

## **Biocidal Products Committee (BPC)**

Opinion on the Union authorisation of the biocidal Product Family:

**CMIT/MIT SOLVENT BASED**

**Product type: 6**

ECHA/BPC/246/2020

Adopted

5 March 2020



## Opinion of the Biocidal Products Committee

### on the Union authorisation of CMIT/MIT SOLVENT BASED Biocidal Product Family

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

**Name of the biocidal product family:** CMIT/MIT SOLVENT BASED Biocidal Product Family

**Authorisation holder:** Specialty Electronic Materials Switzerland GmbH

**Active substance common name:** C(M)IT/MIT

**Product type:** 6

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

### Process for the adoption of BPC opinions

Following the submission of an application on June 2017, recorded in R4BP3 under case number BC-NN032576-24, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 28 August 2019. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-34) and its Working Groups (WG V 2019). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: France**

The BPC opinion on the Union authorisation of the biocidal product family was reached on 5 March 2020.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA website.

## Detailed BPC opinion and background

### 1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of CMIT/MIT SOLVENT BASED Biocidal Product Family referred to in Article 22(2) of Regulation (EU) No 528/2012.

### 2. BPC Opinion

#### 2.1 BPC Conclusions of the evaluation

##### a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

##### General

The biocidal product family CMIT / MIT SOLVENT BASED consists of products containing 1.50 to 1.75% of pure active substance reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) (C(M)IT/MIT). Products are to be used for the preservation of aviation fuels, crude oil and middle distillate fuel. Butyl carbitol was identified as a substance of concern<sup>1</sup>. One of the co-formulants was identified as potentially having endocrine disruptor properties. It was however not possible to conclude on whether this co-formulant meets the scientific criteria for the determination of endocrine disrupting properties as laid down in Regulation (EU) 2017/2100.

The biocidal product family (BPF) is composed of 2 meta SPCs, containing one representative product each. The structure of the BPF into meta SPCs is based on the formulation of each meta SPC (different solvents involved) and on the intended uses:

- Meta SPC 1: Preservation of aviation fuels, crude oils and middle distillate fuels;
- Meta SPC 2: Preservation of crude oil and middle distillate fuels.

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<sup>1</sup> A European Union OEL for butyl carbitol of 67.5 mg/m<sup>3</sup> (without skin notation) has been set, which triggers a categorization as a Band C substance of concern. Therefore, butyl carbitol is a substance of concern.

The following intended claims were assessed:

User	Meta-SPC	Uses
Professionals	Meta SPC 1 (representative product: KATHON FP 1.5 BIOCIDES)	(a) Preservation of aviation fuels, crude oils and middle distillate fuels for mid and long-term storage against bacteria, yeasts and fungi. (b) Curative treatment, against bacteria, yeasts and fungi for preservation of aviation fuels, crude oils and middle distillate fuels.
Professionals	Meta SPC 2 (representative product: KATHON HP120 BIOCIDES)	a) Preservation of crude oil and middle distillate fuels for mid and long-term storage against bacteria, yeasts and fungi. (b) Curative treatment, against bacteria, yeasts and fungi for preservation of crude oil and middle distillate fuels.

Conclusions of the assessments of each section are given here below:

### Physico-chemical properties

Products of the CMIT/MIT SOLVENT BASED Biocidal Family are ready-to-use liquid formulations. The products in the table above are representative for a meta SPC, therefore, the evaluation of each product is extrapolated to its respective meta SPC. Acceptable physico-chemical data were provided for each product.

The results of the accelerated as well as long-term storage studies support a shelf-life of 24 months for meta SPC 1 (KATHON FP). The long-term storage stability study for meta SPC 2 (KATHON HP) demonstrates a 3-months stability. Therefore, as no justification and information about degradation products and efficacy after a storage superior to 3 months are provided, the shelf-life is set at 3 months for meta SPC 2.

Products of CMIT/MIT SOLVENT BASED BPF do not produce persistent foam.

None of the products needs to be classified with regard to physical and chemical hazards.

The analytical method for the determination of CMIT/MIT content are validated for biocidal formulations at C(M)IT/MIT concentrations ranging from 1.5 to 15%. This method can therefore be used for all biocidal products included in the BPF.

### Efficacy

An efficacy study on the effectiveness of a solvent based C(M)IT/MIT product KATHON FP 1.5 BIOCIDES in three different fuel types (jet fuel, crude oil and biodiesel) has been performed covering different in-use concentrations of C(M)IT/MIT.

