Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

OIT

Product type: 8

ECHA/BPC/139/2016

Adopted

15 December 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance OIT for product type 8

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 8 of the following active substance:

Common name:	**OIT**
Chemical name:	**2-Octyl-isothiazol-3(2H)-one**
EC No.:	**247-761-7**
CAS No.:	**26530-20-1**

Existing active substance submitted under Article 11 of the Biocidal Products Directive 98/8/EC

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 27 April 2010, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to ECHA on 4 February 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-18) and its Working Groups (WG III 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance OIT in product type 8 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 OIT in product type 8 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 OIT in product type 8. OIT acts by a two step mechanism involving rapid inhibition (minutes) of growth and metabolism, followed by irreversible cell damage (hours).

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. Validated analytical methods are required and available for soil and water. However as only single ion monitoring methods were used, confirmatory methods are required before the date of approval.

Current harmonised classification and labelling for OIT according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4*, H302 Acute Tox. 3*, H311, H331 Skin Corr. 1B, H314 Skin Sens.1, H317 Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS09
Signal Word	Danger
Hazard Statement Codes	H302 Harmful if swallowed H311 Toxic in contact with skin H331 Toxic if inhaled H314 Causes severe skin burns and eye damage H317 May cause an allergic skin reaction H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	H317 May cause an allergic skin reaction: specific concentration limit C ≥ 0.5% M = 100 (acute) M = 1000 (chronic)

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

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3, H301, H311, H331 Skin Corr. 1, H314 STOT SE 3, H335 Skin Sens.1A, H317 Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS09
Signal Word	Danger
Hazard Statement Codes	H301 Toxic if swallowed H311 Toxic in contact with skin H331 Toxic if inhaled H314 Causes severe skin burns and eye damage H335 May cause respiratory irritation H317 May cause an allergic skin reaction H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	H317 May cause an allergic skin reaction: specific concentration limit C ≥ 0.005% M = 100 (acute) M = 1000 (chronic)

b) Intended use, target species and effectiveness

OIT is a fungicide used in industrial wood preservation to protect freshly sawn timber from blue staining fungi and surface mould growth during storage and processing for use class 1 and 2 according to the OECD Environmental Emission Scenario as defined in the EN 335[1].

OIT acts by a two step mechanism involving rapid inhibition (minutes) of growth and metabolism, followed by irreversible cell damage (hours).

The data on OIT and the representative biocidal product have demonstrated sufficient efficacy against the target species.

For industrial wood preservation using OIT resistance is not an issue. For all kinds of preservation with OIT-containing products, cases of resistance are not reported or known up to the present time. The mode of action of OIT is non-specific (see above) both with respect to microbes as well as regarding the target molecules on cell surface or within a cell. This multiple attack mode precludes the possibility for organisms to develop mechanisms that can be passed on to future generations in the form of "resistance".

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

Human health

The critical endpoints for OIT are driven by its local toxicity: skin sensitisation for the dermal route, respiratory tract irritation for the inhalation route and stomach irritation for the oral route. A local risk assessment is therefore required for these effects. Unspecific systemic effects are also seen with OIT but at much higher dose levels. Systemic AELs have been derived and a systemic risk assessment performed to supplement the local risk assessments.

[1] Since 2007 and the revision of the EN335-1, use classes has replaced hazard classes.

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**
Mixing & loading	Primary exposure to 8 % OIT Coupling /uncoupling transfer lines Gloves, coveralls, eye protection, fully automated process.	Industrial / professional	Acceptable with PPE and other RMMs
Automated dipping	Primary exposure to 0.025 % OIT Gloves, coveralls, automated process.	Industrial / professional	Acceptable with PPE and other RMMs
Vacuum-pressure impregnation	Primary exposure to 0.15 % OIT Gloves, coveralls.	Industrial / professional	Acceptable with PPE
Cleaning dip tank	Primary exposure to 0.025 % OIT Gloves, coveralls.	Industrial / professional	Acceptable with PPE
Handling treated wet wood	Primary exposure to 0.025 % OIT Gloves, coveralls.	Industrial / professional	Acceptable with PPE
Professional sanding OIT-treated wood	Secondary exposure: Assuming a transfer efficiency of 2 % for rough-sawn wood	Industrial / professional	Acceptable
Non-professional sanding OIT-treated wood	Secondary exposure: Assuming a transfer efficiency of 2 % for rough-sawn wood	General public	Acceptable
Infants playing on playground OIT-treated wood structures	Secondary exposure: Assuming a transfer efficiency of 2 % for rough-sawn wood	General public	Acceptable
Inhalation exposure of volatilised residues from indoor OIT-treated timber	Secondary exposure	General public	Acceptable

Systemic toxicity

With regard to primary exposure, acceptable risks were identified for all scenarios without the need for PPE.

With regard to secondary exposure, acceptable risks were identified for all scenarios. For exposure to volatilised residues from indoor OIT-treated timber, risks are acceptable when realistic conditions are considered (ventilated room, constant rate model).

Local toxicity

With regard to primary exposure, a quantitative assessment for respiratory tract irritation has been performed which identified acceptable risks for all scenarios without the need for RPE. For local dermal effects (sensitisation and corrosivity), a qualitative assessment has been undertaken in accordance with current guidance. This identified acceptable risks for all scenarios as long as appropriate PPE (eye protection, gloves and coveralls) are worn and

appropriate engineering controls (fully automated processes) are in place.

