Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Document I

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

PTs 6 and 13

(Preservative for products during storage and Working or cutting fluid preservatives)

February 2022

RMS: Spain

1,2-Benzisothiazol-3-(2*H*)-one (BIT) (PTs 6 and 13)

Document I

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Introduction

This Competent Authority (CA) report has been prepared by the Spanish Competent Authority (Dirección General de Salud Pública– Ministerio de Sanidad and Dirección General de Calidad y Evaluación Ambiental – Ministerio para la Transición Ecológica y el Reto Demográfico, scientific support has been provided by the Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA), Ministry de Ciencia e Innovación and Universidad Miguel Hernández for submission to the European Commission as PTs 6 and 13 (Preservative for products during storage and Working or cutting fluid preservatives).

This document has been established as a result of the evaluation of the active substance 1,2-Benzisothiazol-3-(2*H*)-one (BIT) in PTs 6 and 13, carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

1,2-Benzisothiazol-3-(2*H*)-one (CAS No. 2634-33-5) was notified, as an existing active substance, by different applicants as is shown in the below Table:

NUMBER	PRODUCT TYPE	APPLICANT
6	Preservative for products during storage	Lonza Cologne GmbH, Thor GmbH, Laboratorios Miret S.A. LANXESS Deutschland GmbH, Nutrition & Biosciences (Switzerland) GmbH and Troy Chemical Company B.V.
13	Working or cutting fluid preservatives	Lonza Cologne GmbH, Thor GmbH, Laboratorios Miret S.A. LANXESS Deutschland GmbH, Nutrition & Biosciences (Switzerland) GmbH and Troy Chemical Company B.V.

Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

1 OJ L 294, 10.10.2014, p. 1–34

In accordance with the provisions of Article 3 paragraph 2 of that Regulation, Spain was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for 1,2-Benzisothiazol-3-(2*H*)-one as an active substance in the Product-types included was the 31 July 2007, in accordance with Annex V of Regulation (EC) No 1451/2007.

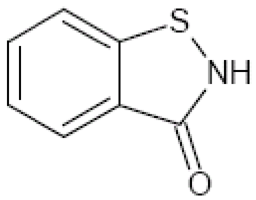
On the 12 July 2007, Spain competent authorities received a dossier from the applicants. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 31 October 2008.

For the implementation of the common principles of Annex VI, the content and conclusions of this document shall be taken into account.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

CAS-No.	2634-33-5
EINECS-No.	220-120-9
Other No. (CIPAC, ELINCS	-
IUPAC Name	1,2-Benzisothiazolin-3-one
Common name, synonym	BIT (Benzisothiazolinone)
Molecular formula	C_7H_5NOS
Structural formula	
Molecular weight (g/mol)	151.19
Purity of a.s. (% w/w)	**EBITTF (Lonza Cologne GmbH, Laboratorios Miret S.A. and Thor GmbH):** ≥ 96.52 **LANXESS Deutschland GmbH:** ≥ 98.27 **Troy Chemical Company B.V.:** ≥ 97.69
Impurities and additives:	See separate standard format in the Confidential Section – None of the impurities identified are classified as a Substance of Concern

1,2-Benzisothiazol-3-(2*H*)-one (BIT) (CAS No. 2634-33-5) is used as a preservative effective against a wide range of microbes.

The use of BIT being supported is the addition of biocidal product to act as a preservative (PTs 6 and 13). (See section 2.1.2: intended uses)

Biocidal products of PT 6 and 13 are used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in cans, tanks or other closed containers by control of microbial deterioration to ensure their shelf life.

BIT is an off-white solid/powder with not obvious odour. It has a melting point of 157.1 - 160ºC, a bulk density of 1.3-1.5 g/mL at 20ºC, a vapour pressure of 8.91 x 10^{-3} – 2.3 x 10^{-4} Pa at 25ºC, a dissociation constant pKa, of 7-7.5, and is moderately to highly soluble in organic solvents such as heptane and ethyl acetate and slightly soluble in water.

BIT has been shown to be stable for at least 12 months at 25°C and when subjected to accelerated storage stability over 14 days at 54ºC. No changes were observed in the packaging after being in contact with the test substance for approximately 14 days.

It is not flammable and its molecular structure indicates that the substance has no explosive properties, oxidizing or reducing potential.

