Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

1,2-BENZISOTHIAZOL-3-(2H)-ONE (BIT)

Product type: 6

ECHA/BPC/286/2021

Adopted

5 October 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance 1,2-BENZISOTHIAZOL-3-(2H)-ONE (BIT) 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:

Common name:	**BIT (Benzisothiazolinone)**
Chemical name:	**1,2-Benzisothiazolin-3-one**
EC No.:	**220-120-9**
CAS No.:	**2634-33-5**

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 the BPC opinion

Following the submission of applications by Lanxess, Troy Chemical Company BV, Rohm and Haas (currently Nutrition & Bioscience (Switzerland) GmbH) and the Task Force (Arch&Clariant&Thor), currently EBITTF (THOR GmbH, Laboratorios Miret, S.A. and Lonza Cologne GmbH) on 12 July 2007, the evaluating Competent Authority Spain submitted an assessment report and the conclusions of its evaluation to the Commission on 18 April 2012. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC Working Groups (WG-V-2015 and WG-II-2021). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Spain

The BPC opinion on the application for approval of the active substance 1,2-Benzisothiazolin-3-one in product type 6 was adopted on 5 October 2021.

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 1,2-Benzisothiazol-3-(2H)-one (BIT) 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 1,2-Benzisothiazolin-3-one (BIT) in product type 6. BIT is used against a wide range of microbes. BIT belongs to the chemical class of isothiazolinones.

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 products.

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

Harmonised classification for BIT is available. A proposal has been submitted to ECHA to change this classification, as indicated below.

The current entry for BIT in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1
Labelling	
Pictogram codes	GHS07 GSH05 GHS09
Signal Word	Dgr
Hazard Statement Codes	H302 Harmful if swallowed H315 Causes skin irritation H318 Causes serious eye damage

	H317 May cause an allergic skin reaction H400 Very toxic to aquatic life
Specific Concentration limits, M-Factors	Skin Sens. 1; H317: C ≥ 0,05 %

The proposed classification and labelling for 1,2-Benzisothiazolin-3-one according to CLP Regulation is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Acute Tox. 2 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS06 GHS05 GHS09
Signal Word	Dgr
Hazard Statement Codes	H302 Harmful if swallowed H330 Fatal if inhaled H318 Causes serious 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	Oral: ATE = 454 mg/kg Inhalation: ATE = 0.25 mg/L Skin Sens. 1B; H317: SCL ≥ 0.05 % M=1 (Aquatic Acute 1) M=1 (Aquatic Chronic 1)
Justification for the proposal	
Although this biocidal active substance has a current entry in Annex VI of CLP regulation, it is necessary to update the current human health and environmental hazards due to differences in acute toxicity, skin irritation, skin sensitization and aquatic chronic hazards, as well as, its ATEs and M-Factors with the current harmonised classification.	

b) Intended use, target species and effectiveness

BIT may be used as active substance product type 6 for the following uses:

- Preservation of detergents and cleaning fluids;
- Preservation of paints and coatings: indoor use and outdoor use;
- Formulation phase of functional fluids;
- Preservation of glues and adhesives;
- Preservation of polymer emulsions: indoor use and outdoor use;
- Preservation of additives used in paper, textile and leather production.

BIT is a broad spectrum antimicrobial biocide which exhibits rapid inhibition of growth at very low levels and biocidal effects at higher levels or for longer contact periods. Given this relationship between concentration and effect, BIT may function as a bactericide, bacteriostat, fungicide, and fungistat, depending on the dose level applied, system conditions, and the level of microbial control desired. BIT is most active as a bactericide, but does show antifungal activity at higher use levels.

The rate of the active ingredient for PT 6 uses is 100-500 ppm BIT in the preserved aqueous system.

The mechanism of action of BIT involves reaction with protein-thiol targets, including specific dehydrogenase and phosphatase 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 BIT 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 BIT. Nevertheless, as microbial resistance to BIT has been described in the literature, special attention should be given at the product authorization stage.

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

Human health

BIT is an isothiazolinone harmful if swallowed and toxic if inhaled. BIT may cause serious damage to the eye. Skin sensitization was observed in test animals and humans.

The critical endpoints for BIT 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 BIT but at much higher dose levels. Systemic AELs have been derived and a systemic risk assessment performed to supplement the local risk assessments.

