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: 11

ECHA/BPC/47/2015

Adopted

5 February 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 11

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 11 of the following active substance:

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

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 two applications by Rohm and Haas Europe Trading ApS, now a subsidiary of The Dow Chemical Company (hereafter referenced as "Dow") on 7 October 2008 and Thor GmbH (hereafter reffered to as "Thor") on 29 October 2008, the evaluating Competent Authority France submitted a combined assessment report and the conclusions of its evaluation to the Commission on 22 April 2013. 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 for 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 11 was adopted on 5 February 2015**.**

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that C(M)IT/MIT in product type 11 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 11, in preservation of liquid cooling and processing systems.
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 continuous directly to its product form. The product mostly on the market is a solution of 14% or higher in water with stabilizers salts.

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. However, futher data are required to fully validate some of the analytical methods before the approval of the active substance (see 2.5 requirements for further information).

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

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

	SGH07 SGH09
Signal Word	Danger Warning
Hazard Statement Codes	H331: Toxic if inhaled H311: Toxic in contact with skin H301: Toxic if swallowed H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H410 Very toxic to aquatic life with long lasting effects.
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: Causes severe skin burns and eye damage C ≥ 0.6% Eye Irrit. 2; H319: Causes serious eye irritation Skin Irrit. 2; H315: Causes skin irritation 0.06% ≤ C < 0.6% Skin Sens. 1;H317: May cause an allergic skin reaction 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 follow:

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

	C ≥ 0.0015% Acute M-factor: 100 Chronic M-factor: 100

The CHL report was sent to ECHA the 17 October 2014. The accordance check is pending.

b) Intended use, target species and effectiveness

C(M)IT/MIT is an isothiazolone substance, which is used as a broad spectrum antimicrobial agent for preventing the growth of microorganisms (bacteria, fungi (and algae for Dow only)) that may occur within the liquid cooling and processing systems. C(M)IT/MIT biocidal products are exclusively used by professionals or industrial users in PT11.

The efficacy of C(M)IT/MIT demonstrated in labaratory tests, is acceptable for the assessment of the use of C(M)IT-MIT in the preservation of liquid cooling and processing systems, with typical use concentrations range claimed by Dow from 1 to 50 mg/L of active ingredient.

For Thor, in the preservation of liquid cooling and processing systems, the typical use concentration of C(M)IT/MIT claimed by the applicant is ranged from 0.2 to 1 mg/l active ingredient by continuous dosing and 2 mg/L active ingredient by shock dosing. Nevertheless, based on the efficacy data submitted an efficacy is demonstrated at a use concentration of C(M)IT/MIT ranged from 0.5 to 5 mg/L a.i. 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**
Process and cooling water	Primary exposure Control of the growth of bacteria, algae and fungi in the circulating water of open and closed cooling water systems (e.g., cooling tower - open cooling water system). - Manual, semi-automated or automated mixing/loading - Cleaning dispensing pumps and fouled system - Cooling water monitoring - Combined exposure of all daily tasks PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration) and RPE (10% penetration) only for manual loading	Professionals
Preservative for aqueous wood preservative treatment solution	Primary exposure Prevent the growth of micro-organisms (mould, slime) in the treatment solutions of wood that could accumulate in storage tanks, block pumps and pipework and hindering the operation of the treatment plant. The biocide is not intended to function as a wood preservative. - Manual, semi-automated or automated mixing/loading - Industrial use of treated wood protective fluid (dipping, deluge, simple or double vacuum pressure systems...) - Cleaning dipping tank - Combined exposure of all daily tasks PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration) for manual loading	Professionals
Textile and spinning fluids	Primary exposure Preservation of textile and spinning fluids, photo processing solutions and print fountain solutions to control the integrity of recirculating fluid by reducing microbial contamination from bacteria, fungi and algae in the bulk solution. - Manual, semi-automated or automated mixing/loading - Industrial use of treated textile process fluid - Cleaning dispensing pumps - Combined exposure of all daily tasks PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration), RPE (10% penetration) only for manual loading	Professionals

Paint spray booths and electrodeposition coating systems	Primary exposure Preservation of fluids in paint spray booths and electrodeposition coating systems to control the integrity of recirculating fluid by reducing microbial contamination from bacteria, fungi and algae in the bulk solution. - Manual, semi-automated or automated mixing/loading - Spraying treated paint - Cleaning spray equipment - Combined exposure of all daily tasks PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration), RPE (10% penetration) only for manual loading	Professionals
Industrial hygiene, clean in place (CIP)	Primary exposure Remediation of industrial water based process fluid streams to control the integrity of recirculating fluid by reducing microbial contamination from bacteria, fungi and algae. - Manual, semi-automated or automated mixing/loading - Cleaning dispensing pumps - Combined exposure of all daily tasks PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration), RPE (10% penetration) only for manual loading	Professionals
Adult exposed to drift from cooling towers	Secondary exposure	Professional and general public
Adult cutting and sanding treated wood	Secondary exposure	Professional and general public
Infant chewing wood off-cut	Secondary exposure	Non professional, general public
Infant inhalating volatilized residues from indoor wood	Secondary exposure	Non professional, general public
Child playing on wood playground structure outdoors	Secondary exposure	Non professional, general public
Infant playing on weathered wood structure and mouthing	Secondary exposure	Non professional, 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).