Analysis of active substance as manufactured

The active substance BIT is commercially available as a 73.10% - 89.40% (typical concentrations) damp powder. Analytical methods for the active substance and impurities greater than 0.1 % are described in the confidential annexes of each applicant. For data on validation of the analytical methods, see Table 2.1.1-1:

Table 2.1.1-1: Analytical methods for the analyses of the active substance and impurities as manufactured.

Analytical Method	Fortification Level / n	Linearity (r)	Specificity	Recovery (%)		
				Range	Mean	RSD
HPLC-UV	-- / 6	4.9 - 14.8 mg/100 mL (0.049-0.148 mg/mL = 49-148 mg/kg) (50 – 150 %) r = 0.9999 n = 6	Yes	--	--	0.7
HPLC-UV	98.82 % / 4	2.9 - 25.8 mg/20 mL (0.145-1.29 mg/mL = 145-1290 mg/kg) (50 – 150 %) r = 0.9999 n = 3x2	Yes	--	--	0.313
HPLC-UV	0.0159 % w/v / 3	0.0506 mg/mL to 0.3966 mg/mL (= 50.6-	Yes	99.71 – 100.05	99.96	0.18
	0.02024 % w/v / 3			100.63 – 101.06	100.63	0.24

Analytical Method	Fortification Level / n	Linearity (r)	Specificity	Recovery (%)		
				Range	Mean	RSD
	0.02504 % w/v / 3	396.6 mg/kg) (0.00506 % w/v to 0.03966 % w/v) r^2 = 1.000 n = 5		100.07 – 100.41	100.24	0.17
HPLC-UV	100 % / 1	1.7-2.5 mg/ mL (= 1700-2500 mg/kg) $r^2 \geq 0.99$ n = 5	Yes	--	--	--
HPLC-UV	--	r^2 = 0.9944	Yes	--	--	--
HPLC-UV	--	340 – 1700 mg/L (0.34-1.7 mg/mL = 340-1700 mg/kg) r^2 = 1.000 n = 5	Yes	--	--	--

Formulation analysis

The active substance is formulated in different products by each applicant and therefore the method for analysis of the active substance is specified in Docs. III-B. A summary of validation data of the analytical methods is shown in Table 2.1.1-2.

Table 2.1.1-2: Analytical methods for determining the a.s. concentration in the biocidal products.

Analytical Method	Fortification Level / n	Linearity (r)	Specificity	Recovery (%)		
				Range	Mean	RSD
HPLC-UV	70 % / 2		Yes	101.2 - 101.1	101.1	0.09

Analytical Method	Fortification Level / n	Linearity (r)	Specificity	Recovery (%)		
				Range	Mean	RSD
	100 % / 2	70.7 – 133.7 mg/100 mL (= 0.707-1.337 mg/ml = 707-1337 mg/kg) (70 – 130 %) r = 0.9999 n = 6		101.0 - 101.2		
	130 % / 2			101.2 - 101.0		
HPLC-UV	900 ppm / 5	20 – 200 mg/L (= 20-200 mg/kg) (70 – 130 %) r = 1.0 n = 5	Yes	--	98.4	0.877
	1000 ppm / 5			--	97.9	1.28
	1100 ppm / 5			--	98.2	0.771
HPLC-UV	50 % / 2	0.230 - 0.507 mg/mL (= 230-507 mg/kg) r = 0.9949 n = 5	Yes	101 - 101	101	0
	100 % / 2			101 – 101	101	0
	150 % / 2			100 - 100	100	0

Residue analysis

Adequate analytical methods for the analysis of the a.s. in different matrices has been submitted and validated. A summary of validation data of the analytical methods is shown in the table below:

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%).			Limit of quantification
						Range	Mean	St. dev	
Soil	BIT	HPLC-MS/MS MS/MS transitions: precursor 152/152, product 105/109.	0.05 mg/kg / n=5	0.05 – 5.0 ng/mL (=0.00005-0.005 mg/kg) r =0.993	Yes	64–72	70	5	0.05 mg/kg
			0.50 mg/kg / n=5			75–80	77	3	
Soil	BIT	LC-MS/MS MS/MS transitions: precursor 152/152, product 105/109.	0.05 mg/kg / n=5	0.102–2.04 ng/mL (= 0.000102-0.00204 mg/kg) r =0.99	Yes	84-95	88	4	0.05 mg/kg
			0.50 mg/kg / n=5			87-90	88	1	
Air	BIT	HPLC-MS/MS MS/MS transitions: precursor 152/152, product 105/109.	At 20 ºC and 40 – 69% relative humidity: 6.0 µg/m³ / n=5 60 µg/m³ / n=4 600 µg/m³ / n=5	0.2 – 20 ng/mL (= 0.0002-0.02 mg/kg) r =0.998	Yes	 52–63 79–87 88–98	 56 82 94	 8 4 4	6.0 µg/m³

			At 35 – 36 ºC and 81 - 88% relative humidity: 6.0 µg/m³ / n=4 60 µg/m³ / n=4 600 µg/m³ / n=5			 85–89 81–100 88–100	 87 94 95	 2 9 5	
Air	BIT	HPLC-UV λ = 274 nm	At 33.3 ºC and 94% relative humidity: 0.0168 mg/m³ / n=4	0.28 - 28 µg/mL (=0.28-28 mg/kg) r =0.999	Yes	 96.3–98.4	 97	 1	0.0168 mg/m³
			At 25.6 ºC and 25% relative humidity: 0.27067 mg/m³ / n=4 6.567 mg/m³ / n=4			 90.9–95.2 95.5–97.0	 93.4 96.3	 1.9 0.5	
			At 27.8 ºC and 78% relative humidity: 0.270 mg/m³ / n=4 0.68 mg/m³ / n=4			 78.7–97.3 88.2–96.1	 90.1 93.9	 9.15 4.1	

			6.567 mg/m^3 / n=4			84.8–97.5	93.7	6.3	
			At 33.3 ºC and 88% relative humidity: 0.043125 mg/m^3 / n=4 0.402083 mg/m^3 / n=4 2.643 mg/m^3 / n=4 4.53 mg/m^3 / n=4			87.4–90.8 90.2–94.8 78.7–93.8 92.6–96.3	89.95 92.88 89.43 94.83	1.9 2.1 8.1 1.9	
Water	BIT	HPLC-MS MS/MS transitions: precursor 152/152, product 105/109	Drinking water 0.1 to 1.0 µg/L n=5 for each concentration	0.025 ng/mL to 1.0 ng/mL BIT (=0.000025-0.001 mg/kg) r = 1.000	Yes	104-115% (overall)	108% (overall)	1-3 (overall)	0.1 µg/L
Water	BIT	HPLC-MS/MS MS/MS transitions: precursor 152/152, product	Drinking water: 0.05 µg/L n=5 0.50 µg/L n=5	0.025– 1.0 ng/mL(= 0.000025-0.001 mg/kg)	Yes	92 – 106 96 – 105	97 101	6 4	0.05 µg/L

		105/109.	Surface water: 0.05 µg/L n=5 0.50 µg/L n=5	r =0.992		 94 – 114 107 – 112	 107 109	 8 2	
			Sea water: 0.05 µg/L n=5 0.50 µg/L n=5			 85 – 106 70 -82	 97 77	 8 6	
Sediment	BIT	HPLC-UV	3 mg/kg n=5 100mg/kg n=5	0.1 – 1.0 ng/mL (=0.0001-0.001 mg/kg) r =1	No interferences were observed.	89 – 92 96 – 98	91 97	1 0.8	3 mg/kg
Food stimulants (water containing ethanol, acetic acid and oil)	BIT	HPLC/MS/MS MS/MS transitions: precursor 152/152, product 105/109.	Acid aqueous food stimulant 0.01 mg/kg / n=5 1.0 mg/kg / n=5	0.2-10 ng/mL (=0.0002-0.1 mg7kg) r = 1	No interferences	 98-100 98-100	 98 99	 2 1	0.01mg/L
			Ethanolic aqueous food stimulants 0.01 mg/kg / n = 5			 100-102 100-105	 101 102	 1 2	

			1.0 mg/kg / n = 5						
			Oil-containing food stimulant 0.01 mg/kg / n = 5 1.0 mg/kg / n = 5			72-78 72-78	75 75	3 3	

No method for determination of residues of BIT in animal and human body fluids and tissues has been provided according to toxicological considerations. All available studies show that BIT is rapidly absorbed by gastrointestinal route, intensively biotransformed (no unchanged BIT was excreted), not bioaccumulated and quickly excreted mainly in urine. The rate of oral absorption was set to 100%. The metabolites do not occur to be of toxicological relevance (e.g. Toxtree (3.1.0) screening did not result in structural alerts for genotoxicity and carcinogenicity). Therefore, the study may be waived based on these toxicological considerations.

