

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

Opinion on the application for approval of the active substance:

**Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1)**

**Product type: 2**

ECHA/BPC/051/2015

Adopted

14 April 2015

## Opinion of the Biocidal Products Committee

### on the application for approval of the active substance, reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for product type 2

In accordance with Article 89(1) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 2 of the following active substance:

|                                  |                                                                                                      |
|----------------------------------|------------------------------------------------------------------------------------------------------|
| <b>Common name:</b>              | <b>C(M)IT/MIT (3:1)</b>                                                                              |
| <b>Chemical name(s):</b>         | <b>Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1)</b> |
| <b>EC No.:</b>                   | <b>not available</b>                                                                                 |
| <b>CAS No.:</b>                  | <b>55965-84-9</b>                                                                                    |
| <b>Existing active substance</b> |                                                                                                      |

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

### Process for the adoption of BPC opinions

Following the submission of an application by Rohm and Haas Europe Trading ApS, now a subsidiary of The Dow Chemical Company (hereafter referenced as "Dow") on 12 July 2007, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the Commission on 19 October 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

### Adoption of the BPC opinion

#### Rapporteur: BPC member of France

The BPC opinion on the approval of the active substance reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) (hereafter C(M)IT/MIT) in product type 2 was adopted on 14 April 2015.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The minority position including its grounds is published on ECHA webpage:

<http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that C(M)IT/MIT in product type 2 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

### 2. BPC Opinion

#### 2.1. BPC Conclusions of the evaluation

##### a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of C(M)IT/MIT in product type 2, in preservation of air conditioning and air washing systems. For this PT, C(M)IT/MIT biocidal products are exclusively used by professional users. Only preservation of air conditioning and air washing system was assessed for the approval of the active substance due to a lack of sufficient data on efficacy for chemical toilets disinfection uses.

C(M)IT/MIT acts by a two-step antimicrobial mechanism, involving rapid binding (association) to cells and inhibition of growth and metabolism (within minutes), followed by irreversible cell damage resulting in loss of viability (hours). Growth inhibition is the result of rapid disruption of essential metabolic pathways of the cell by inhibition of specific (thiol-containing) deshydrogenase enzymes involved in the Krebs (tricarboxylic acid) cycle and electron transport (NADH).

The active substance as manufactured is a reaction mass of 5-chloro-2-methylisothiazol-3(2H)-one (C(M)IT) and 2-methylisothiazol-3(2H)-one (MIT) in ratio (3:1).

The active substance is manufactured as a technical concentrate (TK) with different solvents and stabilizers.

C(M)IT/MIT (3:1) is very reactive with some substances and should be stabilized in the product. For this reason, the active substance is manufactured directly to its product form.

Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Analytical methods are available for the active substance as manufactured, for the stabilizers and for the relevant and significant impurities and the relevant matrices soil, water and air.

The current classification and labelling for C(M)IT/MIT according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

| <b>Classification according to the CLP Regulation</b> |                                                                                                                                                          |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard Class and Category Codes                       | Acute Tox. 3/H331<br>Acute Tox. 3/H311<br>Acute Tox. 3/H301<br>Skin Corr. 1B/H314<br>Skin Sens. 1/H317<br>Aquatic Acute 1/H400<br>Aquatic chronic 1/H410 |
| <b>Labelling</b>                                      |                                                                                                                                                          |
| Pictograms                                            | SGH05<br>SGH06<br>SGH07<br>SGH09                                                                                                                         |

|                                                 |                                                                                                                                                                                                                                                                            |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Signal Word                                     | Danger<br>Warning                                                                                                                                                                                                                                                          |
| Hazard Statement Codes                          | H331: Toxic if inhaled<br>H311: Toxic in contact with skin<br>H301: Toxic if swallowed<br>H314: Causes severe skin burns and eye damage<br>H317: May cause an allergic skin reaction<br>H410 Very toxic to aquatic life with long lasting effects.                         |
| <b>Specific Concentration limits, M-Factors</b> | Skin Corr. 1B; H314: Causes severe skin burns and eye damage<br>C ≥ 0.6%<br>Eye Irrit. 2; H319: Causes serious eye irritation<br>Skin Irrit. 2; H315: Causes skin irritation<br>0.06% ≤ C < 0.6%<br>Skin Sens. 1; H317: May cause an allergic skin reaction<br>C ≥ 0.0015% |

