# European Chemicals Agency

## Opinion on the administrative change of the Union authorisation of the biocidal product family : HYPRED's iodine based products

## Opinion N° UAD-C-1383628-34-00/F

18 June 2019

# Opinion of the European Chemicals Agency

**on administrative changes of the Union authorisation of HYPRED's iodine based products**

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:** HYPRED's iodine based products

**Authorisation holder:** HYPRED SAS

**Target asset number:** EU-0018397-0000

**Active substance common name:** Iodine

**Product type :** PT 3

## 1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 04 April 2019 and recorded in R4BP under case number BC-KC049719-36.

Following its acceptance by ECHA, the validation of the notification was initiated on 10 April 2019.

The validation included a check that the proposed changes of the 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 that 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.
    - Authorisation holder - change N° 4: Change of the name of the authorisation holder, which remains in the EEA.
    - Manufacturer(s) of the active substance(s) - change N° 5: Addition of a manufacturer of the active substance or in their manufacturing location or process.
- 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.

Accordingly, it is proposed that the Commission amends the existing authorisation with the listed administrative changes 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

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

| Identification | Description |
|---|---|
| **1** | Addition of names for the biocidal product family in the Section 7.1 of Meta SPC 1, Meta SPC 2, Meta SPC 3 and Meta SPC 5 |
| **2** | The name of the authorisation holder changed from HYPRED SAS to HYPRED SAS – KERSIA Group in the Section 1.3 of the SPC document |
| **3** | Addition of two manufacturers for the active substance and their respective manufacturing sites in the Section 1.5 of the SPC document. |
| **4** | - Change of administrative details of the manufacturer in the Section 1.4 of the SPC<br><br>- Addition of the manufacturing location site for HYPRED SAS in the Section 1.4 of the SPC<br><br>- Change of the administrative details for the manufacturing location site for HYPRED SAS in the Section 1.4 of the SPC |

### 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 | Assessment | Result of the assessment | Comments |
|---|---|---|---|---|
| **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 |
| **2** | Title 1, section 1, Authorisation holder - change N° 4 | The two new manufacturers of the active substance are alternative sources for which a technical equivalence decision has been provided | Acceptable | The decision on technical equivalence of these two sources is provided in the notification.<br><br>Change requiring prior notification before implementation |
| **3** | Title 1, section 1, Manufacture of the active substance - change N° 5 | The requested change matches the description in the Regulation | Acceptable | Change requiring prior notification before implementation |
| **4** | Title 1, section 2, Formulator of the biocidal product - change N° 2 | The requested change matches the description in the Regulation | Acceptable | - |

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**Annex**

**Draft Summary of Product Characteristics**