

European Chemicals Agency

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

Hydroflex IPA 70 Biocide

Opinion N° UBS-C-1703496-07-00/F

12 January 2024

Opinion of the European Chemicals Agency

on the application for Union authorisation of the same biocidal product Hydroflex IPA 70

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	Hydroflex IPA 70 Biocide
Authorisation holder	Hydroflex Group GmbH
Active substance common name	Propan-2-ol (CAS number 67-63-0)
Product types	2, 4
Name of the related reference product	Isopropanol 70 Biocide
Asset number of the related reference Union authorisation	EU-0027707-0022

Procedural history

The application for Union authorisation of a same biocidal product was submitted to ECHA on 20 September 2023 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 ("SBP Regulation")¹ and recorded under case number BC-BX088801-11.

Following its acceptance by ECHA, the validation of the application was initiated on 28 September 2023. The applicant was requested additional information on 3 October 2023. The application was subsequently validated on 15 December 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 Hydroflex IPA 70 Biocide may be granted a Union authorisation.

All reported differences between Hydroflex IPA 70 Biocide 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 in question, as defined in Article 3(1)(r) of the BPR, meets the conditions laid down in Article 19(1) of that Regulation and, therefore may be authorised for the uses

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

specified in this opinion. The detailed grounds for the overall conclusion are described in the Product Assessment Report ("PAR") of the related reference authorisation.

A draft summary of product characteristics ("SPC") of Hydroflex IPA 70 Biocide, 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 are described in the PAR of the related reference authorisation. The conclusions are described in Commission Implementing Regulation (EU) 2022/2252 of 11 November 2022. The same conclusions apply to Hydroflex IPA 70 Biocide.

b) Differences compared to the related reference Union authorisation

Hydroflex IPA 70 Biocide differs from the related reference authorisation by the following information.

Differences in the structure of Hydroflex IPA 70 Biocide compared to the related reference authorisation

Hydroflex IPA 70 Biocide is a single biocidal product linked to the product Isopropanol 70 Biocide of the reference product family Brenntag GmbH Propan-2-ol Product Family.

Reference Union authorisation		Same biocidal product	
Meta SPC	Product name	Meta SPC	Product name
Meta SPC 1	Wofasept AHA Budenat® Protect Hand D807 Handsteril OG Handsteril OG blau Easysept Witty-Lavalin D Curacid HD-sept Esept Gel Mano Germs Deogel Mani Isogel Alcodet profumato Handsan ELIGEL ELIGEL Perfum Desmila VSI Desmila VSI C Desmila LSI Desmila LSI C Desmila LSI pure	-	-
Meta SPC 2	proCura Spray PUR Isopropanol 70 Biocide Budenat® Rapid Effect D 446 Isopropanol/Wasser 65/35% Curacid Food Rapid Deogerm Desmila HSI C Desmila HSI D	Not relevant – Hydroflex IPA 70 is a single biocidal product	- Hydroflex IPA 70 Biocide - - - - -

	Desmila HSI P Desmila AFI		- -
Meta SPC 3	Frend Hand Sanitiser Gel Biogat H-Des Neo-Amisept	-	-

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
<p>Product name and trade name were changed from 'Isopropanol 70 Biocide' to 'Hydroflex IPA 70 Biocide' as a consequence of the same biocidal product application (UA-BBS).</p> <p>In addition, the following trade names were removed: Isopropanol 70 Isopropylalkohol Königseer Biozid Isogel Königseer Biozid Plus Gold Füllersteril PPP Isopropylalkohol 70% Gew. Fast Germs BACTINYL IPA 70 % SAFE CLEANER SR Isopropylalkohol Königseer Flächen Biozid Isonet Isonet AL Sanificante Alcolico Isogerm Isogerm AL Isonet PU Alidet Sanocasa Frigosano Hygien Food Medicalsan Alcohol Sanitized Alkosan Biofarm Allkill DETERQUAT PRO SR Galtec Isoprop Bactericide Amphisol 70 AISW 100 Steril Spray PPP Hand- und Oberflächendesinfektion</p>	<p>This change reflects the product name given to the same biocidal product by Hydroflex Group GmbH for the same biocidal product. The name presents no risk of confusion with the names of other biocidal products.</p>

c) Presentation of the biocidal product including classification and labelling

The description of Hydroflex IPA 70 Biocide 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.

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, and subject to compliance with the draft SPC, Hydroflex IPA 70 Biocide meets the conditions laid down in Article 19(1)(b) of the BPR. Therefore, it is proposed that Hydroflex IPA 70 Biocide shall be authorised² for the uses described in the SPC.

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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