Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

5-chloro-2-methyl-2H-isothiazol-3-one (CIT)

Product type: 6

ECHA/BPC/421/2024

Adopted

27 May 2024

Opinion of the Biocidal Products Committee

on the application for approval of the active substance 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) for product type 6

In accordance with Article 8 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 non-approval in product type 6 of the following active substance:

Common name:	5-chloro-2-methyl-2H-isothiazol-3-one (CIT)
Chemical name:	5-chloro-2-methyl-2H-isothiazol-3-one (CIT)
EC No.:	247-500-7
CAS No.:	26172-55-4
New 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 22 of August 2017, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to ECHA on 18 of September 2019. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-35 and its Working Groups (WG-I-2020)). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

At BPC-35, the Committee had a discussion on the insufficient dataset presented in the dossier to conclude on the endocrine disruptor (ED) assessment for non-target organisms and did not adopt the opinion: the eCA was requested to ask for additional data in order to continue with the evaluation and to finalise the assessment of ED properties before endorsing the opinion.

In light of this conclusion, the eCA requested to the applicant information to complete the ED data set, and, in addition, requested several physico-chemical and analytical data identified also as necessary to confirm the assessment of the active substance.

Such data were submitted to the eCA in December 2022 and the assessment was updated on these issues in an updated AR submitted to ECHA on 27 September 2023 for finalizing the opinion forming phase. The Agency organised consultations via the BPC (BPC-51) and its Working Groups (WG-I-2024).

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the application for approval of the active substance 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) in product type 6 was adopted on 27 May 2024.

The BPC opinion was adopted by consensus. The opinion 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 is that the 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) in product type 6 should not 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 the 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) in product type 6. CIT is a substance belonging to isothiazolinones which 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 cells and of critical physiological functions (respiration, ATP synthesis).

The active substance CIT is the major component of the reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one in ratio (3:1) (C(M)IT/MIT (3:1)), an existing biocidal active substance already approved for several product types in July 2017.

The identity of the active substance is defined as CIT and its stabilizer (as the active substance as produced is not considered stable (rapid degradation)).

The active substance is manufactured in solution with solvents and stabilizers. CIT is always manufactured in a solution in order to have a stabilized product (technical concentrate).

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. The active substance is classified as Unst. Expl. H200.

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

There is currently no harmonized classification and labelling available for this active substance according to Regulation (EC) No 1272/2008 (CLP Regulation).

The proposed classification and labelling for the mixture of CIT and stabilizer according to the CLP Regulation is:

Proposed Classification according to the CLP Regulation (CIT + stabilizer)	
Hazard Class and Category Codes	Unst. Expl. Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Skin Corr. 1C Eye Dam 1

	Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS01 GHS05 GHS06 GHS07 GHS09
Signal Word	Danger
Hazard Statement Codes	H200: Unstable explosive H300: Fatal if swallowed H310: Fatal in contact with skin H330: Fatal if inhaled 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 EUH071: Corrosive to the respiratory tract.
Specific Concentration limits, M-Factors	H314 ≥ 0,45% H318 ≥ 0,45% H315: 0,045% ≤ C <0,45% H317 ≥ 15 ppm H319: 0,045% ≤ C <0,45% M=100 (acute) M=100 (chronic)
Justification for the proposal	
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b) Intended use, target species and effectiveness

CIT is used for the preservation of manufactured products, other than food stuff or feeding stuff or cosmetics, in containers (product type 6) by the control of microbial deterioration to ensure their shelf life during storage (bacteria, yeasts, moulds).

Biocidal products with CIT will be used as wet-state preservation of a wide range of aqueous formulations such as washing and cleaning fluids (except human hygienic products) (6.1.2), paints and coatings (6.2), additives used in paper production (6.3.1), glues and adhesives (6.6) and various other products (6.7) such as pigment pastes, slurries, polymer dispersions and colourants. Biocidal products with CIT will be used industrially by professional workers during the manufacturing process of the formulated products. The formulated products (treated articles) are used in- and outdoor by professionals and general public.

The data on CIT and the representative biocidal product have demonstrated sufficient efficacy against bacteria, yeasts and moulds, with and without preconditioning, for the following uses:

- PT 6.1.2 Preservation of washing and cleaning fluids (general) and other detergents (not intended for human hygiene);
- PT 6.2 Preservation of paints and coatings;
- PT 6.3.1 Preservation of additives used in paper production;

- PT 6.6 Preservation of glues and adhesives;
- PT 6.7 Other: preservation of polymer dispersions;
- PT 6.7 Other: preservation of pigment pastes;
- PT 6.7 Other: preservation of colourants;
- PT 6.7 Other: preservation of slurries ($CaCO_3$, TiO_2).