Manual mixing and loading of C(M)IT/MIT based products and post application phases to process fluids present an unacceptable risk for dermal local effects.

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.

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

Exposure of professionals to C(M)IT/MIT was evaluated for the scenarios summarised in the table above.

The mixing and loading, application and post-application tasks could potentially occur on the same day. Therefore combined exposure was considered for all daily tasks. Safes uses were identified for all the primary exposure scenarios if wearing of appropriate personal protective equipment (PPE), including impermeable coverall, and gloves and if a rinse step is considered before the cleaning phase of the dispensing pump.

No unacceptable risk was identified for the secondary exposure scenarios.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Large open recirculating cooling systems	Regular discharge of cooling water (blowdown): direct emission to surface water. Direct emission to air due to evaporation and spray and wind drift, subsequent deposition on soil and emission to groundwater

small open recirculating cooling systems without STP	Regular discharge of cooling water (blowdown): direct emission to surface water and soil through air deposition.
small open recirculating cooling systems with STP Air conditioning and air washing systems	Regular discharge of cooling water (blowdown): emissions to surface water, soil and groundwater via STP
Other liquid processing system different from cooling system (ex: wood treatment solution preservative, photographic processing solution, textile processing fluids…)	Formulation and the industrial use of the substance: Direct emission to air and waste water. Emissions to surface water, soil and groundwater via STP In-use phase of treated wood: three worst case scenarios have been assessed: house (worst case for soil), noise barrier (worst case for the STP) and sheet piling (worst case for water)

Two emission routes of C(M)IT/MIT through its use in the representative biocidal product have been considered. In the case of the use in open recirculating cooling systems, direct release to surface water and to soil through air deposition have been assessed. Similarly, direct releases to surface water and to soil have been taken into account for the in-use phase of treated wood used respectively for sheet pilling and house. For small open recirculating system which can be connected to a STP and in other cases, releases via the wastewater to sewage water treatment plants (STP) and subsequent release via effluents and STP sludge to surface water, soil and groundwater have been assessed. Exposure of the environment via the atmosphere is considered to be negligible. The sediment compartment is deemed not relevant considering the low Koc value. In addition secondary poisoning is not assessed due to the low bioaccumulative properties of the substance.

No unacceptable risk for environment have been identified for the use in small open recirculating cooling systems, when releases from the systems are directed to a STP and when drift eliminator is in place to reduce direct contamination of terrestrial compartment via air deposition. For uses in closed systems and in air cleaning and washing systems, and for uses in print fountain solutions, in textile processing fluids, car refinishing, OEM car manufacture fluids, industrial hygiene, and other minor uses intended by the applican no unacceptable risk for environment have been identified.

Unacceptable risks have been determined for uses in large open recirculating cooling tower, in small open recirculating cooling tower when releases are directed to the river, and for uses in photographic processing liquid and in wood treatment solution preservatives (in-use phase).

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 properties	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"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] agreed at the 54th and 58th 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).

2.2.2. POP criteria

C(M)IT/MIT does not fulfil criteria for being a persistant 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 11

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] 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)
2 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)

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 wet 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. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
4. Products should not be authorized for uses in photographic processing liquid, in wood treatment solution preservatives and large open recirculating cooling systems unless it can be demonstrated at product authorization that risks to environment can be reduced to an acceptable level.
5. Unless it can be demonstrated at product authorisation that risks to the environment can be reduced to an acceptable level, labels and, where provided, safety data sheet of products shall indicate that:
    a. For the use in small open recirculating cooling systems, risk mitigation measures as drift eliminator should be in place to reduce the direct contamination of terrestrial compartment via air deposition.
    b. For other uses than those specified under provision 4, release of waste water from the facilities should be directed to a sewage treatment plant.

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 have to be submitted to the Competent Authority (FR) no later than six 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.
2. A confirmatory method for the determination of C(M)IT and MIT in soil should be provided by Dow if the use which induces a continuous rejection of C(M)IT and MIT in soil is claimed and acceptable at the product authorisation stage.
3. A validated method for analysis of MIT in soil is required and should be provided by Thor if the use which induces a continuous rejection of C(M)IT and MIT in soil is claimed and acceptable at the product authorisation stage.