Efficacy of the biocidal product family CMIT/MIT SOLVENT BASED BPF is demonstrated for the following uses and application rates:

#### Meta-SPC 1 (KATHON FP):

- 1) Preservation of Aviation fuels (such as Jet Fuel (Kerosene)) for mid or long-term storage for bacteria and fungi: 0.75 - 1.5 ppm v/v CMIT/MIT.
- 2) Curative treatment for Aviation fuels (such as Jet Fuel (Kerosene) against bacteria and fungi: 0.75 - 1.5 ppm v/v CMIT/MIT.
- 3) Preservation of Middle distillate Fuels (such as Biodiesel Automotive gas oil, Marine diesel oil, Heating oil, etc.) for mid and long-term storage: 0.75 - 2.25 ppm v/v CMIT/MIT, contact time needs to be 1 to 4 weeks, depending on the dose used.

- 4) Curative treatment for Middle distillate Fuels (such as Biodiesel Automotive gas oil, Marine diesel oil, Heating oil, etc.): 3 - 6 ppm v/v CMIT/MIT against bacteria and 6 ppm v/v CMIT/MIT against fungi.
- 5) Preservation of Crude oils for mid and long-term storage: 0.75 - 2.25 ppm v/v CMIT/MIT, contact time needs to be 1 to 4 weeks, depending on the dose used.
- 6) Curative treatment for Crude oils: 3 - 6 ppm v/v CMIT/MIT against bacteria and 6 ppm v/v CMIT/MIT against fungi.

#### Meta-SPC 2 (KATHON HP):

- 1) Preservation of Middle distillate Fuels (such as Biodiesel Automotive gas oil, Marine diesel oil, Heating oil, etc.) for mid and long-term storage: 0.5 - 3 ppm v/v CMIT/MIT for bacteria and 0.75 - 3 ppm v/v CMIT/MIT for fungi, contact time needs to be 1 to 4 weeks, depending on the dose used.
- 2) Curative treatment for Middle distillate Fuels (such as Biodiesel Automotive gas oil, Marine diesel oil, Heating oil, etc.): 3 - 6 ppm v/v CMIT/MIT against bacteria and 6 ppm v/v CMIT/MIT against fungi.
- 3) Preservation of Crude oils for mid and long-term storage: 0.5 - 3 ppm v/v CMIT/MIT for bacteria and 0.75 - 3 ppm v/v CMIT/MIT for fungi, contact time needs to be 1 to 4 weeks, depending on the dose used.
- 4) Curative treatment for Crude oils: 3 - 6 ppm v/v CMIT/MIT against bacteria and 6 ppm v/v CMIT/MIT against fungi.

#### Conclusion

Efficacy of the products of the CMIT/MIT SOLVENT BASED Biocidal Family has been demonstrated for mid and long term preservation and curative treatment of middle distillate fuels, crude oils for both meta-SPC 1 and meta-SPC 2, and aviation fuels for meta SPC 1 only.

#### **Resistance**

In the literature, resistance to increasing levels of isothiazolones was shown for bacteria adapted in lab cultures. Depending on the references, adaptation phenomena induced during exposure of bacteria can be stable or unstable, and may lead to resistance. It is important to emphasize that the use of preservatives induces a continuous contact between active substances and microorganisms, leading to a pressure of selection that maintains this adapted state whatever the stability of the phenomenon.

Resistance management should be addressed at the renewal of authorisation if appropriate guidelines are available.

#### **Human health**

The biocidal product family C(M)IT/MIT SOLVENT BASED is intended to be applied in aviation fuels, crude oils and middle distillate fuels by professionals (industrial users who are primary exposed) for their preservation. After dilution in fuels or crude oils, the active substance C(M)IT/MIT is present at a maximum concentration of 0.0006% (6 ppm a.i). The preserved fuels and crude oils can be used by professionals or general public who can be exposed during handling of fuels by contact or splashes e.g refuelling car tanks (secondary exposure).

Products of C(M)IT/MIT SOLVENT BASED biocidal product family induce skin corrosivity and skin sensitization, as well as eye damage according to the CLP regulation. They are classified as:

- H314: Causes severe skin burns and eye damage;
- H317: May cause an allergic skin reaction;
- H318: Causes severe eye damage;
- EUH 071: Corrosive to the respiratory tract.

For both meta SPCs:

Primary exposure (industrial users)

*Systemic effects*

The risk is considered acceptable for industrial users during manual loading of product of CMIT/MIT SOLVENT BASED BPF into the blend tank containing fuels or crude oils, provided the wearing of gloves. The risk is considered acceptable for industrial users during manual filling containers of preserved fuels or crude oils (no PPE required).

