

European Chemicals Agency

Opinion on the application for Union authorisation of the same biocidal
product family:

Lysoform IPA Surface

Opinion N° UBS-C-1652736-15-00/F

31 March 2023

Opinion of the European Chemicals Agency

on the application for Union authorisation of the same biocidal product family Lysoform IPA Surface

In accordance with Article 6 of 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 ("BPR"), the European Chemicals Agency ("ECHA") has prepared this opinion on the Union authorisation of the same biocidal product:

Name of the biocidal product family	Lysoform IPA Surface
Authorisation holder	Lysoform Dr. Hans Rosemann GmbH
Active substance common name	Propan-2-ol (CAS number [67-63-0])
Product types	2 and 4
Name of the related reference Union authorisation	Lyso IPA Surface Disinfection

Procedural history

The application for Union authorisation of same biocidal product was submitted to ECHA on **25 November 2022** in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 ("SBP Regulation")¹ and recorded under case number **BC-DP082158-26**.

Following its acceptance by ECHA, the validation of the application was initiated on **16 December 2022**. The application was subsequently validated on **1 March 2023** following ECHA's conclusion that the information indicated in Article 2 of the SBP Regulation had been submitted.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA is that Lysoform IPA Surface may be granted a Union authorisation.

All reported differences between Lysoform IPA Surface and the related reference product are limited to information that can be the subject of an administrative change in accordance with the Changes Regulation.

The biocidal product family in question, as defined in Article 3(1)(s) of the BPR, meets the conditions laid down in Article 19(1) of that Regulation and, therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the Product Assessment Report ("PAR") of the related reference authorisation of Lyso IPA

¹ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Surface Disinfection.

A draft summary of product characteristics ("SPC") of Lysoform IPA Surface, as referred to in Article 22(2) of the BPR, is attached as an annex.

2. ECHA opinion

2.1. Conclusions of the evaluation

a) Risks associated with the use of the same biocidal product

The risk assessment for the related reference product family are described in the PAR of the related reference authorisation of Lyso IPA Surface Disinfection. The conclusions are described in Commission Implementing Regulation (EU) 2020/1991 of 27 November 2020. The same conclusions apply to Lysoform IPA Surface.

b) Differences compared to the related reference Union authorisation

Lysoform IPA Surface differs from the related reference authorisation by the following information.

Differences in the structure of Lysoform IPA Surface compared to the related reference authorisation

The family was reduced: the products in meta-SPC 1 through 6 were removed from the family.

Reference Union authorisation		Same biocidal product	
Meta SPC	Product name	Meta SPC	Product name
meta-SPC1 perform IPA liquid	Product	-	-
meta-SPC 2 perform wipes IPA	Product	-	-
meta-SPC 3 mikrozid liquid	Product	-	-
meta-SPC 4 mikrozid wipes	Product	-	-
meta-SPC 5 kodan wipes IPA pro	Product	-	-
meta-SPC6 kodan wipes IPA	Product	-	-
meta-SPC7-AntiLy SD	AntiLy 5 AntiLy 6	Superficid®	Superficid® Superficid® pure
meta-SPC8- AntiLy SD wipes	AntiLy 5 wipes AntiLy 6 wipes	Descorapid®	Descorapid® wipes Superficid® pure wipes

Differences that can be classified as administrative in accordance with **Title 1** of the Annex to the Changes Regulation

Detailed description of the differences	Justification that the differences are of administrative nature
Change of the name of the biocidal product family: Change from old name: "Lyso IPA Surface Disinfection" to new name: "Lysoform IPA Surface"	Change of the name of the biocidal product family.
Removal of trade names of the biocidal products:	Addition and removal of trade

