



Rīga

07.05.2021 Nr. 4-6/669

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On an authorisation of the biocidal product DX3 Gel

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by Zapi S.p.A. on 22 March 2021 concerning the authorisation of **DX3 Gel** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **DX3 Gel** developed by the reference Member State – France.

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 **DX3 Gel** on the basis of mutual recognition process.

The authorisation holder of **DX3 Gel** in Latvia is:

Zapi S.p.A.

Additional trade names for **DX3 Gel** in Latvia is:

- *DX3 GEL;*
- *DX3 ĒSMAS ŽELEJA;*
- *DX3 ANT GEL;*
- *DX3 SKUDRU ĒSMAS ŽELEJA;*
- *DX3 ANT GEL BOX;*
- *DX3 SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *SKULD ANT GEL;*
- *SKULD SKUDRU ĒSMAS ŽELEJA;*
- *SKULD ANT GEL BOX;*
- *SKULD SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *KAMAZIL ANT GEL;*
- *KAMAZIL SKUDRU ĒSMAS ŽELEJA;*
- *KAMAZIL ANT GEL BOX;*

- *KAMAZIL SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *KAPTER ANT GEL;*
- *KAPTER SKUDRU ĒSMAS ŽELEJA;*
- *KAPTER ANT GEL BOX;*
- *KAPTER SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *KELT ANT GEL;*
- *KELT SKUDRU ĒSMAS ŽELEJA;*
- *KELT ANT GEL BOX;*
- *KELT SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *FX3 ANT GEL;*
- *FX3 SKUDRU ĒSMAS ŽELEJA;*
- *FX3 ANT GEL BOX;*
- *FX3 SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *IMITEC ANT GEL;*
- *IMITEC SKUDRU ĒSMAS ŽELEJA;*
- *IMITEC ANT GEL BOX;*
- *IMITEC SKUDRU ĒSMAS ŽELEJAS KASTĪTE;*
- *BROS Skudru slazds ZP.*

DX3 Gel contains **0.0204% (w/w)** of *Imidacloprid* (CAS No. 138261-41-3, EC No. 428-040-8) as active substance (content of pure active substance is 0.02% (w/w)).

LEGMC assigns the authorisation number for DX3 Gel:

LV/2021/MR/004

The authorisation is valid until 8 March 2025.

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

The authorisation for **DX3 Gel** through mutual recognition is granted on the following terms:

- Product type: 18 – Insecticides, acaricides and products to control other arthropods;
- Target organisms for gel bait application - in all development stages (Eggs, Larvae, Pupae, Adults): black ant (*Lasius niger*), argentine ant (*Linepithema humile*) and pharaoh ant (*Monomorium pharaonis*). Target organisms for bait box application - in all development stages (Eggs, Larvae, Pupae, Adults): black ant (*Lasius niger*).
- Users: Trained professional; Professional; General public (non-professional);
- Product description: Gel Bait (ready for use);
- Product stability: shelf life – 2 years;
- Field of use – for gel bait application: indoors (indoors crack and crevices, along the walls) and outdoors (outdoors crack and crevices, outdoors around buildings, or in nest entrances); for bait box application: indoors and outdoors (outdoors around buildings, near the nest).
- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the **DX3 Gel** in the composition, form and packing for which the first authorisation is granted by reference Member State to **DX3 Gel**.

The information on the label (and if applicable an enclosed instruction of use) of the **DX3 Gel** 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.

Zapi S.p.A. 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 **DX3 Gel** through mutual recognition may be re-opened for review before 8 March 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 Zapi S.p.A. is fully responsible of the content of the biocidal product **DX3 Gel** 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.

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