Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

2-methylisothiazol-3(2H)-one

Product type: 11

ECHA/BPC/138/2016

Adopted

15 December 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance 2-methylisothiazol-3(2H)-one 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:	**MIT**
Chemical names:	**2-methylisothiazol-3(2H)-one**
EC No.:	**220-239-6**
CAS No.:	**2682-20-4**
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 Thor GmbH on 5 November 2008, the evaluating Competent Authority Slovenia submitted an assessment report and the conclusions of its evaluation to the ECHA on 7 April 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-18) and its Working Groups (WG IV 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Slovenia

The BPC opinion on the approval of the active substance MIT in product type 11 was adopted on 15 December 2016.

The BPC opinion was adopted by consensus.The opinion is published on the ECHA webpage at:

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 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 MIT in product type 11, in preservation of liquid cooling and processing systems.

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.

Validated analytical methods are available for the active substance as manufactured, for the relevant and significant impurities and the relevant matrices water and air.

No harmonised classification and labelling according to CLP is available. The opinion proposing a harmonised classification and labelling for MIT was adopted by the Committee for Risk Assessment (RAC) on 10 March 2016, but the harmonized classification and labelling in Annex VI of the Regulation (EC) No 1272/2008 (CLP Regulation) has not been published yet.

The proposed classification and labelling for MIT according to CLP Regulation is:

Proposed classification and labelling in accordance to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2/H330 Acute Tox. 3/H311 Acute Tox. 3/H301 Skin Corr. 1B/H314 Skin Sens. 1A/H317 Aquatic Acute 1/H400 Aquatic Chronic 1/H410
Labelling	
Pictogram codes	GHS06 GHS05 GHS09
Signal Word	Danger
Hazard Statement Codes	H330: Fatal if inhaled H311: Toxic in contact with skin H301: Toxic if swallowed

	H314: Cause severe skin burns and eye damage H317: May cause an allergic skin reaction H410: Very toxic to aquatic life with long lasting effects
Supplementary hazard statement	EUH071
Specific Concentration limits, M-factors	Skin.Sens. 1A; H317: SCL ≥ 0.0015 % Aquatic acute M-factor: 10 Aquatic chronic M-factor: 1

b) Intended use, target species and effectiveness

MIT is intended to be used for preservation of open and closed liquid cooling and processing systems against harmful microorganisms. The prevention of bacterial and fungal growth is usually sufficient for the protection of these systems. Biocidal product will be administered by shock or continuous dosing with an end-use concentration of 0.0005 % of the active substance. MIT containing biocidal products are exclusively used by professionals or industrial users in PT11.

MIT utilizes a two step mechanism involving rapid inhibition (within minutes) of growth and metabolism, followed by an irreversible cell damage resulting in loss of viability (within hours). Cells are inhibited by the disruption of metabolic pathways and cell death results from the destruction of protein thiols and the production of free radicals.

The data on MIT and the representative biocidal product have demonstrated sufficient efficacy against the target species for the intended use.

The specific mechanism of action ensures that microbial resistance and cross-resistance to MIT does not present a significant problem. Since the adaptive resistance to MIT in use was described in the literature, several remedies are available in such occasion, for example adding an additional biocide (combination treatment) to broaden the spectrum of efficacy and/or provide different mechanisms of action, switching or alternating to another active ingredient and adding an adjuvant material (ex. EDTA or surfactants) which may improve biocide penetration.

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

Human health

Inhalation of MIT irritates the respiratory tract. MIT is corrosive to the skin and may cause serious damage to the eye. Skin sensitization was observed in test animals and humans. After repeated exposure only minor systemic effects were observed, like reduction in body weight gain. MIT is not genotoxic, mutagenic, carcinogenic, reproductive or developmental toxicant.

