

## **Biocidal Products Committee (BPC)**

Opinion on the application for approval of the active substance:

**MBIT**

**Product type: 6**

ECHA/BPC/154/2017

Adopted

27 June 2017



## Opinion of the Biocidal Products Committee

### on the application for approval of the active substance MBIT for product type 6

In accordance with Article 90(2) 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 6 of the following active substance:

<b>Common name:</b>	MBIT
<b>Chemical name:</b>	2-Methyl-1,2-benzisothiazol-3(2H)-one
<b>EC No.:</b>	-
<b>CAS No.:</b>	2527-66-4
<b>New active substance</b>	

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 on 26 November 2009, the evaluating Competent Authority Poland submitted an assessment report and the conclusions of its evaluation to ECHA on 24 March 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-21) 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: Poland**

The BPC opinion on the approval of the active substance MBIT in product type 6 was adopted on 27 June 2017.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are 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 the MBIT in product type 6 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 MBIT in product type 6. MBIT belongs to chemical class of isothiazolinones. The active substance is obtained by chemical synthesis. 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 relevant and significant impurities and the relevant matrices soil, water and air.

A harmonised classification for MBIT is not available and the active substance is not listed in Annex VI of the Regulation (EC) No 1272/2008. A CLH dossier was submitted to ECHA in May 2017<sup>1</sup>.

The proposed classification and labelling for MBIT according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

<b>Proposed classification according to the CLP Regulation</b>	
Hazard Class and Category Codes	Acute Tox. 3, H301 Acute Tox. 4 H332 Acute Tox. 4 H312 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic chronic 2, H411
<b>Labelling</b>	
Pictogram codes	GHS05 GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H301: Toxic if swallowed H332: Harmful if inhaled H312: Harmful in contact with skin H314: Causes severe skin burns and eyes damage H317: May cause an allergic skin reaction H410 Very toxic to aquatic life with long lasting effects
<b>Specific Concentration limits, M-Factors</b>	M = 1 (Aquatic acute)

<sup>1</sup> Different H statements (H311 and H331 instead of H312 and H332, respectively) were proposed in the CLH dossier submitted to ECHA.

### Justification for the proposal

H301: Based on oral LD<sub>50</sub> in female rats = 175 mg/kg body weight

H332: Due to the absence of mortality and complete lack of clinical findings observed in the acute inhalation study at 2.22 mg/L of product (0.53 mg/l of MBIT).

H312: 1000 mg/kg/d < LD<sub>50</sub> for MBIT <2000 mg/kg/d.

H314: Based on skin irritation study where at one of rabbits' skin necrosis was observed.

H317: Based on skin sensitisation study where MBIT is a skin sensitizer at 1800 ppm a.s.; EC<sub>3</sub> = 10455 ppm and 6900 ppm.

H400: Based the 48 hours ErC<sub>50</sub> of 0.24 mg/l from the *Pseudokierchneriella subcapiata* study and 96h LC<sub>50</sub> of 0.24 mg a.i./L for *Oncorhynchus mykiss*.

H411: Based the 48 hours NOErC of 0.012 mg/l from the *Pseudokierchneriella subcapiata* and the substance being rapidly biodegradable.

Taking into account that the simulation tests show rapid primary biodegradation of MBIT in the environment and the degradation products N-Methyl-2-(methylthio)-benzamide, 2-(methylcarbamoyl)- benzene sulfonic acid and 2-carbamoyl- benzene sulfonic acid are not classified as hazardous to the environment it can be concluded that MBIT is rapidly degradable for the purposes of aquatic hazard classification.

### b) Intended use, target species and effectiveness

MBIT biocide is active against a wide variety of microorganisms (bacteria, fungi) over a broad range of environmental conditions that occur within in-can preservation systems. These products include but are not limited to the polymer latex, adhesive, ink, mineral slurries, paints or detergents. MBIT biocidal products are exclusively used by industrial users in PT 6.

The action of MBIT against target organisms is based on a two step mechanism, which involves rapid inhibition of growth and metabolism followed by irreversible cell damage resulting in loss of viability. Its mode of action significantly affect the potential of the cells to maintain the energy balance required for growth, nutrient metabolism, biosynthesis, and repair of excess damage (from overproduction of radicals). All these processes are essential in bacteria and fungi, which explains why MBIT is such a broad-spectrum biocide.

MBIT 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 MBIT against mixed pools of bacteria and fungi. The efficacy of MBIT against bacteria and fungi has been proven for application rates between 50 to 300 ppm of active ingredient, related to target organism.