After evaluating the exposure and characterizing the risk to human health of the biocidal products and treated articles according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Loading	**Primary exposure** Automated loading of a liquid biocidal product into final product to be preserved PPE: gloves, coated coverall and goggles/face mask RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Industrial workers	Acceptable with PPE and RMM
Loading	**Primary exposure** Filling of a pres erved product PPE: gloves, coated coverall	Industrial workers	Acceptable with PPE
Paints			
Mixing & loading	**Primary exposure** Mixing and loading of spray equipment PPE: protective gloves (new gloves for each work shift) and impermeable coverall	Professionals	Acceptable with PPE
Application	**Primary exposure** Spraying of paint PPE: protective gloves (new gloves for each work shift) and impermeable coverall	Professionals	Acceptable with PPE
Post - application	**Primary exposure** Cleaning of spray equipment PPE: protective gloves (new gloves for each work shift) and impermeable coverall	Professionals	Acceptable with PPE
Mixing & loading	**Primary exposure** Mixing and loading of paint into a receiving vessel PPE: protective gloves and coated coverall	Professionals	Acceptable with PPE

Summary table: human health scenarios			
Application	**Primary exposure** Application of the paint using paint brush or a roller PPE: protective gloves and coated coverall	Professionals	Acceptable with PPE
Post - application	**Primary exposure** Cleaning of the equipment (brush or a roller) PPE: protective gloves and coated coverall	Professionals	Acceptable with PPE
Mixing & loading	**Primary exposure** Loading the paint into a receiving vessel RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitiser.
Application	**Primary exposure** Application of paint using a brush or a roller RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitiser
Post - application	**Primary exposure** Cleaning of the equipment (brush or roller) RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitiser
Post - application	**Secondary exposure** Inhalation of volatilized residues of BIT	General public	Acceptable
Post - application	**Secondary exposure** Dermal exposure from contact with BIT in wet/dried paint and oral exposure from hand to mouth transfer Specific RMM - labelled treated article: ‘Do not enter a room until the painted walls and ceilings are completely dry.’	General public	Acceptable with RMM
Detergent			

Summary table: human health scenarios			
Mixing & loading	**Primary exposure** Loading a washing machine or a washing bowl PPE: gloves and coated coverall	Professionals	Acceptable with PPE
Application	**Primary exposure** Hand washed laundry PPE: gloves and coated coverall	Professionals	Acceptable with PPE
Application	**Primary exposure** Use of detergents for pre-treatment of clothes PPE: gloves and coated coverall	Professionals	Acceptable with PPE
Mixing & loading	**Primary exposure** Loading detergent for dishwashing PPE: gloves and coated coverall	Professionals	Acceptable with PPE
Application	**Primary exposure** Manual dishwashing PPE: gloves and coated coverall	Professionals	Acceptable with PPE
Mixing & loading	**Primary exposure** Mixing and loading for hand washing laundry RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Acceptable with RMM
Application	**Primary exposure** Hand washing laundry RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Acceptable with RMM
Application	**Primary exposure** Use of detergents for spot treatment of clothes RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Acceptable with RMM
Mixing & loading	**Primary exposure** Mixing and loading for hand dishwashing RMM: labelling, instructions for use, childproof closure, packaging	Non-Professionals	Acceptable with RMM

Summary table: human health scenarios			
	eliminating exposure		
Application	**Primary exposure** Hand dishwashing RMM: labelling, instructions for use, childproof closure, packaging eliminating exposure	Non-Professionals	Acceptable with RMM
Post - application	**Secondary exposure** Dermal exposure towards residues of BIT on textiles	General public	Acceptable
Post - application	**Secondary exposure** Dermal and oral exposure towards residues of the BIT on surfaces.	General public	Acceptable
Post - application	**Secondary exposure** Indirect oral exposure from utensils and dishware	General public	Acceptable

For the human exposure four population groups are potentially exposed: industrial users, professional users, non-professional users and the general public via indirect exposure. Primary and secondary exposure was considered where relevant.

Concerning the systemic effects, acceptable risks were identified for industrial, professionals and non-professionals for primary exposure, when PPE and RMM are used, as indicated in the Summary Table: Human health scenarios.

