



Rīga

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Ideal Chimic S.A.

Rte de St-Julien 34
1227, Carouge, Geneva
Switzerland

On an authorisation of the same biocidal product Asepto Pax

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **SALVECO S.A.S** on behalf **Ideal Chimic S.A.** on 21st January 2021 concerning an authorisation of the biocidal product **Asepto Pax** 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 **SALVESAFE C16_GPPRO** (EU-0016328-0039)¹ is a member of the biocidal product family **SALVESAFE C** (Asset No. EU-0016328-0000) 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) in Latvia on 7th June 2017. Authorisation holder is **SALVECO S.A.S., Avenue Pierre Mendès-France, Saint Die Des Vosges, 88100, France.**

SALVECO S.A.S submitted application for authorisation of a same biocidal product **Asepto Pax** according to Article 2 and 4a² of the Regulation (EU) No 414/2013.

LEGMC accepts and agrees with proposed difference between same biocidal product and reference biocidal product - trade names, manufacturer of the product and 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 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 Asepto Pax on the basis of same biocidal product procedure.

The biocidal product **Asepto Pax** contains **Lactic acid** (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration **1.75% w/w.**

¹ The product is notified in biocidal product family **SALVESAFE C** on 22th July 2020.

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*

Asepto Pax is authorised for **product type 1** – as hygienic handrub with a bactericidal, yeasticidal and virucidal (only against enveloped viruses) efficacy in domestic, medical, institutional and industrial area.

Additional trade names are:

- *Desinsur Pax*,
- *Disinsafe Pax*,
- *Igiena Pax*.

The biocidal product 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-0025700-0000** for the biocidal product **Asepto Pax**.

The authorisation is valid until **7th June 2027**.

Authorisation holder is **Ideal Chemic S.A.**, Broplatsen 3, Rte de St-Julien 34, 1227, Carouge, Geneva, Switzerland.

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

The authorisation applies only to the same product *Asepto Pax* in the composition, conditions of use, form and packing according to reference product *SALVESAFE C16_GPPRO* 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.

Head of Information Analysis Department



A. Jantone

biocides@lvgmc.lv

