LATVIJAS VIDES, ĢEOLOĢIJAS
UN METEOROLOĢIJAS CENTRS

Riga

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DeLaval NV

Industriepark-Drongen 10
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Belgium

On authorisation of the DeLaval iodine-based teat disinfectant family through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by DeLaval NV on 24th April 2015 concerning an authorisation of the DeLaval iodine-based teat disinfectant family through mutual recognition in Latvia.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics developed by the reference Member State – The Netherlands.

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 DeLaval iodine-based teat disinfectant family.

DeLaval iodine-based teat disinfectant family contains active substance **iodine** (CAS No.7553-56-2, EC No.231-442-4) at the concentration range **0.15-0.75%.**

LEGMC assigns the authorisation number **LV/2019/MR/010** for DeLaval iodine-based teat disinfectant family.

The following members and trade names are authorised within family:

Biocidal product	Additional trade names	Active substance concentration, %	Authorisation number
GMP 51	Tri-Fender	0.25	LV/2019/MR/010/01/001
F-2506		0.214	LV/2019/MR/010/01/002
GMP 44		0.25	LV/2019/MR/010/02/001
GMP 54	IodoFence	0.25	LV/2019/MR/010/02/002
GMP 56	Fortex	0.23	LV/2019/MR/010/02/003
GMP 34		0.15	LV/2019/MR/010/03/001
GMP 36		0.15	LV/2019/MR/010/04/001
GMP 48	Dipal Conc.	0.75	LV/2019/MR/010/05/001
GMP 42		0.15	LV/2019/MR/010/06/001
GMP 43		0.15	LV/2019/MR/010/07/001

The authorisation number is valid until **1st August 2029.**

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

The authorisation of the DeLaval iodine-based teat disinfectant family is granted on the following terms:

- Product type: 3 – Veterinary hygiene;
- Target organisms: bacteria, yeasts and viruses;
- Fields of use: teat disinfection;

- Methods: spraying and dipping;
- Users: professionals;
- Product description: ready to use and soluble concentrate;
- Pack sizes and packaging material: according to SPC;
- Product stability: ready to use products up to 12 months, soluble concentrate up to 24 months.

The authorisation applies only to the DeLaval iodine-based teat disinfectant family in the composition, form and packing for which the first authorisation is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) shall be as it is indicated in the first authorisation of above mentioned product family, 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 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 (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.

DeLaval NV 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 may be re-opened for review before 1st August 2029.

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 DeLaval NV is fully responsible of the content of the biocidal products, as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask DeLaval NV to notify the above mentioned information down to supply chain.

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