With regard to secondary exposure, acceptable risks were identified for all scenarios.

Concerning local effects, direct or indirect dermal exposure to BIT is possible.

With regard to primary exposure, a qualitative assessment for sensitization has been undertaken in accordance with current guidance. This identified acceptable risks for all scenarios as long as appropriate PPE (Substance/task appropriate gloves, Skin coverage with appropriate barrier material based on potential for contact with chemicals and Eye protection) are worn and appropriate engineering controls (fully automated processes, good ventilated areas) are in place for professionals and labelling, instructions for use, childproof closure, packaging eliminating exposure for non-professionals.

With regard to secondary exposure, a qualitative assessment for local dermal effects (sensitisation) has been undertaken. For dermal exposure to paints, risks are acceptable when realistic conditions are considered (labelled treated article: ‘Do not enter a room until the painted walls and ceilings are completely dry.’).

In addition, the daily exposure to BIT from eating with utensils and dishware that have been washed with detergent is estimated to be acceptable.

Concerning non-professional uses and the post application exposure, the end-use concentration in the preserved products (paints and liquid detergents) must be reduced below the threshold value of 500 ppm in order to take into account the sensitizing properties of BIT.

Environment

BIT shows rapid photolysis (DT50 of 2 hours) in the aquatic environment over a wide range of environmentally relevant pH values. It is stable to hydrolysis at pH 4, 7 and 9 with a half-life greater than 1 year. Given the low VP (3.02×10^{-3}– 6.3×10^{-5} Pa at 20ºC) and slight water solubility (ca. 1.2 g/L at 20ºC and pH 7), the concentration of BIT in the air is expected to be low. For biotic degradation, BIT was shown to be non ready biodegradable. Simulation tests show very short half-lives of BIT which transforms into several metabolites. In aquatic systems with estuarine and sea water, BIT can be degraded rapidly with half-lives at 12ºC of 0.95 and 1.24 days in estuarine water and 5-12 days in sea water. In soil BIT degrades very fast with DT50 < 1 day

BIT has a log K_{ow} = 0.7 and its potential for bioaccumulation is very low. The experimental (not normalised) BCF for fish of 6.9 L/Kg_{wwt} led to similar conclusions, even with a non-reliable test result. BIT koc = 196.87kg/L showing medium or moderate adsorption properties.

For acute toxicity algae were the most sensitive trophic level with a 24-hour ErC50 value = 0.108 mgBIT/L based on the geomean (four studies) of P.subcapitata endpoints. Again algae were demonstrated to be the most sensitive trophic level regarding long-term effects with a 24-hour ErC10 of 0.026 mg BIT/L (geomean *P. subcapitata*). Endocrine acticity could not be sufficiently investigated for the environment. Yet, it is unlikely that BIT accomplishes such properties although no conclusion can be reached.

The evaluation of the exposure and characterization of the risk to the environment of the biocidal products have been performed according to the pattern of use requested by the applicants.

Due to the physico-chemical properties of BIT and its rapid degradation in surface waters, it may be expected that this active substance will not partition into sediment to a significant extent and therefore the exposure to this compartment has not been included in the assessment, taking into account BPR Guidance Parts B+C, Vol IV, 2017, section 3.5.2.

Summary table: environment scenarios			
Scenario		**Description of scenario including environmental compartments**	**Conclusion**
Preservation of detergents and cleaning fluids			
Formulation		Emission to sewage treatment plant (STP); indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
Use		Emission to STP; and indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
Preservation of paints and coatings			
Formulation		Emission to STP; indirect emission via STP to surface water, soil and groundwater. RMM: the addition of the biocidal product must be carried out only in plants connected to an industrial STP	Acceptable risk for indoor application for all environmental compartments (for BIT) with RMM.
CITY Scenario			
Application	Spray – via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Brush/roller (amateur) – via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Spray – direct rainwater discharge	Direct emission to surface water.	Not acceptable because of unacceptable risk to the surface water compartment (due to BIT).
	Brush/roller (amateur) – direct rainwater discharge	Direct emission to surface water.	Acceptable risk (for BIT).
Service life	Via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Bypass STP (mixed sewer system)	Direct emission to surface water.	Acceptable risk (for BIT).