However, a new proposal for the classification and labelling for C(M)IT/MIT according to Regulation (EC) No 1272/2008 (CLP Regulation) is proposed as follows:

| <b>Classification according to the CLP Regulation</b> |                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard Class and Category Codes                       | Acute Tox. 3 for acute oral hazard/H301<br>Acute Tox 2 for acute dermal hazard/H310<br>Acute Tox 2 for acute inhalation hazard/H330<br>Skin Corr. 1B/H314<br>Skin Sens. 1A/H317<br>Aquatic acute 1/H400<br>Aquatic Chronic 1/H410                                                                                           |
| <b>Labelling</b>                                      |                                                                                                                                                                                                                                                                                                                             |
| Pictograms                                            | SGH05<br>SGH06<br>SGH07<br>SGH09                                                                                                                                                                                                                                                                                            |
| Signal Word                                           | Danger<br>Warning                                                                                                                                                                                                                                                                                                           |
| Hazard Statement Codes                                | H 330: Fatal if inhaled<br>H 310: Fatal in contact with skin<br>H 301: Toxic if swallowed<br>H 314: Causes severe skin burns and eye damage<br>H 317: May cause an allergic skin reaction<br>H410 Very toxic to aquatic life with long lasting effects.                                                                     |
| <b>Specific Concentration limits, M-Factors</b>       | Skin Corr. 1B; H314: Causes severe skin burns and eye damage<br>C ≥ 0.6%<br>Eye Irrit. 2; H319: Causes serious eye irritation<br>Skin Irrit. 2; H315: Causes skin irritation<br>0.06% ≤ C < 0.6%<br>Skin Sens. 1A; H317: May cause an allergic skin reaction<br>C ≥ 0.0015%<br>Acute M-factor: 100<br>Chronic M-factor: 100 |

The CLH report was sent to ECHA on 17 October 2014.

**b) Intended use, target species and effectiveness**

C(M)IT/MIT is an isothiazolone substance, used as a preservative to control the growth of bacteria, algae and fungi in the sump water of air conditioning and air washer systems.

Air conditioning has been described as the process of treating air to control its temperature, humidity and cleanliness, and distributing this air to meet the needs of the conditioned space.

Air washers in air conditioning systems are used extensively for example in tobacco and textile facilities to clean and temper the air. The high degree of recirculation in air washers leads to a variety of problems including slime formation, deposits, corrosion and odours. The deposits are mainly microbial slimes combined with dirt, corrosion products and crystalline matter. In order to control the fouling and deposition problems that occur, chilled water is treated with C(M)IT/MIT, and air washers are periodically shut down and washed out. The intervals between successive shutdowns and washouts vary from one to 5-6 weeks, depending on the severity of the problems. Waste water from air washing systems is released to site equilibration/remediation facilities (if available) prior to release to municipal sewer, then finally STP.

The efficacy of C(M)IT/MIT on *Legionella pneumophila*, demonstrated in a laboratory test, is acceptable for the assessment of the use of C(M)IT/MIT in air conditioning and air washing system, with the dose in C(M)IT/MIT of 1 mg/L with a contact time of 48H and of 2 to 5 mg/L with a contact time of 24H. Efficacy of the shock dose (15 mg/L in 30 min) claimed by the applicant, has not been demonstrated.

C(M)IT/MIT has been used as a commercial antimicrobial agent since 1980. During this period of use, situations where resistance to C(M)IT/MIT have occurred. In commercial use, C(M)IT/MIT is often used in combination or rotation with other biocides in various applications, which helps to avoid the potential risk of developing resistance.

Microbial resistance to C(M)IT/MIT has been described in the literature; thus, special attention should be given at the product authorisation stage.

**c) Overall conclusion of the evaluation including need for risk management measures****Human health**

C(M)IT/MIT induces a local irritation observed by oral, dermal and inhalation routes. No systemic effects were observed in the absence of local effects in any available study, except on body weight gain and food consumption.

