Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

2-methylisothiazol-3(2H)-one

Product type: 12

ECHA/BPC/141/2017

Adopted

2 March 2017

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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 12

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 12 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 BPC-19) 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 12 was adopted on 2 March 2017.

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 12 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 12 to preserve systems in paper mills against harmful microorganisms.

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 and 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. However, 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 based biocidal products are intended to be used as a slimicide for preservation against harmful microorganisms in aqueous products such as paper or pulp slurries in paper mills. The prevention of bacterial and fungal growth needs to be achieved for the protection against slime producing organisms in these systems. Biocidal product will be administered by shock or continuous dosing with an end-use concentration of 0.0015 % of the active substance. It will be used indoors by industrial and professional users.

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 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 (for example 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 in addition to the assessment for systemic effects.

The table below summarises the exposure scenarios assessed. The conclusion of the scenarios reflects the outcome of both local and systemic risk assessments.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Automated loading into the sump	Primary exposure to biocidal product. Automated loading into the sump by disconnecting an empty drum and reconnecting a full drum. Technical and organizational RMM adequate for high hazard chemicals and appropriate PPE: chemical-resistant gloves, impermeable coverall and face mask.	Professionals	Acceptable with PPE and other RMMs
Application - process operation	No exposure foreseen.	n.r.	n.r.
Post application - sampling process liquid (dip slide)	Primary exposure to preserved process liquid. Testing of the cooling water via a dip slide to monitor for microbial contamination. PPE: gloves and impermeable coverall.	Professionals	Acceptable with PPE
Post application – cleaning dispensing pumps and empty containers	Primary exposure to biocidal product. 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
Post application – process equipment maintenance	Primary exposure to preserved process liquid. Process equipment maintenance. PPE: gloves and impermeable coverall.	Professionals	Acceptable with PPE
Inhalation of humidified air containing the active substance in the paper mill	Secondary exposure to preserved process liquid. Inhalation exposure of a worker to a vapour phase due to volatilisation of the active substance and to an aerosol due to rotating system.	Professionals	Acceptable
Dermal exposure from contact with paper	Secondary exposure to preserved process liquid. Dermal exposure from contact with paper contaminated with MIT. 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).

The risk for local dermal effects has been considered acceptable for professionals taking into account appropriate technical and organisational RMM adequate for the high hazard category chemicals, including high ventilation and use of personal protective equipment (protective gloves, impermeable coverall and face shield) in order to prevent any spillage on skin.

No risk for local dermal effects was identified for general public exposed to MIT residues through contact with paper.

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.

Systemic effects

The mixing and loading, post application tasks, inhalation of humidified air containing biocidal product and dermal contact with MIT residues in paper 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 worn, including impermeable coverall, protective gloves and face mask during automated loading and cleaning of connection pipes and empty drums.

For secondary exposure scenarios, relevant for professionals and general public, the exposure to MIT was acceptable. Besides that, the transfer of MIT residues from food packaging material to food items is not expected.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Paper mill without connection to a pulp mill.	Water from the paper mill is subjected to settling and mechanical/chemical treatment in the paper mill and then discharged to surface water. Emission to surface water.	Not acceptable
Paper mill with connection to a pulp mill.	Wastewater after settling is discharged to an industrial STP and then discharged to surface water. Emissions to surface water, soil and groundwater via STP.	Acceptable (with RMM to reduce emission to STP)

Two emission routes of MIT through its use in the representative biocidal product have been considered. In the case of a paper mill without connection to a pulp mill, direct release to surface water after settling and mechanical/chemical treatment has been assessed. For paper mills with connection to a pulp mill and discharge of waste water after settling, 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 surface water has been identified for the use in paper mills, when releases from the facility are directed to a STP and the dilution in the receiving river is sufficient. An unacceptable risk to microorganisms in the STP was concluded. This risk can be mitigated by various RMMs to reduce exposure of microorganism in the STP to MIT. These could include (but should not be restricted to) the following operational and technical control measures:

i. measurement of MIT concentration in the waste water (to be compared with the PNEC) or/and performing a test on the total toxicity of the waste water before a biological treatment at the STP;

ii. increase the minimum retention time to 8 hours for a primary settling and/or introduce chemical/mechanical treatment before biological treatment at the STP;

iii. addition of different agents (e.g. reducing agent and/or flocculation agents) to reduce the amount MIT content during a chemical/mechanical treatment; v. use of collecting tanks to store waste water in case large amounts of waste water with higher MIT concentration occur, e.g. in case of system cleaning or maintenance work.

Independent from the above mentioned RMMs it is recommended to regularly control the biological treatment plant and the active biomass and if relevant, adjust the nutrition supply (nitrogen and phosphorus) to the actual need of the active biomass to maintain a sufficient amount and growth of microorganisms.

Unacceptable risks for surface water have been determined for use in paper mills, when releases are directed to the river.

Overall conclusion

An acceptable risk is identified for industrial/professional users applying adequate risk management measures to limit exposure to mixtures meeting the criteria for classification as skin sensitiser, considering paper mills connected to a pulp mill with discharge of waste water after settling via sewage water treatment plants (STP). In addition, risk mitigation measures are required to reduce exposure of microorganisms in STP as well as applying an appropriate dilution factor for industrial release from the paper mill facilities into the watercourse.

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 12

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;

        iii. Sewage treatment plant.

3. The placing on the market of treated articles is subject to the following condition(s):
    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 does not fulfil the requirements of 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 identified for surface water for products used in paper mills with direct release to surface water. The risk is acceptable in case of release to waste water from paper mills to a sewage treatment plant and considering an appropriate dilution factor of industrial release from the paper mill facilities into the watercourse. If the risk cannot be reduced by appropriate risk mitigation measures or by other means, these uses should not be authorised.

    An unacceptable risk is identified for microorganisms in the STP. If risks to

microorganisms cannot be reduced to acceptable level by other means, it should be considered that labels and/or safety-data sheets of products authorised clearly indicate that attention should be paid to the functioning of the STP by appropriate RMMs. A non exhaustive list of possible RMMs is given in section 2.1.c of this opinion. The different proposed RMM will not lead to the same level of risk mitigation and the efficiency of the RMMs applied should be checked at product authorization level, when necessary.

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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