The mechanism of action of MBIT involves rapid inhibition of growth, respiration, and thiol-containing dehydrogenase enzymes, affecting a variety of metabolic processes within the cell. Developing resistance to multiple targets simultaneously by microorganisms is very difficult and cells have to expend significant amounts of energy to repair and modify the various MBIT targets and repair the damage from the radicals while their overall metabolic processes and energy systems are shut down. This explains why it is difficult for cells to become resistant to biocides like MBIT. Using MBIT in combination or rotation with other biocides may help to avoid the potential risk of developing resistance.

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

#### Human health

MBIT is corrosive to the skin and eyes. Data from studies in animals show that MBIT is also a skin sensitiser. The critical endpoints for MBIT are driven by its local toxicity, therefore a local risk assessment was carried out. The apparent systemic effects of MBIT, are considered secondary to local effects. Nonetheless, a systemic risk assessment was performed to supplement the local risk assessments. 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 mixing and loading	<p><b>Primary exposure to biocidal product:</b> Formulation of biocidal product (25% of MBIT) into end-use applications (addition of biocide into products to be preserved) End-use concentration of MBIT in paints is up to 500 ppm, and in detergents – up to 300 ppm. Dermal and inhalation exposure.</p> <p>PPE: goggles; additional PPE and RMM are needed, unless product specific data ensures that local effects can be excluded</p>	Industrial	Acceptable with PPE
Cleanup of Minor Spill	<p><b>Primary exposure to biocidal product:</b> Cleanup of minor spill from the mixing and loading operation for paints and liquid detergents. Dermal and inhalation exposure.</p> <p>PPE: no PPE</p>	Industrial	Acceptable
Hand washed laundry	<p><b>Primary exposure to preserved laundry detergent:</b> Direct skin contact from hand washed laundry End-use concentration: up to 300 ppm Dermal exposure.</p> <p>PPE: no PPE</p>	Professionals	Acceptable
Pre-treatment of clothes	<p><b>Primary exposure to preserved laundry detergent:</b> Direct skin contact with MBIT when clothing stains are being removed by spot-treatment with neat liquid detergent. End-use concentration: up to 300 ppm Dermal exposure.</p> <p>PPE: no PPE</p>	Professionals	Acceptable
Hand dishwashing	<p><b>Primary exposure to preserved hand dishwashing detergent:</b> Dermal as well as inhalation exposure, due to evaporation from the dishwashing water, when hand washing dishes with diluted dishwashing liquid End-use concentration: up to 300 ppm Dermal and inhalation exposure.</p> <p>PPE: no PPE</p>	Professionals	Acceptable
Paint spray application	<p><b>Primary exposure to preserved paint:</b> Exposure to the a.s. result from loading paint into the airless sprayer and applying paint with the airless sprayer. End-use concentration: up to 500 ppm Dermal and inhalation exposure.</p> <p>PPE: gloves and coated coveralls</p>	Professionals	Acceptable with PPE

Paint brush and roller application	<p><b>Primary exposure to preserved paint:</b> Exposure to MBIT in paint and/or primer when the coatings containing the biocide are applied by brush and roller to surfaces. End-use concentration: up to 500 ppm Dermal and inhalation exposure.</p> <p>PPE: no PPE</p>	Professionals	Acceptable
Hand washed laundry	<p><b>Primary exposure to preserved laundry detergent:</b> Direct skin contact from hand washed laundry. Adult and child End-use concentration: up to 300 ppm Dermal exposure.</p> <p>PPE: no PPE</p>	Non-professionals	Acceptable
Pre-treatment of clothes	<p><b>Primary exposure to preserved laundry detergent:</b> Direct skin contact with MBIT when clothing stains are being removed by spot-treatment with neat liquid detergent. Adult and child End-use concentration: up to 300 ppm Dermal exposure.</p> <p>PPE: no PPE</p>	Non-professionals	Acceptable
Hand dishwashing	<p><b>Primary exposure to preserved hand dishwashing detergent:</b> Dermal as well as inhalation exposure, due to evaporation from the dishwashing water, when hand washing dishes with diluted dishwashing liquid Adult and child End-use concentration: up to 300 ppm Dermal and inhalation exposure.</p> <p>PPE: no PPE</p>	Non-professionals	Acceptable
Misuse of neat hand dishwashing liquid	<p><b>Primary exposure to preserved hand dishwashing detergent:</b> Dermal exposure if neat dishwashing liquid is used to wash up hands. Adult and child End-use concentration: up to 300 ppm Dermal exposure.</p> <p>PPE: no PPE</p>	Non-professionals	Acceptable
Paint brush and roller application	<p><b>Primary exposure to preserved paint:</b> Exposure to MBIT in paint and/or primer when the coatings containing the biocide are applied by brush and roller to surfaces. Adult End-use concentration: up to 500 ppm Dermal and inhalation exposure.</p> <p>PPE: no PPE</p>	Non-professionals	Acceptable



