

Riga

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Bábolna Bioenvironmental Centre Ltd.

> Szállás u. 6. H-1107, Budapest Hungary

On an authorisation of Biopren mosquito larvicide tablet through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Bábolna Bioenvironmental Centre Ltd.** on 31st August 2015 concerning an authorisation of **Biopren mosquito larvicide tablet** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Biopren mosquito larvicide tablet** developed by the reference Member State – Italy.

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 **Biopren mosquito larvicide tablet** on the basis of mutual recognition process.

The authorisation holder for **Biopren mosquito larvicide tablet** in Latvia is:

Bábolna Bioenvironmental Centre Ltd.

Biopren mosquito larvicide tablet contains **0.50** % (w/w) of S-methoprene (CAS No.: 65733-16-6; EC No.: not indicated) as active substance.

LEGMC assigns the authorisation number for biocidal product Biopren mosquito larvicide tablet:

LV/2021/MR/003

The authorisation is valid until 20th January 2031.

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

The authorisation of **Biopren mosquito larvicide tablet** through mutual recognition is granted on the following terms:

- Product type: 18 Insecticides, acaricides and products to control other arthropods.
- Target organism mosquitoes (Aedes spp and Culex spp (L3-L4 larvae));
- Users: non-professional and professional;
- Product description: tablets for direct application;



- Product stability: shelf life 2 years;
- Use area: effervescent tablets for water treatment to control larvae of mosquitos in garden ponds, fountains, unused pools, gully and any other natural or man-made depression suitable to catch and hold water not connected to the sewage treatment plant or surface water.

The authorisation applies only to the biocidal product **Biopren mosquito larvicide tablet** 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 **Biopren** mosquito larvicide tablet 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 (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 the biocidal products,
- 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 **Biopren mosquito larvicide tablet** through mutual recognition may be reopened for review before the 20th January 2031.

Additionally LEGMC would like to inform that **Bábolna Bioenvironmental Centre Ltd.** is fully responsible of the content of the biocidal product **Biopren mosquito larvicide tablet** 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.

Head of Information Analysis Department

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Kods: UNLALV2X Konts: LV25 UNLA 0055000617927