*Local effects*

Considering the classification of both meta SPCs industrial users must wear protective chemical resistant gloves, a protective coverall (at least type 6 EN13034), chemical goggles during product handling phase. Moreover, application of technical and organisational RMM are required such as:

- a very high level of containment is required;
- design closed system to allow for easy maintenance;
- clean regularly the equipment and work area;
- the use of a dosing pump for manual loading is required;
- minimisation of manual phases;
- adequate ventilation is needed.

Direct secondary exposure (professionals)

*Systemic effects*

The risk is considered acceptable for professionals during contact with preserved fuels or crude oils and no PPE is required.

*Local effects*

The risk is considered acceptable.

Direct secondary exposure (general public)

*Systemic effects*

The risk is considered acceptable for general public due to contact with preserved fuels (e.g refuelling car tanks).

*Local effects*

The risk is considered acceptable.

**Indirect exposure via food**

For the intended uses of the biocidal products of the CMIT/MIT SOLVENT BASED biocidal product family, no contact to food and feedingstuffs, neither residues in food and feedingstuffs is expected.



## Environment

CMIT/MIT SOLVENT BASED biocidal product family is classified for the environment as:

- H400: Very toxic to aquatic life;
- H410: Very toxic to aquatic life with long lasting effects.

Emission of C(M)IT and MIT was calculated based on a worst case scenario, considering a complete release of spent water without degradation during storage.

The estimated risks of C(M)IT/MIT for the non-target species of aquatic, sediment and terrestrial compartments and the microorganisms in wastewater treatment plants, are acceptable only for the preservation of de-watered crude oil and for the preservation of aviation fuels and middle distillate fuels, with a maximum water content of 2%.

The estimated concentrations in groundwater, related to the use of the biocidal product family CMIT/MIT SOLVENT BASED biocidal product family, are below the threshold value defined by Directive 98/83/EC.

## Overall conclusion

According to the assessment performed for the biocidal product family CMIT/MIT SOLVENT BASED, the following uses are proposed for authorization:

User	Meta-SPC	Uses
Professionals	Meta SPC 1	Preservation of de-watered crude oils, aviation fuels and middle distillate fuels , with a maximum water content of 2% (a) Preservation for mid and long-term storage against bacteria, yeasts and fungi. (b) Curative treatment against bacteria, yeasts and fungi.
Professionals	Meta SPC 2	Preservation of de-watered crude oils and middle distillate fuels, with maximal water content of 2% (a) Preservation for mid and long-term storage against bacteria, yeasts and fungi. (b) Curative treatment, against bacteria, yeasts and fungi.

### With the following risk mitigation measures:

- For preservation up to the dose of 6 ppm, the maximum amount of de-watered treated crude oil or refined products emptied daily per site is 15 000 m<sup>3</sup>.
- For preservation up to the dose of 3 ppm, the maximum amount of de-watered treated crude oil or refined products emptied daily per site is 35 000 m<sup>3</sup>.

### For industrial application

- A very high level of containment is required;
- Design closed system to allow for easy maintenance;
- Clean regularly the equipment and work area;
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least type 6 EN13034) shall be worn;
- Wear chemical goggles during product handling phase.
- Technical and organisational RMM such as:
  - o the use of a dosing pump for manual loading is required;
  - o minimisation of manual phases;
  - o adequate ventilation is needed.

**With the following instructions for use:**

- Always read the label or leaflet before use and follow all the instructions provided;
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.);
- Products are to be used only for mid or long-term storage or for curative treatment. Efficacy in case of high turnover systems has not been tested;
- Check regularly the residual concentration of the biocide (both in the fuel and aqueous phases) between fuel transfers in order to ensure lack of contamination between treatments. The choice of intervals between treatments is based on the check of the residual biocide concentrations;
- Microbiological tests to prove adequacy of preservation have to be undertaken (both in the fuel and aqueous phases) by the user of the product in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product;
- Inform the authorisation holder if the treatment is ineffective;
- For preservation during mid/long-term storage, contact time needs to be 1 to 4 weeks, depending on the dose used. For curative treatment, the biocidal effect is achieved after 1-3 days.

**b) Presentation of the biocidal product family including classification and labelling**

The description of the biocidal product and of the structure of the biocidal product family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

**c) Description of uses proposed to be authorised**

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

**d) Comparative assessment**

The active substance CMIT/MIT contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

**e) Overall conclusion of the evaluation of the uses proposed to be authorised**

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate uses, storage and transportation of the biocidal products.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, 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 or unnecessary suffering and pain for vertebrates;
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 family 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.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

## **2.2 BPC opinion on the Union authorisation of the biocidal product family**

As the conditions of Article 19(1) are met it is proposed that biocidal product family shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

For the co-formulant identified as potentially having endocrine disrupting properties, a process under REACH will be triggered by the eCA (France) in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final entitled "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation".