

European Chemicals Agency

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

Opinion N° UAD-C-1382805-41-00/F

18 June 2019

Opinion of the European Chemicals Agency

on an administrative change of the Union authorisation of Ecolab Iodine 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 change to the Union authorisation of:

Name of the biocidal product family: Ecolab Iodine PT3 Family

Authorisation holder: Ecolab Deutschland GmbH

Target asset number: EU-0018398-0000

Active substance(s) common name: Polyvinylpyrrolidone iodine and Iodine

Product type(s): PT 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 11 March 2019, and recorded in R4BP under case number BC-QF049804-33.

Following its acceptance by ECHA, the validation of the notification was initiated on 05 April 2019.

The validation included a check that the proposed change of the existing authorisation is 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 that the change made in the SPC document provided by the applicant is an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following change to the biocidal product family sought by the authorisation holder is a change falling under Article 3(1)(aa) of the BPR, and, after the implementation of the change, 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.

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

2.2. ECHA assessment

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

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

<u>Identification</u>	<u>Description</u>
1.	Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products. Addition of the trade name "ESI-POST" which is identical to "IoKlar Multi" to Meta SPC 3.

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

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

<u>Identifi- cation</u>	<u>Corresponding reference in the Annex to Regulation (EU) No 354/2013</u>	<u>Assessment</u>	<u>Result of the assessment</u>	<u>Comments</u>
1.	Title 1, section 1, Name of the biocidal product - change N° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification before implementation

Annex

Draft Summary of Product Characteristics