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: 4

ECHA/BPC/052/2015

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 4

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 4 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 an application by Rohm and Haas Europe Trading ApS, now a subsidiary of The Dow Chemical Company (hereafter referenced as "Dow") on 12th of 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 4 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 4 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 4, as an antimicrobial product for the preservation of pasteurization tunnels and conveyor lubricants in food and feed area. The aim is to avoid contamination of food/beverage with pathogenic organisms in these two industrial processes.

For this PT, C(M)IT/MIT biocidal products are exclusively used by professionals users.

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, air and food/feeding stuffs.

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 follows:

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 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, which is used in food preparation aeras such as breweries, beverages plants, dairy, food processing companie as a preservative to control the growth of bacteria, algae and fungi in:

- pasteurization tunnels : the application of C(M)IT-MIT has the objective to maintain the quality of the flush water to avoid the introduction of potential pathogens in the system. Pathogen free water is necessary to avoid residual pathogen for example at the neck of bottles.
- as an additive to conveyor lubricants which are sprayed onto the conveyor belt to prevent stick-slippage of the packaging or the food. The addition of CMIT/MIT to the lubrifying fluid is to ensure a pathogen-free process and avoid bio-contamination of the food which is transported.

The efficacy of C(M)IT/MIT as an antimicrobial agent was demonstrated in laboratory tests at a dose between 1 to 5 ppm a.i., and is acceptable for the assessment of the use of C(M)IT-MIT as an antimicrobial agent against a variety of micro-organisms (bacteria, fungi, green algae and cyanobacteria).

The recommended 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 product in the system	Primary exposure Disconnecting/connecting lines for automated transfer or insert a dip-pipe or lance into the vessel and draw off product into a day tank for semi-automated transfer. PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration).	Professionals (industrial workers)
Application in pasteurisation tunnels or conveyor lubricants	Primary exposure Supplying process fluids (water or lubricant) into food processing systems, via automated dosed systems. No exposure is considered due to the automated system.	Professionals (industrial workers)
Post application: maintenance of equipments	Primary exposure Rinsing deposits from surfaces or simply allowing to dry off, monitoring of the system (swab samples), and maintenance of equipments (dispensing pumps and spray nozzles). Waste fluids are disposed to treatment plants without exposure to operators, PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration),	Professionals (industrial workers)
Combined exposure: loading and maintenance of equipments	Primary exposure PPE: chemical-resistant gloves (10% penetration), impermeable coveralls (5% penetration).	Professionals (industrial workers)
Exposure of workers and general public via contact with packaging	Secondary exposure Handling contaminated packages with residues of C(M)IT/MIT.	Workers/general public
Exposure of general public via food	Secondary exposure Indirect ingestion of residues of C(M)IT/MIT on food packaging.	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.

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 the daily tasks.
Concerning the scenarios for industrial workers using biocidal products in diluting process, no unacceptable risks for combined systemic exposure where identified, when an automated system for loading is considered, provided chemical resistant gloves and impermeable coveralls are worn during the cleaning phase and a rinsing step is added. When considering manual system for loading, chemical resistant gloves, impermeable coveralls and RPE (respiratory protection equipement) additionally worn during the loading phase, risk for workers is still unacceptable.

The same provisions apply for the cleaning phase as for the automated loading scenario.
No unacceptable risk has been identified for secondary exposure of workers and general public.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Application in pasteurisation tunnels or conveyor lubricants	Emission to wastewater due to leakage or rinse-off and via cleaning of treated area (sewage treatment plant (STP), surface water, 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 Koc value. In addition secondary poisoning is not assessed due to the low bioaccumulative properties of the substance.
No unacceptable risk for any environmental compartment was identified for the use of C(M)IT/MIT in pasteurisation tunnels or conveyor lubricants.

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"[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).

[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)

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 4

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. Biocidal products containing C(M)IT/MIT should only be loaded by automated systems unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.

5. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

6. Products containing C(M)IT/MIT shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of C(M)IT/MIT into food or it has been established pursuant to that Regulation that such limits are not necessary.

7. 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 dietary risk assessment, it shall be considered whether available exposure scenarios need to be reviewed or amended at product authorization stage.

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 datashould 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 :

1. 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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