

## **European Chemicals Agency**

Opinion on the administrative change of the Union authorisation of the biocidal product family: Ecolab Iodien PT3 Family

*Opinion N° UAD-C-1582110-47-00/F*

**27 June 2022**

## Opinion of the European Chemicals Agency

### on administrative changes of the Union authorisation of Ecolab Iodien PT3 Family

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:** Ecolab Iodien PT3 Family

**Authorisation holder:** Ecolab Deutschland GmbH

**Target asset number:** EU-0018398-0000

**Active substances common name:** Polyvinylpyrrolidone iodine / Iodine

**Product type:** 3

### 1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 10 May 2022, and recorded in R4BP under case number BC-UX075448-87.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 7 June 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° 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.

<u>Identification</u>	<u>Description</u>
1.	<p>Addition of a name for the biocidal products where there is no risk of confusion with the names of other biocidal products.</p> <p>In particular:            Addition of the trade name "Iod Spray" which is identical to the other products listed in meta SPC3.</p>
2.	<p>Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.</p> <p>In particular the addition of the formulator:            "Cid Lines nv, Waterpoortstraat 2, 8900 Ieper Belgium"</p>

### 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:

<u>Identification</u>	<u>Corresponding reference in the Annex to Regulation (EU) No 354/2013</u>	<u>Evaluation</u>	<u>Result of the evaluation</u>	<u>Comments</u>
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 2, change n°4	The requested change matches the description in the Regulation	Acceptable	
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**Annex**

**Draft Summary of Product Characteristics**