European Chemicals Agency

Opinion on administrative changes of the Union authorisation of the biocidal product family: Contec IPA Product Family

Opinion N° (UAD-C-1539242-29-00/F)

19 October 2021

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of Contec IPA Product 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: Contec IPA Product Family

Authorisation holder: Contec Europe

Target asset number: EU-0020460-0000

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

Product type(s): PT02, PT04

1. Process for the adoption of the opinion

The notification for the administrative changes was submitted to ECHA on 04 August 2021 and recorded in R4BP under case number BC-QS069138-06.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 17 August 2021.

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 evaluation 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 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.

- 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.

- 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.

It is ECHA's opinion that the following change to the biocidal product family sought by the authorisation holder is not in accordance with Article 3(1)(aa) of the BPR:

- Change not mentioned in Title 1, section 1 or section 2 of the Annex to the Regulation (EU) No 354/2013 : Removal of confidential information in Section 6 of meta SPC 2 concerning the description of the carrier.

The removal of the information on the carrier is not an administrative change.

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.

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.	The name Ipasept is to be added to the list of trade names in meta SPC 1.
2.	An additional manufacturer of the active substance is to be added as

	follows: Address of manufacturer: INEOS Solvents Germany GmbH Römerstraße 733 47443 Moers Germany Location of manufacturing site: INEOS Solvents Germany GmbH Römerstraße 733 47443 Moers Germany
3.	An additional biocidal product manufacturer is to be added as follows: Address of manufacturer: VWR International BVBA Researchpark Haasrode 2020 Geldenaaksebaan 464 B - 3001 Leuven Belgium Location of manufacturing site: VWR International BVBA Researchpark Haasrode 2020 Geldenaaksebaan 464 B - 3001 Leuven Belgium
4.	Removal of confidential information in Section 6 of meta SPC 2. <u>Current text:</u> "*Other Information*: *Polypropylene, polyester, kitted polyester, 55 % cellulose / 45 % polyester or 50 % rayon / 50 % polyester wipes, 34-240 gsm, containing 5 - 38 ml product (2.75 - 20.9 g propan-2-ol)* *The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129.28 mg/m3 for the professional user was agreed and used for the risk assessment of the product."* <u>New text should be:</u> "*Other Information*: *The product contains propan-2-ol (CAS No: 67-63-0), for which a European reference value of 129,28 mg/m^3 for the professional user was agreed and used for the risk assessment of the product."*

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, change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation.	Acceptable	Change requiring prior notification
2.	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
3.	Title 1, section 2, change N° 4 – Formulator(s) of the biocidal product	The requested change matches the description in the Regulation.	Acceptable	
4.	Not indicated in the Annex to the Regulation (EU) No 354/2013	The requested change do not match the description in the Regulation.	Rejected	

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Annex

Draft Summary of Product Characteristics