LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

Riga

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On an authorisation of the biocidal product family SANYTOL LACTIC NA-APP

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **GRUPO AC MARCA S.L.** on 24 April 2019 concerning an authorisation of **SANYTOL LACTIC NA-APP** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **SANYTOL LACTIC NA-APP** developed by the reference Member States – 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 (EU) No 528/2012), LEGMC authorises the **SANYTOL LACTIC NA-APP** on the basis of mutual recognition process.

SANYTOL LACTIC NA-APP contains active substance **L(+)-Lactic acid** at the concentration range **0.90 – 0.938 %**.

LEGMC assigns the authorisation number **LV/2021/MR/020.**

The authorisation is valid until **18th October 2031.**

In accordance with Article 22(2)(d) of the Regulation (EU) 528/2012 authorisation numbers with the following suffix for biocidal products within family are indicated in the following table:

Biocidal product	Authorisation number
SANYTOL DEZODORANTS AUDUMIEM PROTECT	LV/2021/MR/020/01/01
SANYTOL AIZSARGĀJOŠS DEZODORANTS - DEZINFEKCIJAS LĪDZEKLIS VISU VEIDU TEKSTILAM UN AUDUMIEM	LV/2021/MR/020/01/02
SANYTOL DEZINFEKCIJAS LĪDZEKLIS – KONCENTRĀTS DAŽĀDĀM VIRSMĀM AR EIKALIPTU	LV/2021/MR/020/02/01
SANYTOL DEZINFEKCIJAS LĪDZEKLIS – KONCENTRĀTS DAŽĀDĀM VIRSMĀM OCEAN	LV/2021/MR/020/02/02
SANYTOL DEZINFEKCIJAS LĪDZEKLIS – KONCENTRĀTS DAŽĀDĀM VIRSMĀM AR CITRONA AROMĀTU	LV/2021/MR/020/02/03
SANYTOL 4 ACTIONS DEZINFEKCIJAS MITRĀS SALVETES	LV/2021/MR/020/03/01
SANYTOL DEZINFEKCIJAS MITRĀS SALVETES VIRTUVEI	LV/2021/MR/020/03/02

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

The authorisation is granted on the following terms:

- Product types: 2 – Disinfectants and algaecides not intended for direct application to humans or animals and 4 - Food and feed area;
- Target organism: bacteria, yeasts and enveloped viruses;
- Users: non-professional;
- Product description: ready-to-use liquids and wipes;
- Product stability: up to 24 months;
- Pack sizes and packaging materials: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to **SANYTOL LACTIC NA-APP** 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) of the **SANYTOL LACTIC NA-APP** 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.

GRUPO AC MARCA S.L. 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 **SANYTOL LACTIC NA-APP** through mutual recognition may be re-opened for review before 18 October 2031.

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 GRUPO AC MARCA S.L. is fully responsible of the content of **SANYTOL LACTIC NA-APP** as well as it classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask GRUPO AC MARCA S.L. to notify the above mentioned information down to supply chain.

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