<p>meta-SPC 7: Removal of the tradenames: AntiLy 5 and AntiLy 6 meta-SPC 8: Removal of the tradenames: AntiLy 5 wipes and AntiLy 6 wipes</p>	names of the biocidal products.
<p>Change of the authorisation holder:</p> <p>New authorisation holder: Lysoform Dr. Hans Rosemann GmbH Kaiser-Wilhelm-Straße 133 12247 Berlin Germany</p>	Change of the authorisation holder.
<p>Deletion of a formulating location or a formulator of the biocidal product:</p> <p>Deletion of the following formulators:</p> <p>BOCHEMIE a.s. Lidická 326, 735 95 Bohumín, Czech Republic</p> <p>Tristel Solutions Limited Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire, United Kingdom</p> <p>Techtex Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton, United Kingdom</p> <p>Innovate GmbH Am Hohen Stein 11, 06618 Naumburg (Saale), Germany</p> <p>Schülke & Mayr GmbH Robert-Koch-Str. 2, 22851 Norderstedt, Germany</p> <p>Rudolf Dankwardt GmbH Gutenbergring 50-52, 22848 Norderstedt, Germany</p>	Deletion of a formulating location or a formulator of the biocidal product.
<p>Addition of a formulator of the biocidal product.</p> <p>Addition of the following formulators:</p> <p>WHR GmbH Am Galgenturm 2, 97638 Mellrichstadt, Germany Location of manufacturing site: Am Galgenturm 2, 97638 Mellrichstadt, Germany</p> <p>Hygan GmbH Srl Meucci-Str. 5, 39055 Leifers Laives, (BZ) Italy Location of manufacturing site: Meucci-Str. 5, 39055 Leifers Laives, (BZ) Italy</p> <p>Laboratoire Sarbec SA 10 rue du Vertuquet, 59960 Neuville-en-Ferrain, France Location of manufacturing site: 10 rue du Vertuquet, 59960 Neuville-en-Ferrain, France</p> <p>Dr. Schumacher GmbH Am Roggenfeld 3, 34323 Malsfeld, Germany Locations of manufacturing sites: Am Roggenfeld 3 34323 Malsfeld, Germany and Jeleniogórska 12, 59-800 Lubań, Poland</p>	Addition of a formulator of the biocidal product.
<p>Deletion of a meta-SPC in the SPC of the SBP application:</p> <p>Deletion of the following meta-SPC:</p> <p>meta-SPC1 perform IPA liquid meta-SPC2 perform wipes IPA</p>	Deletion of a meta-SPC in the SPC of the SBP application.

<p>meta-SPC3 mikroqid liquid meta-SPC4 mikroqid wipes meta-SPC5 kodan wipes IPA pro meta-SPC6 kodan wipes IPA</p> <p>The following meta-SPCs will be part of the same biocidal product family:</p> <p>meta-SPC7: Change of the name (identifier) from "AntiLy SD" to "Superficid®" meta-SPC8: Change of the name (identifier) from "AntiLy SD wipes" to "Descorapid®"</p>	
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c) Presentation of the biocidal product family including classification and labelling

The description of Lysoform IPA Surface and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC attached as an annex to this opinion.

d) Description of uses proposed to be authorised

The assessment supporting the intended uses in the application is described in the PAR of the related reference authorisation of Lyso IPA Surface Disinfection.

The description of the intended uses proposed to be authorised is available in the SPC attached as an annex to this opinion.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

Based on the assessment of the related reference authorisation of Lyso IPA Surface Disinfection, and subject to compliance with the draft SPC, Lysoform IPA Surface meets the conditions laid down in Article 19(1)(b) of the BPR. Therefore, it is proposed that Lysoform IPA Surface shall be authorised² for the uses described in the SPC.

One of the non-active substances of Lysoform IPA Surface and related reference authorisations has been identified as potentially having endocrine disrupting properties, requiring further examination as concluded in the Commission Implementing Regulation (EU) 2020/1991. Concerning this examination, any conclusions on the related reference authorisation of Lyso IPA Surface Disinfection will also be applicable to Lysoform IPA Surface.

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² This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of Regulation (EU) No 528/2012.

Annex

Draft Summary of Product Characteristics