Concerning systemic effects, PPE are presented in the table below and concerning local effects, PPE are presented with other RMMs in the local effects section.

The table below summarises the exposure scenarios assessed.

| Summary table: human health scenarios                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Scenario                                                        | Primary or secondary exposure and description of scenario                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Exposed group  |
| Mixing/loading of the Biocidal product in chilled-water systems | Primary exposure of water treatment service worker.<br>Manual or automated administration of the biocidal product (containing C(M)IT/MIT) to the chilled water sump.<br>Biocidal product concentration: C(M)IT/MIT 14%.<br>Concentration in chilled water: 15 ppm a.i.<br>Daily task: 4 facilities visited per day, with up to 3 loadings (2 minutes) and 1 pump cleaning (5 minutes) per facility.<br>PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration).<br>Dermal absorption: concentration > 0.6%: 100 %; diluted solutions (< 0.6%): 50%. | professionals  |
| Cleaning dispensing pumps                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
| Cleaning air-washed systems                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
| System monitoring and waste disposal                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
| Combined exposure: loading and cleaning pumps                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
| Inhaling residues of C(M)IT/MIT in washed air                   | Secondary exposure.<br>Workers in factories.<br>Concentration in chilled water: maximum 15 ppm.<br>Task duration and frequency: 8 hours for workers.                                                                                                                                                                                                                                                                                                                                                                                                                                 | professionals  |
| Inhaling residues of C(M)IT/MIT in conditioned air              | Secondary exposure.<br>General public.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | general public |

### Local effects

According to the criteria of the Regulation 1272/2008 C(M)IT/MIT is proposed to be classified as a corrosive and a skin sensitizer category 1A. The most critical local effect is skin sensitization, with a proposed specific concentration limit (SCL) of maximum 0.0015% (15 ppm).

Unacceptable risks of local effects were identified following dermal exposure to a solution of C(M)IT/MIT (3:1). However, the risk has been considered acceptable for professionals taking into account that appropriate risk mitigation measures are applied during the different phase of use of the products in order to prevent any spillage on skin.

Possible measures (not exhaustive list) are:

- The containers of the products are designed to prevent spillages during pouring;
- Automated systems preventing contacts with the product are used;
- Procedures are implemented to prevent contacts and spillages;
- Chemical-resistant coveralls, gloves, shoes and face-mask are worn;
- Use is restricted to operators informed of the hazards and formed for safe handling of the products.

Labels, SDS and use instructions of the products shall inform the users of the hazards and of the protective measures. Written procedures and protective equipments shall be available at the places where the products are handled.

Other dermal exposure scenarios (cleaning, monitoring and waste disposal) are in contrast considered as safe since the operator will be exposed to a diluted solution (maximum 15 ppm).

Unlike dermal exposure, no unacceptable risk was identified for the respiratory tract, whatever the scenario considered. This applies for both primary and secondary exposure scenarios.

### **Systemic effects**

The mixing and loading, application and post-application tasks could potentially occur on the same day. Therefore combined exposure was considered for all tasks. Except the cleaning phase of the air washer-system where no PPE are needed, safe uses were identified for all the primary exposure scenarios if wearing appropriate personal protective equipment (PPE), including impermeable coverall, and gloves, during these tasks.

Regarding the combined primary exposure scenario, risk for workers is acceptable when considering a rinse step of the system before opening for cleaning operations, in addition to the PPE.

The secondary exposure to C(M)IT/MIT is limited to the inhalation of washed air, which is considered as very unlikely because of the removal of water aerosols by mist eliminators and the very low volatility of C(M)IT/MIT from water. Therefore, no risk was identified for these scenarios.

### **Environment**

The table below summarises the exposure scenarios assessed.

| <b>Summary table: environment scenarios</b>                                        |                                                                                                                                                                |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Scenario</b>                                                                    | <b>Description of scenario including environmental compartments</b>                                                                                            |
| Air washing system to preserve the sump water in open recirculating cooling system | Emission to wastewater due to leakage or rinse-off and via cleaning of treated area (sewage treatment plant (STP), surface water, sediment, soil, groundwater) |

The main emission route of C(M)IT/MIT through its use in the representative biocidal product is via the wastewater to sewage water treatment plants (STP) and subsequent release via effluents and STP sludge to surface water, soil and groundwater. Exposure of the environment via the atmosphere is considered to be negligible. The sediment compartment is deemed not relevant considering the low K<sub>oc</sub> value. In addition secondary poisoning is not assessed due to the low bioaccumulative properties of the substance.

