

LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

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Diversey Europe Operations B.V.

Maarssenbroeksedijk 2 3542DN, Utrecht The Netherlands

On an authorisation of the biocidal product SURE Antimic Hand Wash

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by *Diversey Europe Operations B.V.* on 23rd May 2023 concerning an authorisation of the biocidal product *SURE Antimic Hand Wash* according to *Commission Implementing Regulation (EU)* No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Regulation (EU) No 414/2013).

The reference product is *SALVESAFE H11* (EU-0028975-0036)¹ is a member of the biocidal product family *SALVESAFE H* (Asset No. EU-0028975-0000) authorised according to simplified authorisation procedure set out in Article 26 of the *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) on 5th December 2022. Authorisation holder is *SALVECO S.A.S., Avenue Pierre Mendès-France, Saint Die Des Vosges, 88100, France.*

Diversey Europe Operations B.V. submitted application for authorisation of a same biocidal product *SURE Antimic Hand Wash* according to Article 2 and 4a² of the Regulation (EU) No 414/2013.

LEGMC accepted and agreed with proposed differences between same biocidal product and reference biocidal product:

- trade name;
- authorisation holder;
- additional formulators of the biocidal product;
- additional manufacturer of active substance.

The above mentioned differences are the subject of an administrative changes in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal

T.: +371 67032600 F.: +371 67145154 E.: lvgmc@lvgmc.lv



¹ Product is notified in the biocidal product family SALVESAFE H on 8th May 2023.

² Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Regulation (EU) No 354/2013).

Therefore, LEGMC authorises the biocidal product *SURE Antimic Hand Wash* on the basis of same biocidal product procedure.

The biocidal product *SURE Antimic Hand Wash* contains the *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration *1.98% w/w*.

The biocidal product *SURE Antimic Hand Wash* is authorised in *product type 1* as ready-to-use disinfectant for hands with bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in domestic, institutional, industrial and medical area.

The biocidal product *SURE Antimic Hand Wash* meets the conditions of the Article 25 of the Regulation (EU) No 528/2012:

• the active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) in the biocidal products appears in Annex I and satisfy the restriction specified in that Annex;

- the biocidal products do not contain any substances of concern;
- the biocidal products do not contain nanomaterials;
- the biocidal products are effective;

• the handling of the biocidal products and those intended use do not require personal protective equipment.

LEGMC assigns an authorisation number EU-0031061-0000 for the biocidal product SURE Antimic Hand Wash.

The authorisation is valid until 5 December 2032.

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

The authorisation applies only to the same product *SURE Antimic Hand Wash* in the composition, conditions of use, form and packing according to reference product *SALVESAFE H11* for which the authorisation is granted by reference Member State - Latvia.

Diversey Europe Operations B.V. shall inform LEGMC about any changes in accordance with Regulation (EU) No 354/2013.

Diversey Europe Operations B.V. is fully responsible of the content of the biocidal product including labels, instructions of use and its safety data sheets.

The biocidal product authorised in accordance with Article 26 of the Regulation (EU) No 528/2012 may be made available on the market in all Member States according to conditions laid down in Article 27 of the Regulation (EU) No 528/2012.

Head of Information Analysis Department

signature*

L. Abele

biocides@lvgmc.lv

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