2.1.2. Intended Uses and Efficacy

BIT is intended to be used:

1. For the preservation of manufactured products, other than foodstuffs or feeding stuffs, in cans, tanks or other closed containers by control of microbial deterioration to ensure their shelf life. Relevant applications include:
    - Washing and cleaning fluids (professional use), hygienic products (professional and non-professional use)
    - Detergents (professional and non-professional use)
    - Paints and coatings (professional and non-professional use)
    - Fluids used in paper, textile and leather production (professional use)
    - Lubricants (professional use)
    - Fuels
    - Glues and adhesives

    The representative formulations ([redacted], [redacted], [redacted], [redacted]), consisting of BIT (20%) and a solvent, are incorporated into products by industrial workers which are applied in indoor and outdoor scenarios (PT 6) for example indoor cleaning products and outdoor paints. BIT is incorporated into the end-use products by industrial workers. These end-products are then sold to professional and non-professional users. The rate of the active ingredient for PT6 uses is 100 - 500 ppm BIT in the preserved aqueous system.
2. In the metal industry, which can be divided into different working sectors, as follows:
    - Blast furnaces: production of steel
    - Iron foundry: moulding of steel into half or end products
    - Rolling mills: rolling of steel to half products to be used by the steel production industry
    - Metal forming: forcing of metal products in the shape of the end product
    - Metal cutting: creation of products by cutting away chips of the product
    - Galvanic industry: application of protective metal coatings to metal products

The representative formulations (xx% XXX/Xxxxxx, Xxxxxxxxx XXX xx X, Xxxxxx xxx, Xxxxxx XXXxx), consisting of BIT (20 %) and a solvent, are incorporated into products by industrial workers which are applied in indoor scenarios (PT 13) by professional users. The rates of the active ingredient for PT13 uses are: 1500-9000 ppm BIT for Metal Working Fluid Concentrate and 100-360 ppm BIT for Metal Working Tank Additive.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Art. 19.1 of Regulation (EU) 528/2012 and the common principles laid down in Annex VI of that Regulation, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against bacteria and fungi and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

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, bacteriostatic, fungicide and fungistatic, 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 most common types of bacteria to be controlled are gram-negative bacteria, including members of the following genera: *Pseudomonas, Burkholderia, Enterobacter, Citrobacter, Klebsiella, Proteus, Serratia, Escherichia, Salmonella, Shigella, Alcaligenes, Acetobacter, Desulfovibrio,* and *Flavobacterium*. Occasionally, gram-positive bacteria such as *Bacillus, Staphylococcus, Sarcina*, and *Streptococcus* are reported. Fungal contaminants may include moulds (*Aspergillus, Chaetomium, Gliocladium, Penicillium, Geotrichum, Aureobasidium* and *Hormoconis*) and yeast organisms (*Candida, Rhototorula,* and *Saccharomyces*).

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.

2.1.3. Classification and Labelling

- ACTIVE SUBSTANCE

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	613-088-00-6	1,2-benzisothiazol-3-(2H)-one;1,2-benzisothiazolin-3-one	220-120-9	2634-33-5	Acute Tox. 4* Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1	H302 H315 H318 H317 H400	GHS05 GHS07 GHS09 Dgr	H302 H315 H318 H317 H400		Skin Sens. 1; H317: C≥0.05 %	
Dossier submitter's proposal	613-088-00-6	1,2-benzisothiazol-3-(2H)-one;1,2-benzisothiazolin-3-one	220-120-9	2634-33-5	Acute Tox. 4 Acute Tox. 2 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H302 H330 H318 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H302 H330 H318 H317 H400 H410		Oral: ATE = 454 mg/kg Inhalation: ATE = 0.25 mg/L (dust or mist) Skin Sens. 1B; H317: C ≥ 0.05% M (acute) =1 M (chronic) = 1	

- **BIOCIDAL PRODUCT**

<u>Current classification</u>

Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.