The critical endpoints of MIT are driven by its local toxicity and so a local risk assessment was performed. The observed systemic effects are considered secondary to local effects, but a systemic risk assessment has been performed to supplement the local ones.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Manual loading into the sump	Primary exposure to the biocidal product: Manual pouring of a measured quantity of the biocidal product into the sump or manual pouring of entire drums into the sump. PPE: chemical-resistant gloves (10 % penetration), impermeable coverall (5 % penetration) and face mask.	Professionals	Not acceptable
Automated loading into the sump	Primary exposure to the biocidal product: Automated loading into the sump by connecting the dip tube/pump to the drums. Technical and organizational RMM adequate for high hazard chemicals and appropriate PPE: chemical-resistant gloves (10 % penetration), impermeable coverall (5 % penetration) and face mask.	Professionals	Acceptable with PPE and other RMMs
Sampling process liquid (dip slide)	Primary exposure to the preserved cooling water: Testing of the cooling water via a dip slide to monitor for microbial contamination. PPE: no	Professionals	Acceptable
Cleaning dispensing pumps and empty drums	Primary exposure to the preserved cooling water: Cleaning dispensing pumps and empty drums for re-use. PPE: chemical-resistant gloves (10 % penetration), impermeable coverall (5 % penetration) and face mask.	Professionals	Acceptable with PPE
Inhalation of spray drift from preserved cooling water	Primary/secondary exposure to the preserved cooling water: Exposure in the proximity of the cooling tower to the drift containing the biocidal product. PPE: no	Professionals/ General public	Acceptable

Local effects

MIT is skin, eye and respiratory irritant and a skin sensitizer. The most critical local effect is skin sensitization with the proposed SCL ≥ 0.0015 % (15 ppm).

Except for manual mixing and loading the risk for local dermal effects has been considered acceptable for professionals taking into account appropriate technical and organisational RMM adequate for high hazard category chemicals, including high ventilation and use of

personal protective equipment (protective gloves, impermeable coverall and face mask) in order to prevent any spillage on skin. To ensure full containment during mixing and loading of MIT based products meeting the criteria for classification as skin sensitiser, automation of this task is required. The risk for local respiratory effects was assessed quantitatively and indicated that inhalation exposure to MIT during all tasks is very low and does not pose a risk for health of professional users. Also for the general public potentially secondary exposed through inhalation of spray drift from the cooling towers the risks were acceptable.

Systemic effects

The mixing and loading, post application tasks (sampling of process liquid and cleanining dispensing pumps and empty drums) and inhalation of spray drift from preserved cooling water could potentially occur on the same day. Therefore combined exposure was considered for all daily tasks. Safe uses were identified for all primary exposure scenarios provided appropriate personal protective equipment is weared, including impermeable coverall, protective gloves and face mask.
For the only secondary exposure scenario, relevant for professionals and general public, the exposure to MIT was acceptable.

Environment

The table below summarises the exposure scenarios assessed.

<table>
<tr><th colspan="2">Summary table: environment scenarios</th><th></th></tr>
<tr><th>Scenario</th><th>Description of scenario including environmental compartments</th><th>Conclusion</th></tr>
<tr><td>Large open recirculating cooling systems with continuous dosing</td><td rowspan="6">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.</td><td rowspan="2">Not acceptable for surface water and soil</td></tr>
<tr><td>Large open recirculating cooling systems with shock-dosing twice a day</td></tr>
<tr><td>Small open recirculating cooling systems with continuous dosing</td><td rowspan="3">Not acceptable for surface water (acceptable for soil provided drift eliminators are used)</td></tr>
<tr><td>Small open recirculating cooling systems with shock-dosing twice a day</td></tr>
<tr><td>Small open recirculating cooling systems with shock-dosing twice a week</td></tr>
<tr><td>Small open recirculating cooling systems with continuous dosing</td><td rowspan="3">Regular discharge of cooling water (blowdown): emissions to surface water via STP, soil and groundwater via sludge application.</td><td>Acceptable (acceptable for soil provided drift eliminators are used)</td></tr>
<tr><td>Small open recirculating cooling systems with shock-dosing twice a day</td><td>Not acceptable for surface water (acceptable for soil provided drift eliminators are used)</td></tr>
<tr><td>Small open recirculating cooling systems with shock-dosing twice a week</td><td>Acceptable (acceptable for soil provided drift eliminators are used)</td></tr>
</table>

Two emission routes of 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. For small open recirculating system which can be connected to a sewage water treatment plants (STP), releases via the wastewater to STP and subsequent release via effluents and STP sludge to surface water, soil and groundwater have been assessed. Indirect 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.

