

European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: CMIT/MIT SOLVENT BASED

UAD-C-1703145-38-00/F

03 January 2024

Opinion of the European Chemicals Agency

On administrative changes of the Union authorisation of CMIT/MIT SOLVENT BASED

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: CMIT/MIT SOLVENT BASED

Authorisation holder: MC (Netherlands) 1 B.V.

Target asset number: EU-0023657-0000

Active substance common name: Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)

Product type: 6

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 17 November 2023, and recorded in R4BP 3 under case number BC-FM090134-40.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 30 December 2023.

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 3.

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 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* –
 - Deletion of a trade name.
 - 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° 3: Deletion of a formulating location or a formulator 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.

o__o

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 3.

<u>Identification</u>	<u>Description</u>
1.	<p>Changes of the name of the biocidal product where there is no risk of confusion with the names of other biocidal products.</p> <p>The following product tradenames have been removed:</p> <p><u>Meta SPC 1</u> BLUECIDE 832 BIOCIDA CARBURANTE DIESEL-BIODIESEL BIOSTOP 15 GL C 412 GP 10 MIRECIDE-KW/615</p> <p><u>Meta SPC2</u> BLUECIDE 833 Predator 9000 FuelClear M68 Pro MIRECIDE-KW/615.C</p>
2.	<p>Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal</p>

	<p>products.</p> <p>The following product trade name has been added:</p> <p><u>Meta SPC 1</u> KATHON(TM) Fuel 15 Biocide</p>
3.	<p>The product manufacturers "Specialty Electronic Materials Switzerland GmbH" and "AD Productions BV" should be deleted.</p>
4.	<p>The following product manufacturer should be added:</p> <p>Microbial Control (Switzerland) GmbH Hungerbuelstrasse 22, 8500 Frauenfeld, Switzerland.</p> <p>The manufacturing site corresponds to our toller AD Productions BV Markweg Zuid 27, 4794 SN Heijningen Netherlands</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, name of the biocidal product	The removal of 9 trade names	Acceptable	Change requiring prior notification
2.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
3.	Title 1, section 2, change n° 3	The requested change matches the description in the Regulation	Acceptable	
4.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	

Annex

Draft Summary of Product Characteristics