	Direct rainwater discharge	Direct emission to surface water.	Unacceptable risk to the surface water compartment (due to BIT).
COUNTRYSIDE Scenario			
Application	Spray	Direct emission to soil. Indirect emission to groundwater.	Acceptable risks for soil and groundwater from BIT. Not acceptable for groundwayer for metabolite 6[b].
	Brush/roller (amateur)	Direct emission to soil. Indirect emission to groundwater.	Acceptable risks for soil and groundwater from BIT. Not acceptable for groundwayer for metabolite 6[b].
Service life		Direct emission to soil. Indirect emission to groundwater.	Not acceptable for groundwater for metabolite 6.
BRIDGE OVER POND Scenario			
Application		Direct emission to surface water.	Acceptable risk (for BIT).
Service life		Direct emission to surface water.	Acceptable risk (for BIT).
Preservation of additives used in paper production			
		Emission to STP; indirect emission via STP to surface water, soil and groundwater	Not acceptable because of the risk to surface water in dry-end operations and the risk for the STP and surface water in the all additives scenario (due to BIT). RMMs are not feasible.
Preservation of additives used in textile production			
		Emission to STP; and indirect emission via STP to surface water, soil and groundwater	Not acceptable because of the risk to the STP and surface water (due to BIT).
Preservation of additives used in leather production			
		Emission to STP; indirect emission via STP to surface water, soil and groundwater	Not acceptable because of the risk to the STP and surface water (due to BIT).
Preservation of functional fluids			
Formulation		Functional fluids are used as fuel additives. Emission to STP; indirect emission via STP to surface water, soil and groundwater	Acceptable risk for all environmental compartments (for BIT).

Preservation of glues and adhesives			
		Emission to STP; indirect emission via STP to surface water, soil and groundwater	Acceptable risk for all environmental compartments (for BIT).
Preservation of polymer emulsions[a]			
Formulation		Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
CITY Scenario			
Application	Spray – via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Brush/roller (amateur) – via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Spray – direct rainwater discharge	Direct emission to surface water.	Acceptable risk (for BIT).
	Brush/roller (amateur) – direct rainwater discharge	Direct emission to surface water.	Acceptable risk (for BIT).
Service life	Via STP	Emission to STP; indirect emission via STP to surface water, soil and groundwater.	Acceptable risk for all environmental compartments (for BIT).
	Bypass STP (mixed sewer system)	Direct emission to surface water.	Acceptable risk (for BIT).
	Direct rainwater discharge	Direct emission to surface water.	Uacceptable risk to the surface water compartment (due to BIT).
COUNTRYSIDE Scenario			
Application	Spray	Direct emission to soil. Indirect emission to groundwater.	Acceptable risks for soil and groundwater from BIT. Not acceptable for groundwayer for metabolite 6[b].
	Brush/roller (amateur)	Direct emission to soil. Indirect emission to groundwater.	Acceptable risks for soil and groundwater from BIT. Not acceptable for groundwayer for metabolite 6[b].

Service life		Direct emission to soil. Indirect emission to groundwater.	Not acceptable for groundwater for metabolite 6.
BRIDGE OVER POND Scenario			
Application		Direct emission to surface water.	Acceptable risk (for BIT).
Service life		Direct emission to surface water.	Acceptable risk (for BIT).
[a] : the assessment was performed using the outcome of the use in paints and coating corrected for the difference in in-use concentrations.			
[b] : this assessment can be further refined by using FOCUS modelling.			

Acceptable uses have been proven for different scenarios. Regarding the unacceptable uses, at product authorisation RMMs can be considered or the assessment can be further refined. For example for preservation of paints and coatings and for polymer emulsions for outdoor use additional refinements could be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, monitoring data to prove the use to be safe for surface water, soil and groundwater. For the preservation of additives used in paper production it is considered that the risk cannot be mitigated by the introduction of RMMs (as communication of specific risk mitigation measure to the end user will be difficult), therefore the risk has to be mitigated by introducing refinements.

Overall conclusion

All human health scenarios resulted in acceptable risk.

Regarding environment, acceptable uses have been proven for the following scenarios:

- Preservation of detergents and cleaning fluids;
- Preservation of paints and coatings: indoor use;
- Formulation phase of functional fluids;
- Preservation of glues and adhesives;
- Preservation of polymer emulsions: indoor use.