However, it has to be noted that efficacy against yeasts in colourants and against bacteria in $CaCO_3$ slurries, with and without preconditioning, has to be confirmed at product authorisation level. Furthermore, as yeasts and moulds have not been tested in slurries ($CaCO_3$ and TiO_2), efficacy against yeasts and moulds in slurries needs to be confirmed at product authorisation level as well.

As microbial resistance and cross-resistance to other biocides and to antibiotics to CIT has been described in the literature, special attention should be given at the product authorisation stage.

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

Human health

The toxicological profile of the active substance CIT has been established via read-across with available data on C(M)IT/MIT.

CIT is fatal by oral, dermal and inhalation route. It induces skin corrosion and severe eye irritations as well as skin sensitization with a specific concentration limit < 15 ppm. CIT is not genotoxic and no carcinogenic potential has been identified. No reprotoxic, neurotoxic or immunotoxic effect has been reported.

The genotoxicity information package is considered to not meet the current standards, especially since UDS assays to assess the mutagenicity are considered to not be relevant due to the lack of sensitivity.

Based on the toxicity profile of the substance and a weight of evidence approach, CIT does not meet the criteria for endocrine disruption with regard to human health.

The table below summarizes the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Mixing/ loading	**Primary exposure**. - Automated loading of a liquid biocidal product into products to be preserved.	Industrial workers	Acceptable
Mixing/ loading	**Primary exposure.** - Manual loading of a liquid biocidal product into products to be preserved.	Industrial workers	Acceptable (with gloves and impermeable coverall and

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
			considering face shield, respiratory protection and specific RMMs)
Mixing/ loading	**Primary exposure.** - Filling of preserved formulation.	Industrial workers	Acceptable (with gloves and impermeable coverall)
<u>Washing and cleaning fluids (general) and other detergents</u>			
Application exposure	**Primary exposure.** - Use of detergents during hand washing laundry.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Use of detergents during hand washing laundry.	Non-professionals	
Application exposure	**Primary exposure.** - Use of detergents during pre-treatment of clothes	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Use of detergents during pre-treatment of clothes	Non-professionals	
Application exposure	**Primary exposure.** - Use of detergents during hand dishwashing.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Use of detergents during hand dishwashing.	Non-professionals	
Application exposure	**Primary exposure.** Use of detergents during surface cleaning (household).	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Use of detergents during surface cleaning (household).	Non-professionals	
Post-application exposure	**Primary exposure.** Exposure towards residues of the AS on textiles.	General public	Acceptable (with a maximal concentration < 15 ppm CIT)
Post-application exposure	**Primary exposure.** Exposure towards residues of the AS on utensils and dishware.	General public	Acceptable (with a maximal concentration < 15 ppm CIT)
Post-application exposure	**Primary exposure.** Exposure towards residues of the AS on surfaces	General public	Acceptable

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
			(with a maximal concentration < 15 ppm CIT)
<u>Paints and coatings</u>			
Application exposure	**Primary exposure.** Spraying paints and coatings.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT considering general public exposed by inhalation)
Application exposure	**Primary exposure.** Spraying paints and coatings.	Non-professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Applying paints and coatings with brush or roller.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT considering general public exposed by inhalation)
Application exposure	**Primary exposure.** Applying paints and coatings with brush or roller.	Non-professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Application exposure	**Primary exposure.** Applying plaster via airless spraying and then working with trowels.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT considering general public exposed by inhalation)
Application exposure	**Primary exposure.** Applying plaster via airless spraying and then working with trowels.	Non-professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Post-application exposure	**Secondary exposure.** Dermal exposure from direct contact with CIT in wet and oral exposure from hand to mouth transfer.	General public	Acceptable (with a maximal concentration < 15 ppm CIT)
Post-application	**Secondary exposure.** Dermal exposure from direct	General public	Acceptable

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
exposure	contact with CIT in dry paint and oral exposure from hand to mouth transfer.		
Post-application exposure	**Secondary exposure** Ingestion of painted chips by toddler	General public	Acceptable
Post-application exposure	**Secondary exposure.** Inhalation of volatilized residues	General public	Acceptable (with a maximal concentration < 15 ppm CIT)
Additives used in paper production			
Application exposure	**Primary exposure.** Use of preserved additives in paper production.	Professionals	Acceptable
Glues and adhesives			
Application exposure	**Primary exposure.** Use of preserved glues and adhesives.	Professionals	Acceptable (with a maximal concentration < 15 ppm CIT considering general public exposed by inhalation)
Application exposure	**Primary exposure.** Use of preserved glues and adhesives.	Non-professionals	Acceptable (with a maximal concentration < 15 ppm CIT)
Preservation of polymer dispersions, pigment pastes and colourants			
Application exposure	**Primary exposure.** Use of preserved polymer dispersions, pigment pastes and colourants.	Professionals	Acceptable
Preservation of slurries			
Application exposure	**Primary exposure.** Use of preserved mineral and pigment slurries.	Professionals	Acceptable

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Dietary risk assessment (DRA)			
<u>Washing and cleaning fluids (general) and other detergents</u>			
DRA 1.a Dietary exposure from dishware	Secondary exposure	Treated article used by General public	Acceptable
DRA 1.b Dietary exposure from cleaned surfaces	Secondary exposure	Treated article used by General public	Acceptable
<u>Paints and coatings, Fluids used in paper production, Glues and adhesives</u>			
DRA 2 Dietary exposure from Food contact material	Secondary exposure	Treated article used by General public for food and feed	Acceptable

Local effects

According to the criteria of the CLP Regulation, CIT is proposed to be classified as 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).