With regard to secondary exposure, a quantitative assessment for respiratory tract irritation has been performed which identified acceptable risks for all scenarios apart from exposure to volatilised residues from indoor OIT-treated timber. However, the air levels calculated by the models, used for this scenario, are considered to represent an unrealistic worst case for pre-treated timber which has been stored before use. Therefore it is considered that this scenario also identifies an acceptable risk. For local dermal effects (sensitisation and corrosivity), a semi-quantitative assessment has been undertaken. Although the predicted concentration in treated wood is above the indicative human NOAEC for skin sensitisation, as OIT is bound to the matrix of the treated wood, it is considered to be unavailable for induction of skin sensitisation. In addition, when a more realistic transfer efficiency of 2 % for rough sawn wood is assumed, risks are acceptable.

Environment

OIT is hydrolytically stable, with a half life of more than one year but has a photolytic half life of 5 days. OIT rapidly biodegrades in freshwater and seawater; M1, M4, M5, M6, M7 and M21 are the major metabolites considered relevant for the environmental risk assessment. OIT also biodegrades very rapidly in the soil environment. The most sensitive aquatic organisms to OIT are marine algae and the most sensitive soil organisms to OIT are soil microbes.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Dipping		
Application	Dipping of freshly sawn timber to prevent fungi and mould growth during storage and processing. Compartments assessed: STP, surface water (indirect via STP), sediment via partitioning and soil (indirect).	Not acceptable for surface water, sediment and soil. Acceptable for STP.
Storage	Treated wood is stored in appropriate locations of the treatment plant following the treatment process. Compartments assessed: surface water (direct), sediment via partitioning and soil (direct)	Not acceptable for surface water, sediment and soil.
Vacuum pressure impregnation		
Application	Dipping of freshly sawn timber to prevent fungi and mould growth during storage and processing. Compartments assessed: STP, surface water (indirect via STP), sediment via partitioning and soil (indirectly).	Not acceptable for surface water, sediment and soil. Acceptable for STP.
Storage	Treated wood is stored in appropriate locations of the treatment plant following the treatment process. Compartments assessed: surface water (direct), sediment via partitioning and soil (direct).	Not acceptable for surface water, sediment and soil.

Unacceptable risks to the aquatic, sediment and terrestrial compartments were identified for application and storage and therefore risk management measures will be required. It is proposed that application be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both. There will be no release to the environment from service life as only use class 1 and 2 are requested as part of this application.

Overall conclusion

Overall a safe use has been identified for both human health and the environment when a product containing OIT is used, if appropriate risk mitigation measures are in place.

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	OIT 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[2]	Persistent (P) or very Persistent (vP)	Not P or vP	OIT 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)	T	
Endocrine disrupting properties	OIT is not considered to have endocrine disrupting properties.		
Respiratory sensitisation properties	No classification required.		
Concerns linked to critical effects	OIT does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	OIT does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

OIT 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"[3] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[4] 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] The PBT status of the metabolites will be established when further information becomes available.
[3] 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)
[4] 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

The criteria for a substance being a persistent organic pollutant (POP) are P, B and having the potential for long range transport. In addition, high toxicity can breach the B criterion, in which case a substance will be a persistent organic pollutant if it is P, demonstrates the potential for long range transport, and is either B or T.

OIT does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance OIT in product type 8

In view of the conclusions of the evaluation, it is proposed that OIT 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: 960 g/kg w/w.
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 and professional users.
3. In view of the risks identified for the surface water, sediment and soil, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil sewer or water, and that any losses shall be collected for reuse or disposal.

The placing on the market of treated articles is subject to the following condition(s):

1. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance OIT 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.

OIT gives rise to concern for both human health and the environment i.e. it is classified with Skin Corr. 1B (H314), Skin Sens. 1A (H317), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). Consequently, according to Article 28(2) (a) of Regulation (EU) 528/2012, inclusion in Annex I of Regulation (EU) 528/2012 is not acceptable.

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 and professional users, safe operational procedures and appropriate organisational 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. Where use of the product may lead to contamination of food and feeding stuffs, an assessment of the risk in food and feed areas may be required at product authorisation. Analytical methods for residues in/on food and/or feedstuffs may be required too.

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 OIT.

However, further data on the active substance are required and must be provided before the date of approval to the eCA (UK):

- Confirmatory methods of analysis for the determination of OIT in soil and water;
- Accuracy data required for method of analysis for the determination of OIT in technical material;
- Outstanding data on the identification of all relevant transformation products:
  - Information on the route of degradation including identification of metabolites and degradation products: Biological Sewage Treatment- STP simulation test;
  - Information on the route of degradation including identification of metabolites and degradation products: Biodegradation in freshwater;
  - Information on the route of degradation including identification of metabolites and degradation products: Biodegradation in sea water;
- Outstanding environmental effects data all relevant transformation products: aquatic effects data for fish, aquatic invertebrates and algae, generated via QSAR modelling or laboratory tests. The scheme outline in the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013) should be used;
- Outstanding data for the PBT classification for all relevant transformation products, namely M1, M4, M5, M6, M7 and M21: aquatic toxicity and bioaccumulative potential need to be determined. This can be done via OECD tests or using QSAR modelling.

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