Additional uses have been applied for, but no safe use has been proven:

- Preservation of paints and coatings outdoor. Nevertheless, additional refinements such as stability studies of the active substance in preserved products, leaching studies, monitoring data could be provided at the product authorization stage to prove the use to be safe for surface water, soil and groundwater;
- Preservation of polymer emulsions used for paints and coatings in outdoor use. Nevertheless, additional refinements such as stability studies of the active substance in preserved products, leaching studies, monitoring data could be provided at the product authorization stage to prove the use to be safe for surface water, soil and groundwater;
- Preservation of additives used in textile and leather production. Nevertheless, additional data and/or refinements could be provided at the product authorization stage to prove the use to be safe for the STP and surface water;
- Preservation of additives used in paper production. This use could be authorized if RMMs are implemented.

Hence, the active substance is proposed for approval in PT 6.

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	BIT 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	BIT 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	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	BIT does not fulfil criterion (d) of Article 5(1) No conclusion can be drawn whether BIT fulfils criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn	
	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. BIT does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects other than those related to endocrine disrupting properties	BIT does not fulfil criterion (e) of Article 10(1)		

Property	Conclusions
Proportion of non-active isomers or impurities	BIT does not fulfil criterion (f) of Article 10(1)

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"[1], with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[2] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[3] 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:

- 1,2-Benzisothiazolin-3-one does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012;
- 1,2-Benzisothiazolin-3-one 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.

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, where additional information should be requested. 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. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of BIT for PT 6 was submitted before 1 September 2013.

2.2.2. POP criteria

Regarding POPs criteria, due to its very low vapor pressure and Henry constant, the release of BIT to the atmosphere will be negligible.

2.3. BPC opinion on the application for approval of the active substance 1,2-Benzisothiazolin-3-one in product type 6

In view of the conclusions of the evaluation, it is proposed that 1,2-Benzisothiazolin-3-one shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

[1] 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)
[2] 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)
[3] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details).

1. Specification: minimum purity of the active substance evaluated:
    a. The active substance 1,2-Benzisothiazolin-3-one as manufactured shall have a minimum purity of 965 g/kg (theoretical calculated dry weight).

2. The authorisations of biocidal products are subject to the following conditions:
    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 and non-professional users,
        ii. Sewage Treatment Plant and surface water for the uses “Preservation of additives used in paper production”, “Preservation of additives used in textile production” and “Preservation of additives used in leather production”,
        iii. Surface water and groundwater due to direct releases from the uses “Preservation of paints and coatings in outdoor use” and “Preservation of polymer emulsions used for paints and coatings in outdoor use”.
3. The placing on the market of treated articles is subject to the following conditions:
    a. The person responsible for the placing on the market of a treated article treated with or incorporating 1,2-Benzisothiazolin-3-one 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.
    b. In view of the risks identified for human health, mixtures treated with or incorporating 1,2-Benzisothiazolin-3-one and placed on the market for use by the non-professional user shall not contain 1,2-Benzisothiazolin-3-one at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.

1,2-Benzisothiazolin-3-one cannot be included in Annex I of Regulation (EU) No 528/2012 because it meets the criteria of Article 28(2) (a) as it is classified as H330 (Acute Tox. 2) and H317 (Skin Sens. 1B).

2.4. Elements to be taken into account when authorising products

1. 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. Some situations of resistance with 1,2-Benzisothiazolin-3-one have been described in the literature and therefore before authorizing products, Member States should pay attention to possible occurrence of resistance.
    b. Unacceptable risks have been identified for the Sewage Treatment Plant and surface water for “Preservation of additives used in paper production” and surface water and groundwater due to direct releases from the uses “Preservation of paints and coatings in outdoor” and “Preservation of polymer emulsions used for paints and coatings in outdoor use”. If these risks cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.
    c. Biocidal products that trigger classification as skin sensitisers shall be used by professionals with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

d. An unacceptable risk for non-professional users using treated articles containing the active substance is identified. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, the use of the biocidal product in these treated articles should not be authorised.

e. A dietary risk assessment may be required at the product authorisation level when the use of the product may lead to food contamination.

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 1,2-Benzisothiazolin-3-one.

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