Manual mixing and loading of CIT based products and filling phases of the different uses, present an unacceptable risk for local effects, because of the foreseen claimed dose in the products.

However, for professional uses, the risk has been considered acceptable taking into account personal protective equipment and that appropriate risk mitigation measures are applied during the different phase of use of the products by the operators in order to prevent any spillage on skin.

Possible measures (not exhaustive list) are:

- Minimization of manual phases;
- Very high level of containment;
- Regular cleaning of equipment and work area;
- Training for staff on good practice.

Labels, safety data sheets (SDS) and use instructions of the products shall inform the users of the hazards and of the protective measures. Written procedures and protective equipment shall be available at the places where the products are handled.

For liquid detergents, skin exposure to the detergent itself cannot be excluded due to the nature of the task during manual washing of dishes or clothes for example. In this situation of manual handling, controlling the exposure of an operator is difficult due to splashes/spilling occurring during the task. The wearing of personal protective equipment (PPE) will not have the same efficiency as usual.

Furthermore, this population of operators is not used to handle chemicals and cannot be considered as trained workers for this kind of task. Considering the high sensitization potential of the substance, the limitation of the concentration of CIT in the liquid detergent is the most appropriate RMM to avoid skin sensitization of operators. So, concerning professional manual uses of product, the concentration of CIT in the detergent must be reduced below the threshold value of 15 ppm active ingredient[1], in order to take into account the sensitizing properties of CIT.

Concerning non-professional uses and the post application exposure, the end-use concentration in the preserved product (liquid detergents) must be reduced below the threshold value of 15 ppm AS, in order to take into account the sensitizing properties of CIT.

For paints and coatings, risk for general public related to post application exposure via direct contact with the wet paints or coatings is acceptable only if the concentration of CIT in the preserved paints or coatings is below the threshold value of 15 ppm active substance.

In consequence, the risk assessment for non-professional and professional users has been conducted taking into account the limit of 15 ppm active substance, in the paints and coatings applied.

Whatever the method of application of the paints or coatings, the risk for professional and non-professional users is acceptable at the maximal concentration of 15 ppm active substance.

For the other uses (additives used in paper production, glues and adhesives, polymer dispersions, pigment pastes, colourants and slurries) the final concentration of CIT in the preserved products is below the threshold value of 15 ppm AS either because the efficacious concentration is below this limit or because of the dilution of the CIT in end-use products. For such uses, risk for professional and non-professional users is acceptable.

Unlike dermal exposure, no unacceptable risk was identified for the respiratory tract, for any of the scenarios of exposure considered.

Systemic effects

Exposure of professionals and non-professionals to CIT was evaluated for the scenarios summarised in the table above.

The mixing and loading tasks (automatic or manual loading and the filling) could potentially occur on the same day. Therefore, combined exposure was considered for all daily tasks.

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1 Active ingredient definition is a technical material (TC) of CIT without solvent and stabilizers salts.

The critical step is the loading of the product in the system where skin can be exposed to the product, leading to sensitization. No unacceptable risk was identified for all the primary exposure scenarios if wearing of appropriate personal protective equipment (PPE), including gloves, coverall and gloves.

Regarding the secondary exposure including via food, risk is considered acceptable for uses washing and cleaning fluids (general) and other detergents, paints and coatings, with a CIT concentration being below the threshold value of 15 ppm for sensitizing properties.

Regarding the primary exposure related to the use of treated articles, risk is considered acceptable for the other uses (preservation of additives used in paper production, glues and additives, polymer dispersions, pigment pastes and colourants, slurries) for the professional users.

Environment

The ecotoxicological profile of the active substance CIT has been established via a direct read-across with available data on C(M)IT/MIT.

CIT is stable against hydrolysis and photo degradation processes in water and in air are of low relevance. CIT is readily biodegradable without the 10-day window. Nevertheless, degradation studies indicate that CIT has the same emission fractions to the sewage treatment plant (STP) as a substance which is readily biodegradable within the 10-day window. CIT has a low potential for adsorption on soil and sediment. Bioaccumulation potential in aquatic and terrestrial organisms is low.

CIT is not a PBT / vPvB substance.

