European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product: ClearKlens product based on IPA

Opinion N° (UAD-C-1543546-33-00/F)

10 November 2021

Opinion of the European Chemicals Agency

on an administrative change of the Union authorisation of ClearKlens product based on IPA

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(s) to the Union authorisation of:

Name of the biocidal product: ClearKlens product based on IPA

Authorisation holder: Diversey Europe Operations B.V.

Target asset number: EU-0022128-0000

Active substance(s) common name: Propan-2-ol

Product type(s): PT02

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 21 October 2021, and recorded in R4BP under case number **BC-DN070816-28**.

Following its acceptance by ECHA, the evaluation of the notification was initiated on **6 November 2021**.

The evaluation 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 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 change made in the SPC document provided by the applicant **is** administrative change in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following change to the biocidal product 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 – Manufacturer(s) of the active substance(s) - change N° 5 : *Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative change to the biocidal product 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 manufacturer of the active substance

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:

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° 5 - Manufacturer(s) of the active substance(s)	The new manufacturer of the active substance is an alternative source for which a technical equivalence decision has been provided.	Acceptable	Change requiring prior notification

Annex

Draft Summary of Product Characteristics