14 – rodenticides;
- Target organisms – house mouse (*Mus musculus*), brown rat (*Rattus norvegicus*), black or roof rat (*Rattus rattus*);

- Users: professionals, trained professionals and general public;
- Use area: indoor and outdoor around buildings;
- Product description: bait (ready for use pasta);
- Product stability: shelf life – 2 years;
- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the biocidal product **BRODITEC P-17F** 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 **BRODITEC P-17F** 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.

ZAPI S.p.A. 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 **BRODITEC P-17F** through mutual recognition may be re-opened for review before the 16th February 2028.

Additionally, LEGMC would like to inform that **ZAPI S.p.A.** is fully responsible of the content of the biocidal product **BRODITEC P-17F** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask **ZAPI S.p.A.** to notify the above-mentioned information down to supply chain.

Head of Information Analysis Department

L. Abele

biocides@lvgmc.lv