Potential endocrine disruption of CIT has been investigated according to the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. Additional level 3 studies on EATS (estrogen, androgen, thyroid and steroidogenesis) modalities were conducted according to OECD 229 and 231 guidelines following the discussions of BPC-35.

For T modality, as available mechanistic information does not give indication of endocrine activity and as the dataset is sufficient, it can be concluded that CIT does not meet the ED criteria *via* the T modality.

For E, A and S modalities, a weight of evidence approach considering the level 1 and 2 data, the mammals data, the mode of action of the active substance (very fast reaction with organic matter), and the partial results obtained with the new OECD 229 study, was discussed at WG-I-2024. The new study contains major deficiencies as the tested concentrations were not high enough while a range finding test indicated higher concentrations to conduct the experiment. The WG concluded that the data set remains incomplete with an information gap for ED and not sufficient to conclude on the ED criteria for non-target organisms.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Preservation of washing and cleaning fluids and detergents (not intended for human hygiene)		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.
- Use of the preserved product		
Preservation of Paints and Coatings		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.
- Use of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment Direct emission to: - Soil (and groundwater), - surface water	
Preservation of additives used in Paper production		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.
- Use of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	
Preservation of Glues and adhesives		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP	Not possible to conclude due to insufficient information related to endocrine disrupting

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
- Use of the preserved product	conditions leading to no release to environmental compartment	properties for non-target organisms.
Preservation of Polymer dispersions		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.
- Use of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment Direct emission to: - Soil (and groundwater), - surface water	
Preservation of Pigment pastes		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.
- Use of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment Direct emission to: - Soil (and groundwater), - surface water	
Preservation of Colourants		
- Formulation of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment	Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
- Use of the preserved product	Emission to the STP with a total degradation of CIT in the STP conditions leading to no release to environmental compartment Direct emission to: - Soil (and groundwater), - surface water	
Preservation of slurries (Clay, mica and other fillers)		
		Not possible to conclude due to insufficient information related to endocrine disrupting properties for non-target organisms.

Risks were assessed for the scenario in the summary table, however it is not possible to conclude on ED properties for non-target organisms for CIT.

Exposure of the environment *via* the atmosphere is considered to be negligible. The sediment compartment is deemed not relevant considering the low Koc value of the active substance. In addition, due to the intended uses and the low bioaccumulative properties of the substance, primary and secondary poisoning are not assessed.

Overall conclusion

It is not possible to conclude on the risks from the use of CIT in PT6 due to insufficient information. The information provided is not sufficient to conclude whether CIT fulfils endocrine-disrupting properties for non-target organisms. Therefore, it is not possible to conclude on a safe use.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria for the CIT

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	CIT does not fulfil criterion (a), (b) and (c) of Article 5(1).
	Mutagenicity (M)	No classification required	

Property		**Conclusions**	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	CIT 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	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	CIT does not fulfil criterion (d) of Article 5(1). However, additional data are necessary to conclude on fulfilling Article 10(1)(e).
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Data set not sufficient to conclude	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. CIT does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	No other concerns identified.		
Proportion of non-active isomers or impurities	Not relevant. CIT does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

CIT does not meet the exclusion criteria laid down in Article 5 of the BPR.

As no conclusion can be drawn on ED with regards to non-target organisms, it cannot be concluded whether CIT may meet the conditions laid down in Article 10 of the BPR.

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"[2], and "Further guidance on the application of the substitution criteria set out under article 10(1) of the

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR.

BPR"[3] and "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment[4]" agreed at the 54th, 58th and 77th 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).

Consequently, the following is concluded:

It cannot be established that CIT is not a candidate for substitution, for the following reason:

> according to the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, EATS mediated adversity and endocrine activity have been sufficiently investigated for human health, but not for environment. Consequently, for the endocrine disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn for environment based on the available data. Hence, it is not possible to establish that CIT does not meet the conditions laid down in Article 10(1)(e) of the BPR.

2.2.2. POP criteria

CIT does not fulfil criteria for being a persistent organic pollutant (POP). CIT does not have potential for long-range transboundary atmospheric transport.

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

Information is not sufficient to conclude whether CIT meets the conditions laid down in Article 4(1) of the BPR. In particular, the provided information is not sufficient to conclude on the assessment of endocrine disruption on non-target organisms.

Consequently, as provided for in Article 9(1)(b), since requisite information and data have not been submitted, it is proposed that CIT should not be approved under the BPR as an active substance in product type 6.

The active substance CIT does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of the BPR. It is classified as unstable explosive, acute toxicity via oral route, via dermal route, via inhalation route (Acute Tox. 2), skin corrosive (Skin Corr 1 C), skin sensitizer (Skin Sens. 1A), and toxic to aquatic life of acute category 1 (Aquatic Acute 1). The substance is not eligible for inclusion to Annex I of the BPR.

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[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR

[4] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment