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**Diversey Europe Operations B.V.** 

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25.11.2022

Maarssenbroeksedijk 2 3542DN, Utrecht The Netherlands

## On an authorisation of the biocidal product Sure Instant Hand Sanitizer Extra

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by *Diversey Europe Operations B.V.* on 25<sup>th</sup> November 2022 concerning an authorisation of the biocidal product *Sure Instant Hand Sanitizer Extra* 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 C16\_GPPRO* (EU-0016328-0039)<sup>1</sup> 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) in Latvia on 7<sup>th</sup> June 2017. The biocidal product <i>SALVESAFE C16\_GPPRO* is a member of the biocidal product family *SALVESAFE C* (Asset No. EU-0016328-0000). 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 Instant Hand Sanitizer Extra* according to Article 2 and 4a<sup>2</sup> of the Regulation (EU) No 414/2013.

LEGMC accepts and agrees with proposed differences between same biocidal product and reference biocidal product - trade names, manufacturers of product and active substance, authorisation holder.

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

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<sup>&</sup>lt;sup>1</sup> Product is notified in the biocidal product family SALVESAFE C on 22<sup>nd</sup> July 2020.

<sup>&</sup>lt;sup>2</sup> 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

of biocidal 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 Instant Hand Sanitizer Extra on the basis of same biocidal product procedure.

The biocidal product Sure Instant Hand Sanitizer Extra contains the Lactic acid (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration 1.75% w/w.

The biocidal product Sure Instant Hand Sanitizer Extra is authorised in product type 1 as ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virudical (only against enveloped viruses) efficacy in domestic, medical, institutional and industrial area.

The biocidal product Sure Instant Hand Sanitizer Extra 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-EU-0030243-0000 for the biocidal product Sure Instant Hand Sanitizer Extra.

The authorisation is valid until 7 June 2027.

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

The authorisation applies only to the same product Sure Instant Hand Sanitizer Extra in the composition, conditions of use, form and packing according to reference product for which the authorisation is granted by reference Member State - Latvia.

Authorisation holder shall inform LEGMC about any changes in accordance with Regulation (EU) No 354/2013.

Authorisation holder is fully responsible of the content of the biocidal product including label, instruction of use and its safety data sheet.

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.

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