European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: Hydrogen Peroxide Family 1

Opinion N° UAD-C-1622642-38-00/F

4 November 2022

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of Hydrogen Peroxide Family 1

In accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013 of the European Commission 18 May 2013 on changes of biocidal products authorised in accordance with Biocidal Product Regulation (EU) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has prepared this opinion on the administrative changes to the Union authorisation of:

Name of the biocidal product family: Hydrogen Peroxide Family 1

Authorisation holder: Ecolab Deutschland GmbH

Target asset number: EU-0024303-0000

Active substance common name: Hydrogen peroxide

Product types: 1, 2, 3, 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 28 September 2022, and recorded in R4BP under case number BC-RU080137-08.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 3 November 2022.

The evaluation included a check that the proposed changes of an existing authorisation are of a purely administrative nature involving no change to the properties or efficacy of the biocidal product family in accordance with Article 3(1)aa of the BPR.

The scope of the assessment itself was based on and limited to the information provided by the authorisation holder in the supporting document for the notification for an administrative change of a Union or simplified authorisation under Regulation (EU) No 354/2013 supplied via R4BP.

ECHA prepared this opinion containing the conclusions of its assessment.

2. Detailed opinion and background

2.1. ECHA opinion

During the evaluation, ECHA has assessed whether the changes made in the SPC document provided by the applicant are administrative changes in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following changes to the biocidal product family sought by the authorisation holder are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **1** of the Annex to the Regulation (EU) No 354/2013 - Name of the biocidal product - change N° 2 : *Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.*

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - Formulator(s) of the biocidal product:

    - Change N° 2: *Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.*

    - Change N° 4: *Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative changes to the biocidal product family sought by the authorisation holder.

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2.2. ECHA assessment

2.2.1. Description of the changes as proposed by the authorisation holder

Changes as described by the authorisation holder in their supporting document supplied via R4BP.

Identification	**Description**
1.	Addition of a name for the biocidal products "Anios Low Peroxide IP sterile" and "Sirafan Oxy" which are identical to: Incidin OxyFoam S Klercide Sporicidal Enhanced Peroxide KitchenPro Oxy Foam S in META SPC 5 (5-c)
2.	Addition of a name for the biocidal product "Sirafan Oxy Conc" which is identical to: KitchenPro Oxy Des Concentrate Incidin OxyPro in META SPC 9 (9-a)
3.	Addition of a name for the biocidal product "Anios Low Peroxide IP sterile wipes" which is identical to: Klerwipe Sporicidal Enhanced Peroxide in META SPC 11 (11-c)
4.	Addition of a name for the biocidal product "Sirafan Oxy Wipes" which is identical to: Incidin OxyWipe S

	KitchenPro Oxy Wipes S in META SPC 11 (11-d)
5.	Addition of the formulator "Sima Pharma" with the details as below: "Sima Pharma 54 Avenue de la Plaine, ZI 13106, Rousset Cedex France"
6.	Addition of the formulator "Techtex (Technical Textile Services Ltd)" with the details as below: "Techtex (Technical Textile Services Ltd) Units 7 & 8, Rhodes Business Park, Silburn Way, Middleton, Manchester, M24 4NE, UK"
7.	Addition of the formulator "Helico B.V" with the details as below: "Helico B.V. Hoogschaijksestraat 31 5374 EC Schaijk Netherlands"
8.	Addition of the formulator "INCARE BV" with the details as below: "INCARE BV Keizersveld 99 5803 AP Venray The Netherlands"
9.	Replace the current details of: "ECL Mullingar Ecolab Ltd. Forrest Park Zone C Mullingar Industrial Estate Mullingar Co. Westmeath, Ireland" With: "ECL Mullingar Ecolab Ltd (IE). Forrest Park Zone C Mullingar Industrial Estate Mullingar Co. Westmeath Ireland" "ECL Mullingar. Ecolab Manufacturing IE Ltd (IE) Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar, Co. Westmeath Ireland"
10.	Replace the current details of: "ECL Weavergate NLC Weavergate Northwich, Cheshire West and Chester CW8 4EE, Northwich United Kingdom" With: "ECL Weavergate Site: Nalco Manufacturing Limited, Winnington Avenue, Northwich, Cheshire CW8 3AA, UK

	Postal Address: PO Box 11, Winnington Avenue, Northwich, Cheshire CW8 4DX" "ECL Weavergate Ecolab Ltd (UK) Winnington Avenue Northwich, Cheshire CW8 3AA" "ECL Weavergate Ecolab Manufacturing UK Ltd (UK) Winnington Avenue Northwich, Cheshire CW8 3AA"

2.2.2. Assessment of the changes as proposed by the authorisation holder

The assessment of the changes sought by the authorisation holder is presented in the following table:

Identification	**Corresponding reference in the Annex to Regulation (EU) No 354/2013**	**Evaluation**	**Result of the evaluation**	**Comments**
1.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
3.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
4.	Title 1, section 1, change n° 2	The requested change matches the	Acceptable	Change requiring prior notification

		description in the Regulation		
5.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	
6.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	
7.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	
8.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	
9.	Title 1, section 2, changes n° 2 and 4	The requested change matches the description in the Regulation	Acceptable	
10.	Title 1, section 2, changes n° 2 and 4	The requested change matches the description in the Regulation	Acceptable	

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Annex

Draft Summary of Product Characteristics