No unacceptable risk for each environmental compartment was identified for the use of C(M)IT/MIT in air washing system.

## **2.2. Exclusion and substitution criteria**

### **2.2.1. Exclusion and substitution criteria**

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

| Property                        |                                                                                | Conclusions                |
|---------------------------------|--------------------------------------------------------------------------------|----------------------------|
| CMR properties                  | Carcinogenicity (C)                                                            | no classification required |
|                                 | Mutagenicity (M)                                                               | no classification required |
|                                 | Toxic for reproduction (R)                                                     | no classification required |
| Respiratory sensitisation       | No classification required                                                     |                            |
| PBT and vPvB properties         | Persistent (P) or very Persistent (vP)                                         | not P or vP                |
|                                 | Bioaccumulative (B) or very Bioaccumulative (vB)                               | not B or vB                |
|                                 | Toxic (T)                                                                      | T                          |
| Endocrine disrupting properties | The active substance is not considered to have endocrine disrupting properties |                            |

Consequently, the following is concluded:

C(M)IT/MIT does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

The criterion (f) laid down in Article 10 of Regulation (EU) No 528/2012 should be applied on the active substance as manufactured. For C(M)IT/MIT, stabilizer salts and solvents present in the active substance as manufactured are intentionally added. In that case, they can not be considered either as non-active isomers or as impurity. In consequence, in the active substance as manufactured, the total impurities content is lower than 20% and there is no non-active isomer. C(M)IT/MIT does not meet the conditions of the criteria (f) laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

C(M)IT/MIT is proposed to be classified as a skin sensitizer category 1A. This critical effect can be managed with very restrictive risk mitigation measures to avoid any skin contact during use of biocidal products by professionals and by limiting the concentration of C(M)IT/MIT in treated articles used by professionals and non professional below the threshold value set for sensitizing properties, when skin contact cannot be avoided by other measures. With the application of these conditions, it can be considered that criterion e) of Article 10(1) of the Biocidal Products Regulation is not fulfilled.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"<sup>1</sup> and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"<sup>2</sup> agreed at the 54<sup>th</sup> and 58<sup>th</sup> meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

<sup>1</sup> See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

<sup>2</sup> See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc))

### **2.2.2. POP criteria**

C(M)IT/MIT does not fulfil criteria for being a persistent organic pollutant (POP) and does not have potential for long-range transboundary atmospheric transport.

### **2.3. BPC opinion on the application for approval of the active substance C(M)IT/MIT in product type 2**

In view of the conclusions of the evaluation, it is proposed that C(M)IT/MIT shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance C(M)IT/MIT (3:1) evaluated: the active substance is manufactured as a technical concentrate (TK) with different solvents and stabilizers. The theoretical (calculated) dry weight specification: minimum purity of C(M)IT/MIT (3:1): 579 g/kg.
2. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
3. For professional users, safe operational procedures, appropriate organisational and technical risk mitigation measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
4. Where a treated article has been treated with or intentionally incorporates one or more biocidal products containing C(M)IT/MIT, and where necessary due to the possibility of skin contact as well as the release of C(M)IT/MIT under normal conditions of use of the article, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

### **2.4. Elements to be taken into account when authorising products**

1. Some situations of resistance with C(M)IT/MIT have been described in the literature and therefore before authorizing products, Member States should pay attention to possible occurrence of resistance.
2. For biocidal products that trigger classification as skin sensitisers the Member States Competent Authorities note for guidance (CA-Sept13-Doc.6.2.a – Final.Rev1) should be used to decide whether they could be authorised for non-professional uses.

### **2.5. Requirement for further information**

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of C(M)IT/MIT. However, the following data should be provided to the Competent Authority (France) as soon as possible but no later than 6 months before the date of approval of the active substance:

1. Some sources could not be validated. Therefore further data will need to be submitted as specified in the confidential annex of the evaluation.