Helsinki, 26 January 2021

ECHA OPINION ON THE APPLICATION FOR AUTHORISATION OF THE SAME BIOCIDAL PRODUCT UNDER ARTICLE 6 OF COMMISSION IMPLEMENTING REGULATION (EU) NO 414/2013.

Opinion number: UBP-C-1491986-08-00/F

Name of the biocidal product family: C(M)IT/MIT formulations

Prospective authorisation holder: Solenis Switzerland GmbH; Mühlentalstrasse 38; 8200 Schaffhausen; CH

Active substance(s): 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 CAS 55965-84-9)

Product type(s): 6, 11, 12

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, has assessed the application for authorisation of the same biocidal product family C(M)IT/MIT formulations.

The application for authorisation was submitted to ECHA on 26 June 2017 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-TY032745-97.

Following its acceptance by ECHA, the validation of the application was initiated on 6 July 2017.

The application was subsequently validated on 11 December 2017 following ECHA's conclusion that the information indicated in Article 2 of Commission Implementing Regulation (EU) No 414/2013 had been submitted.

The validation included a check that the proposed differences between the biocidal product family and the related reference biocidal product family ("related reference product") are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

Following the adoption of the BPC opinion of the related reference product (including the draft SPC) and the subsequent submission of a revised version of the draft SPC of the same biocidal product family, ECHA re-confirmed that all differences between these two families concern information which can be the subject of an administrative change.

The scope of the assessment itself was based on the information provided by the applicant in relation to the related reference product.

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, ECHA's opinion is set out below.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA's opinion is that the biocidal product family C(M)IT/MIT formulations is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and all differences between this biocidal product family and the related reference product are limited to information which can be the subject of an administrative change

in accordance with Implementing Regulation (EU) No 354/2013.

The biocidal product family meets the definition in Article 3(1)(s) of Regulation (EU) No 528/2012, and maybe expected to fulfil the conditions laid down in Article 19 of Regulation (EU) No 528/2012 and therefore maybe authorised. The detailed grounds for the overall conclusion are described in the PAR of the related reference product.**Error! Bookmark not defined.**

A draft summary of biocidal product family characteristics ("SPC"), as referred to in Article 22(2) of Regulation (EU) No 528/2012, is attached as an annex to this opinion.

2. ECHA opinion

2.1. Summary of the evaluation and conclusions of the risk assessment

The summary of the evaluation and the conclusions of the risk assessment for the same biocidal product family "C(M)IT/MIT formulations" are based on the evaluation of the related reference product family "CMIT-MIT Aqueous 1.5-15" and described in BPC opinion N°ECHA/BPC/273/2020.

2.2. Presentation of the biocidal product family including classification and labelling

The description of the biocidal product family and its structure, and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC, see annex to this opinion.

2.3. Description of uses proposed to be authorised

The assessment supporting the intended use(s) in the application is described in the PAR of the related reference product "CMIT-MIT Aqueous 1.5-15".

The description of the use(s) proposed to be authorised is available in the SPC, see annex to this opinion.

2.4. Overall conclusion of the evaluation of the uses proposed to be authorised

For the use(s) proposed to be authorised, according to Article 19(1)(b) of Regulation (EU) No 528/2012, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

Therefore, it is proposed that the biocidal product family "C(M)IT/MIT formulations" shall be authorised, for the uses described under section 2.3 of this opinion, subject to compliance with the proposed SPC.

Annex I: draft Summary of Product Characteristics