

European Chemicals Agency

Opinion on the Application for Union Authorisation of the Same Biocidal Product under Article 6 of Commission Implementing Regulation (EU) No. 414/2013

Opinion number: UBP-C-1717568-04-00/F

Date: 11 March 2024

Name of the product family	Hydrogen peroxides biocides family
Authorisation holder	ILR GmbH
Active substance common name	Hydrogen peroxide
Product types	2, 4
Name of the related reference product family	Hydrogen peroxide product family
BPC Opinion number of the related reference product family	ECHA/BPC/392/2023

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013¹, has evaluated the application for Union authorisation of Hydrogen peroxides biocides family.

The application for Union authorisation was submitted to ECHA on 26 January 2017 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP 3 under case number BC-YP029411-22.

Following its acceptance by ECHA, the validation of the application was initiated on 1 February 2017.

ECHA requested additional information on 7 February 2017, 24 March 2017 and 13 July 2017. Such information was provided by the applicant on 7 February 2017, 24 March 2017 and 1 August 2017.

The application was subsequently validated on 11 December 2017 following ECHA's conclusion that the information indicated in Article 2 of Commission Implementing Regulation (EU) No 414/2013 had been submitted.

The validation included a check that the proposed differences between Hydrogen peroxides biocides family and the related reference product family are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013².

Following the adoption of the BPC opinion of the related reference product family and the subsequent submission of a revised version of the draft SPC of Hydrogen peroxides biocides family, ECHA confirmed again that all differences between Hydrogen peroxides biocides family

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

² 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.

and the related reference product family are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The evaluation was based on the information provided by the applicant in relation to the related reference product family.

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, ECHA's opinion is set out below.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA's opinion is that Hydrogen peroxides biocides family is eligible for Union authorisation, and all reported differences between Hydrogen peroxides biocides family and the related reference product family are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The biocidal product family Hydrogen peroxides biocides family, as defined in Article 3(1)(s) of Regulation (EU) No 528/2012, 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 product family.

A draft summary of product characteristics ("SPC") of Hydrogen peroxides biocides family, as referred to in Article 22(2) of Regulation (EU) No 528/2012, is attached as an annex.

2. ECHA opinion

2.1. Conclusions of the evaluation

The conclusions of the risk assessment for Hydrogen peroxides biocides family are based on the evaluation of the related reference product family and described in BPC opinion ECHA/BPC/392/2023 of 13 September 2023.

2.2. Changes compared to the related reference biocidal product family

The following changes of the biocidal product family Hydrogen peroxides biocides family compared to the related reference biocidal product family were proposed by the applicant and deemed to be acceptable.

A/ Changes in the structure of the biocidal product family Hydrogen peroxides biocides family compared to the related reference product family

Reduced family:

Product meta SPC and product names

Reference product: meta SPC	Reference product: product name	Same biocidal product: meta SPC	Same biocidal product: product name
Meta SPC 1	HP-BPF-12 HP-BPF-14 HP-BPF-07 HP-BPF-03 HP-BPF-08	Meta SPC 1	- - Wepos Schimmel Entferner chlorfrei Klina Mould X -
Meta SPC 2	HB-BPF-01 HP-BPF-06	-	-

Meta SPC 3	HP-BPF-15	-	-
Meta SPC 4	HP-BPF-09	-	-
Meta SPC 5	HP-BPF-10	-	-

B/ Administrative changes referred to in **Section 1 of Title 1** of the Annex to Regulation (EU) No 354/2013 (changes requiring prior notification)

Change number*	Detailed description of the change	Justification that the change is of administrative nature
1.	Changes of the name of the biocidal product The product name 'HP-BPF-07' is changed into 'Wepos Schimmel Entferner chlorfrei', the product name 'HP-BPF-03' is changed into 'Klina Mould X'.	Only the name of the product is changed. The composition of the reference product is not changed. This change is of administrative nature.
2.	Addition of a name for the biocidal product - Please see SPC file of the same biocidal application for an overview of all trade names per product	Only the name of the product is changed. The composition of the reference product is not changed. This change is of administrative nature.
3.	Transfer of authorisation holder: ILR GmbH, Kirchstrasse 2, 34131 Kassel, Germany	The identity of the authorisation holder is changed. This is pure administrative and does not change the existing authorisation in any way.

*according to the left column of the table in **Section 1 of Title 1** of the Annex to Regulation (EU) No 354/2013

C/ Administrative changes referred to in **Section 2 of Title 1** of the Annex to Regulation (EU) No 354/2013

Change number*	Detailed description of the change	Justification that the change is of administrative nature
3.	Deletion of formulators of biocidal products: - MPD plus, s.r.o. - E'COSi s.r.l. - MELLERUD CHEMIE GMBH -	The same biocidal product application only refers to some of the formulators of the original dossier. This is pure administrative and does not change the existing authorisation in any way.
6.	Deletion of manufacturers of active substance: - Arkema France	The same biocidal product application only refers to some of the manufacturers of the original dossier. This is pure administrative and does not change the existing authorisation in any way.
8.	Removal of specific uses: - surface disinfection healthcare, concentrate - surface disinfection non-healthcare and food/feed areas, concentrate -disinfection of inner surfaces (incl. CIP and drinking water systems), concentrate -room disinfection by fogging,	This same biocidal product application only applies to a part of the original product family. Therefore, some of the uses of the original dossier are not included in the current same biocidal application. As the uses that are included in the same biocidal product application are still covered by the

	concentrate - equipment/instruments disinfection, concentrate -laundry disinfectant in non-healthcare areas, SL	original product dossier, this is a pure administrative change.
8.	Deletion of Meta-SPC Meta-SPC 2, 3, 4 and 5 and not covered in the same biocidal product application	This same biocidal product application only applies to a part of the original product family. Meta-SPC 2, 3, 4 and 5 of the original dossier are not included in the current same biocidal product application. The remaining meta-SPCs are still covered by the original product dossier, this is a pure administrative change.
8.	Deletion of products The products HP-BPF-12, HP-BPF-14, HP-BPF-08, HP-BPF-09, HP-BPF-15, HP-BPF-06, HP-BPF-01 and HP-BPF-10 are not included in the same biocidal product application	This same biocidal product application only applies to a part of the original product family. Some products of the original dossier are not included in the current same biocidal product application. The remaining products are still covered by the original product dossier, this is a pure administrative change

*according to the left column of the table in **Section 2 of Title 1** of the Annex to Regulation (EU) No 354/2013

2.3. Presentation of the product family including classification and labelling

The description of Hydrogen peroxides biocides family and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC, see annex to this opinion.

2.4. 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 product family.

The description of the intended uses proposed to be authorised is available in the SPC, see annex to this opinion.

2.5. Overall conclusion of the evaluation of the uses proposed to be authorised

For the uses proposed to be authorised, according to Article 19(1)(b) of Regulation (EU) No 528/2012, it has been concluded that Hydrogen peroxides biocides family:

1. is sufficiently effective;
2. has no unacceptable effects on the target organisms;
3. has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. has no unacceptable effects itself, or because of its residues, on the environment, having regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,

- the impact of the biocidal product on biodiversity and the ecosystem.

Therefore, it is proposed that Hydrogen peroxides biocides family shall be authorised³ for the uses described under section 2.4 of this opinion, subject to compliance with the proposed SPC.

This biocide product family contains non-active substances that in formulation have been identified as having an endocrine disrupting potential based on the CompTox Chemistry Database. However, the screening performed showed that none of them should be considered substance of concern in term of endocrine disrupting properties.

Annex I: draft Summary of Product Characteristics

³ 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.