Open recirculating cooling systems with releases directed to a STP

No unacceptable risk for surface water has been identified for the use in small open recirculating cooling systems with continuous dosing or shock dosing twice a week, when releases from the systems are directed to a STP. Unacceptable risk for surface water has been identified for the use in small open circulating cooling systems with shock dosing twice a day, even when releases from the systems are directed to a STP. Acceptable risks were determined for soil when drift elimators are used to reduce the direct emission to air (via evaporation and wind drift), and subsequently the deposition to soil.

Open recirculating cooling systems with releases directed to the river

Unacceptable risks for surface water have been determined for uses in large and small open recirculating cooling towers, when releases are directed to the river, even considering high dilution (up to a factor 1000). Acceptable risks were determined for soil for small recirculating cooling systems when drift elimators are used to reduce the emission to air, and subsequently the deposition to soil.

MIT containing products can also be used in closed systems. There is no release to the environment, and subsequently no risk, for these systems.

Overall conclusion

Overall acceptable risk is identified in small open recirculating cooling systems with continuous dosing or shock dosing twice a week, when releases from the systems are directed to a STP and drift eliminators are used, and in closed systems. In addition, these uses are considered safe for professional users applying adequate risk management measures where exposure to MIT is possible at or above concentrations meeting the criteria for classification as skin sensitiser.

The risk is unacceptable for manual mixing and loading where dermal contact to mixtures with a potential for sensitisation cannot be prevented and for uses in large and small open recirculating cooling towers, when releases are directed to the river.

2.2. Exclusion, substitution and POP 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	MIT does not fulfil criterion (a), (b) and (c) of Article 5(1).
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	MIT does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	not T	
Endocrine disrupting properties	MIT is not considered to have endocrine disrupting properties. MIT does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. MIT does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	MIT is classified as skin sensitiser 1A. This critical effect can be managed with risk mitigation measures to avoid any skin contact during use of biocidal products by professionals and by limiting the concentration of MIT in treated articles used by professionals and non professionals below the threshold value set for sensitizing properties when skin contact cannot be avoided by other means. With the application of these conditions, it can be considered that criterion (e) of Article 10(1) is not fulfilled.		
Proportion of non-active isomers or impurities	MIT does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

MIT does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. 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" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" 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

MIT does not meet the criteria for being a persistent organic pollutant (POP) and does not have potential for long-range transport.

2.3. BPC opinion on the application for approval of the active substance MIT in product type 11

In view of the conclusions of the evaluation, it is proposed that 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 evaluated: > 950 g/kg**.** Relevant impurity: CMIT: < 1 g/kg.

2. The authorisations of biocidal products are subject to the following condition(s):

    a. 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.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Industrial/professional users;

        ii. Surface water and soil for products used in large and small open recirculating cooling systems with direct emission to surface water.

3. The placing on the market of treated articles is subject to the following condition:
    a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance MIT shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance is classified as acutely toxic cat. 2/3, skin sensitisation cat. 1A and aquatic acute cat. 1, so it fulfills the criteria according to Article 28 (1)(a) and cannot be included in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. If an unacceptable risk is identified for industrial/professional users, safe operational procedures and appropriate organizational 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.

b. An unacceptable risk is identidied for soil and surface water for products used in small and large open recirculating cooling systems with direct release to surface water. If the risk cannot be reduced by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. An unacceptable risk was identified for soil due to drift which was mitigated using risk mitigation measures. At product authorization stage it should be verified, whether drift eliminators can be considered fully implemented. If the risk cannot be reduced by appropriate risk mitigation measures such as drift eliminators or other means, these uses should not be authorized.

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 MIT.

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