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: 13

ECHA/BPC/055/2015

Adopted

17 June 2015

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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 13

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 13 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)[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 15 June 2007 and Thor GmbH (hereafter reffered to as "Thor") on 31 July 2007, the evaluating Competent Authority France submitted a combined assessment report and the conclusions of its evaluation to the Commission on 27 November 2012. 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.

This opinion was adopted at BPC-10 on 14 April 2015. However, after this BPC meeting section 2.3 of the opinion for PT 13 was reconsidered with respect to the requirements for (semi-)automated machines during the application and post application phase. It was identified that one element of the condition under point 5 adopted at BPC-10 was in fact redundant. A written procedure according to Article 20 of the Rules of Procedure (RoP) of the BPC was initiated on 4 May 2015 containing a proposal from the rapporteur to amend the opinion adopted at BPC-10. Following this written procedure the proposal from the rapporteur was adopted. According to Article 20 of the RoP of the BPC the BPC Secretariat prepared the written procedure report and presented this at BPC-11 (BPC-11-2015-25).

[1] According to the guidance for substance identification and naming of substances under REACH and CLP

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 13 was adopted on 17 June 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 13 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 13, in preservation of metalworking fluid.
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:

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 on 17 October 2014.

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) as a metalworking fluid preservative. C(M)IT/MIT biocidal products are exclusively used by professionals or industrial users in PT13.

C(M)IT/MIT was shown to be an effective antimicrobial agent when tested in standard biocide efficacy tests. Minimum Inhibitory Concentration (MIC) studies were conducted to demonstrate the lowest level of biocide which inhibits the growth of common spoilage microorganisms (bacteria and fungi). Additional studies showed cidal effects of C(MI)T/MIT against mixed pools of bacteria and fungi.

The efficacy of C(M)IT/MIT (static and cide effects) against bacteria and fungi has been proven for application rates between 10 to 42 ppm of active ingredient, related to target organism.

C(M)IT/MIT has been used as a commercial antimicrobial agent since 1980. During this period of use, resistance to C(M)IT/MIT has been observed. 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**
Professional use of preserved metal working fluids (MWF)	Primary exposure to the biocidal product - Manual, semi-automated or automated mixing/loading of the product to the sump. PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration)	professionals
Professional use of preserved metal working fluids (MWF)	Primary exposure to MWF: - Application: operating the machines, handling objects wetted with MWF, cleaning the wetted tools and surfaces; - post application: fluid monitoring, sump maintenance, disposal and recycling of MWF.	
Professional use of preserved metal working fluids (MWF)	Primary exposure Combined exposure of all daily tasks. PPE only for loading task: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration).	

Professional use of preserved metal working fluids (MWF)	Secondary exposure to MWF treated with C(M)IT/MIT: cleaning surfaces and equipment, collecting shaving storage. Potential exposure from these tasks is anticipated to be covered by the exposure during the M&L and the application phases.	

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 local effects.

Therefore, the products are classified and labelled as corrosive and sensitising, they should be handled with sufficient risk mitigation measures, including collective systems (e.g. automated dosing and mixing systems) additionally to PPE, in order to prevent any spillage on skin. However, exposure to metalworking fluids (application phase) cannot be prevented with gloves since they could be a safety hazard if worn near rotating machinery. In order to take into account the sensitizing properties of the C(M)IT/MIT, the product concentration of use in MWF must be reduced below the threshold value of 15 ppm a.i. when exposure cannot be reduced to an acceptable level by other means (i.e. closed system,…).

Therefore, packaging, equipments and procedures, e.g. automated dosing systems, should be designed to prevent exposure as much as possible. Moreover, effective skin protection such as gloves, goggles, protective overalls and boots is required under all the identified scenarios for use of C(M)IT/MIT based products. MSDS and product use instructions shall inform the users of the potential risks and prevention measures.

By using adapted processes, protective equipments and respecting good professional practices, the exposure potential to C(M)IT/MIT based products can be avoided and the risk of adverse health effects can be reduced to an acceptable level.

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. Safe uses were identified for all the exposure scenarios evaluated. Wearing of appropriate personal protective equipment (PPE), including impermeable coverall, gloves is needed, and risk mitigation measures, such as automated dosage, have to be applied to avoid exposure during loading tasks.

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**
Preservative for water-soluble metalworking fluids	Emission to sewage treatment plant (STP), surface water, sediment, soil, groundwater)
Preservative for emulsifiable metalworking fluids	Emission to 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 wastewater to sewage water treatment plants (STP) and subsequent release via effluents to surface water and sediment. There are no direct emissions to surface water or sediment, and aquatic or sediment organisms are not directly exposed to the active substance.
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 can be identified for aquatic, sewage treatment plant and terrestrial compartments taking into account the simulation study in the STP showing that only MIT is released at the outlet of the STP, for a use of the substance as preservative in water soluble metal working fluid at the doses rates proposed (10, 14, 35 and 42 ppm) and for a use as preservative in emulsifiable metal working fluid at the doses rates proposed (10 and 14 ppm). For the highest intended doses used in emulsifiable metal working fluid, for which there are unacceptable risks for the aquatic compartment, the assessment should be revised at product authorisation level in the light of the new guidance for PT 13 currently under preparation.

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	The active substance is not considered to have endocrine	

properties	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"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] 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 13

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: **t**he 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.

[2] 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)
3 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)

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. Labels and/or safety data sheets for products should indicate that the end-use concentration of C(M)IT/MIT in metal working fluids should not exceed the specific concentration limit for sensitisation, as the use of gloves is not common practice during metalworking on turning machines unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.
5. Loading of the products into metalworking fluids shall be semi-automated or automated, unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.

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 emulsifiable metal working fluid, for which there are unacceptable risks for the aquatic compartment at high doses rates. At product authorisation, if available, the revised ESD has to be considered. The revised ESD will also contain on-site treatment of waste which was not considered in the current evaluation.
3. 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 evaluating Competent Authority (France) as soon as possible but no later than 6 months before the date of approval of the active substance:

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

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