Contact from wearing treated Clothes	<b>Indirect exposure:</b> Residues of components of laundry detergents remain on textiles after washing and come in contact with the skin via transfer from textile to skin. Adult and child End-use concentration: up to 300 ppm Dermal exposure.	Non-professionals	Acceptable
Residues on utensils and dishware	<b>Indirect exposure:</b> MBIT residues remaining on eating utensils and dishes washed with dishwashing detergents. Adult and child End-use concentration: up to 300 ppm Oral exposure.	Non-professionals	Acceptable
Inhalation exposure from painted walls	<b>Indirect exposure:</b> residents of homes and/or offices painted with paint containing MBIT. Adult and child End-use concentration: up to 500 ppm Inhalation exposure.	Non-professionals	Acceptable
Contact of a freshly painted wet surface	<b>Indirect exposure:</b> post-application dermal contact of a freshly painted wet surface. Child End-use concentration: up to 500 ppm Dermal exposure.	Non-professionals	Acceptable
Contact of a dry coated surface	<b>Indirect exposure:</b> chronic exposure to MBIT in paint and coatings from a dry coated surface. Child End-use concentration: up to 500 ppm Dermal exposure.	Non-professionals	Acceptable
Ingestion of paint	<b>Indirect exposure:</b> intentional ingestion of a dried paint chips containing MBIT Child End-use concentration: up to 500 ppm Oral exposure.	Non-professionals	Acceptable

Product specific data showed that the representative product containing 25% MBIT is damaging to the eyes, but is not a skin irritant or a skin sensitizer. However, considering that MBIT belongs to isothiazolinone family, the proposed classification as a Cat 1A sensitizer and that MBIT is a new active substance, the use of additional PPE as a good practice is recommended where exposure may be to the concentrated biocidal product. In the absence of product specific data on local effects a full local effect assessment is required. All primary and secondary exposures of professionals are acceptable. During spray application of preserved paint appropriate PPE (gloves and coated coveralls) are necessary to reduce exposure via dermal route.

General public may be exposed to the product during use of products preserved with MBIT, i.e. liquid detergents and paints. This exposure scenario is considered acceptable as MBIT is present in the preserved products at concentration that do not require classification for local effects.

Dietary risk assessment of an indirect exposure to residues of MBIT on dishware, indicated no risk for general public (adult and children) even when no rinsing step is assumed.

The scenarios for the preservation of paints and detergents cover the use of MBIT for preservation of fluids used in paper, leather and textile production.

Based on assessment of the scenarios listed above, it is concluded that exposure levels of industrial users, professionals and general public are acceptable.

### **Environment**

The table below summarises the exposure scenarios assessed.

<b>Summary table: environment scenarios</b>		
<b>Scenario</b>	<b>Description of scenario including environmental compartments</b>	<b>Conclusion</b>
Detergents	Emission to sewage treatment plant (STP) Release via STP to surface water, sediment, soil, groundwater	Formulation and use:  Acceptable risk for all environmental compartments for MBIT and metabolites
Paints and plasters	Emission to sewage treatment plant (STP) Release via STP to surface water, sediment, soil, groundwater  Direct emission to soil Direct emission to surface water	Formulation:  Acceptable risk for all environmental compartments for MBIT and metabolites
		Outdoor use:  Acceptable risk for MBIT and metabolites for all environmental compartments with exception of: * unacceptable risk for MBIT in surface water in rivers * unacceptable risk for metabolites in groundwater
		Indoor use:  Acceptable risk for all environmental compartments for MBIT and metabolites
Fluids used in paper production	Emission to sewage treatment plant (STP) Release via STP to surface water, sediment, soil, groundwater	Formulation:  Acceptable risk for all environmental compartments for MBIT and metabolites
		Use during dry-end operations:  Acceptable risk for MBIT and metabolites for all environmental compartments with exception of:  * unacceptable risk for metabolites in groundwater

