LATVIJAS VIDES, ĢEOLOĢIJAS
UN METEOROLOĢIJAS CENTRS

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Laboratoire Mériel S.A.S.

12 rue de Malacussy,
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France

On authorisation of the biocidal product IODOL 100 through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by Laboratoire Mériel S.A.S. on 30th April 2019 concerning an authorisation of IODOL 100 through mutual recognition in Latvia.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics 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 528/2012), LEGMC authorises IODOL 100.

IODOL 100 contains active substance **iodine** (CAS No.7553-56-2, EC No.231-442-4) at the concentration **1.0%.**

Additional trade names are:

- **IODAVIC** and
- **AQUACEET IODE**.

LEGMC assigns the authorisation number **LV/2019/MR/012** for **IODOL 100 (IODAVIC, AQUACEET IODE**).

The authorisation number is valid until **20th August 2028.**

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

The authorisation of the IODOL 100 is granted on the following terms:

- Product type: PT3 – Veterinary hygiene and PT4 - Food and feed area;
- Fields of use: disinfection of equipment for animals (PT3), disinfection of empty breeding buildings (PT3) and disinfection of drinking water pipes for drinking water for animals (PT4);
- Target organisms: bacteria (PT3), bacteria and yeasts (PT4);
- Methods: soaking and spraying (PT3), filling and cleaning in place (PT4);
- Users: professionals;
- Product description: soluble concentrate;
- Pack sizes and packaging material: according to SPC;

- Product stability: up to 24 months.

The authorisation applies only to the IODOL 100 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, 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.

Laboratoire Mériel S.A.S. 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 20th August 2028.

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 Laboratoire Mériel S.A.S. 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 Laboratoire Mériel S.A.S. to notify the above mentioned information down to supply chain.

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