		<p>Use during wet-end operations:</p> <p>Acceptable risk for MBIT and metabolites for all environmental compartments with exception of:</p> <ul style="list-style-type: none"> <li>* unacceptable risk for MBIT in surface water</li> <li>* unacceptable risk for metabolites in groundwater</li> </ul>
Fluids used in textile production	Emission to sewage treatment plant (STP) Release via STP to surface water, sediment, soil, groundwater	<p>Formulation:</p> <p>Acceptable risk for all environmental compartments for MBIT and metabolites</p>
		<p>Use:</p> <p>Acceptable risk for MBIT and metabolites for all environmental compartments with exception of:</p> <ul style="list-style-type: none"> <li>* unacceptable risk for MBIT in surface water</li> <li>* unacceptable risk for metabolites in groundwater</li> </ul>
Fluids used in leather production	Emission to sewage treatment plant (STP) Release via STP to surface water, sediment, soil, groundwater	<p>Formulation:</p> <p>Acceptable risk for all environmental compartments for MBIT and metabolites</p>
		<p>Use:</p> <p>Acceptable risk for MBIT and metabolites for all environmental compartments with exception of:</p> <ul style="list-style-type: none"> <li>* unacceptable risk for MBIT in surface water</li> <li>* unacceptable risk for metabolites in groundwater</li> </ul>

No unacceptable risk can be identified for the sewage treatment plant, aquatic, and terrestrial compartments, and groundwater for the formulation stage of the preserved products in all the assessed PT 6 sub-categories.

No unacceptable risk for MBIT (including metabolites) was also identified for all the

environmental compartments for the use phase of preserved detergents.

In case of use and/or service life of products from the other sub-categories:

- MBIT poses no unacceptable risk to STP, soil and groundwater. However, an unacceptable risk is identified to surface water during:
  - service life of preserved paints and plasters after direct emission to the river via rainfall or storm water events in the urban areas;
  - use of preserved fluids used in paper production if preservative is added during wet-end operations of paper making ;
  - use of preserved fluids used in textile and leather production.
- MBIT metabolites pose no unacceptable risk to STP, surface water and soil. However, the concentration in groundwater is above the limit of the Drinking Water Directive 98/83/EC for the use/service life of preserved paints and plasters, fluids used in paper, textile or leather production.

However, as additional item for all other scenarios the following risk mitigations and refinements can be proposed:

- due to risk identified for surface water and groundwater for preserved paints and plasters at the active substance approval stage only indoor use would result in the safe use/service life of these products;
- as for use of preserved fluids used in paper production, there were some scenarios with acceptable risk for surface water (if MBIT has been added during dry-end operations of paper making only) for these reason e.g. new soil studies on metabolites could be submitted at product authorization stage to refine the risk to groundwater.

## Overall conclusion

A safe use for human health and environment is identified for the following scenarios: formulation and use of preserved detergents and indoor use of paints and plasters.

## 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	MBIT 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	MBIT does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	

	Toxic (T)	not T	10(1)
Endocrine disrupting properties	MBIT is not considered to have endocrine disrupting properties. MBIT does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. MBIT does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	MBIT does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	MBIT does not fulfil criterion (f) of Article 10(1).		

Based on ecotoxicological data the metabolites of MBIT are not toxic or bioaccumulative. Metabolite#2 and Metabolite#3 are also not persistent. Metabolite#1 should be considered as potentially persistent or very persistent, however as it can consequently meet only 1 out of the 3 criteria for PBT, a further clarification of its P status is not required.

Consequently, the following is concluded:

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

MBIT 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"<sup>2</sup> and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"<sup>3</sup> agreed at the 54<sup>th</sup> and 58<sup>th</sup> 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

MBIT and its metabolites do not meet the criteria for being persistent organic pollutants.

### 2.3. BPC opinion on the application for approval of the active substance MBIT in product type 6

In view of the conclusions of the evaluation, it is proposed that MBIT 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:  $\geq 997$  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.

<sup>2</sup> 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>)

<sup>3</sup> 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](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))

- b. In view of the possible risks identified for the uses assessed, the product assessment shall pay particular attention to:
    - i. professional users;
    - ii. surface water and groundwater for the outdoor use of preserved paints and plasters and the use of preserved fluids used in paper, textile or leather production.
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 MBIT 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 does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012. MBIT gives rise to the following concerns: it is classified as skin sensitizer (Skin Sens. 1A), corrosive (Skin Corr. 1B, Eye Dam. 1), and toxic to aquatic life (Aquatic Acute 1, Aquatic Chronic 2).

#### **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 for professional users is identified, 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. Unacceptable risks were identified for surface or ground water for the use of preserved paints and plasters outdoors and the use of preserved fluids in paper, textile or leather production. If the unacceptable risk for surface water and/or groundwater remains and cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorized.
- c. The Emission Scenario Document for PT 6 is currently under revision. At product authorization the revised ESD has to be considered for the use phase of preserved detergents (sub-category PT 6.1).

#### **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 MBIT. However, further data on the active substance are required and must be provided to the evaluating Competent Authority (Poland) as soon as possible but no later than the date of approval of the active substance:

- granulometry test;
- the validation of the confirmatory method for detection and identification of MBIT in water;
- analytical method for detection and identification of Metabolite#1, #2 and #3 in soil and water.