As a representative formulation not placed on the market, there is no current classification.

LANXESS Deutschland GmbH

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 3	H302, H315, H318, H317, H412	GHS05, GHS07	Danger	H302, H315, H318, H317, H412	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P304+P340, P310+P321, P405+P403+P233, P501

Nutrition & Biosciences (Switzerland) GmbH

Not applicable.

Troy Chemical Company B.V.

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye	H302, H332, H315, H318, H317, H400	GHS05, GHS07, GHS09	Danger	H302, H332, H315, H318, H317, H400	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P302+P305+P351+P338,

Dam. 1, Aquatic Acute 1						P304+P340, P310+P321, P405+P403+P233, P273+P391+P501

Proposed classification

Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1B	H332, H315, H318, H317	GHS05, GHS07	Danger	H332, H315, H318, H317	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P304+P340, P310+P321, P405+P403+P233, P501

LANXESS Deutschland GmbH

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1B	H302, H332, H315, H318, H317	GHS05, GHS07	Danger	H302, H332, H315, H318, H317	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P304+P340, P310+P321, P405+P403+P233, P501

Nutrition & Biosciences (Switzerland) GmbH

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Acute Tox. 3, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1B	H302, H331, H315, H318, H317	GHS05, GHS06	Danger	H302, H331, H315, H318, H317	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P304+P340, P310+P321, P405+P403+P233, P501

Troy Chemical Company B.V.

Classification		Labelling				
Hazard Class and Category	Hazard statements	Pictograms	Signal word	Hazard statements	Suppl. Hazard statements	Precautionary statements
Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1B, Aquatic Acute 1	H302, H332, H315, H318, H400	GHS05, GHS07, GHS09	Danger	H302, H332, H315, H318, H317, H400	-	P261+P271, P264, P280+P272+P362+P364, P302+P352, P302+P305+P351+P338, P304+P340, P310+P321, P405+P403+P233, P273+P391+P501

2.1.4. Assessment of exclusion, substitution criteria and POP

Property			Conclusions
CMR properties	Carcinogenicity (C)	no classification required	BIT does not fulfil criterion a), b) and c) of Art. 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 Art. 5.1 and does not fulfil criterion d) of Art. 10.1
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	not T	
Endocrine disrupting properties	BIT is not considered to have endocrine disrupting properties. No conclusion could be drawn of ED properties with respect to non-target organisms. BIT does not fulfil criterion d) of Art. 5.1.		
Respiratory sensitisation properties	No classification required. BIT does not fulfil criterion b) of Art. 10.1		
Proportion of non-active isomers or impurities	BIT does not fulfil criterion f) of Art. 10.1		

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Toxicokinetics and metabolism

Toxicokinetics and metabolic studies with ^{14}C-BIT in rats demonstrated that nearly 100% of the BIT dosed by gavage was absorbed.

Dermal absorption was calculated using an *in vitro* dermal absorption study with human skin following the 2017 EFSA guidance:

Dose (ppm)	% Mean value	k	s	Result (%)
300	28.85	1.0	14.112	43
30	29.87	1.0	16.275	46

A value of 46% must be considered for dermal absorption of BIT after 8 hours of exposure. Regarding the dermal absorption of the representative products, in the absence of specific *in* *vitro* dermal penetration data, the default values according to the EFSA (2017) guidance should be used. For the water-based end use dilutions a 50% default value was considered and for the solvent-based concentrate a 25% default value was considered."

The compound was also extensively and quickly metabolized and excreted in males and females mainly into urine following single or multiple (one daily during 5 days) doses of 10 mg/kg. A single dose of 100 mg/kg was also mainly excreted in urine in rats of both sexes. The percentage of radioactivity found in urine of 96 hours after whatever of these dosages ranged between 75 and 87%, while the radioactivity found in faeces was always lower than 6% of the dose. ^{14}C-BIT and related metabolites did not bioaccumulate because the recovered radioactivity in 14 different rat studied tissues never was higher than 0.1% of the dose.

Four main metabolites were found in urine or faeces after a single dose of 10 mg ^{14}C-BIT/kg bw and none of them was unchanged ^{14}C-BIT. It is proposed that two of these metabolites appear when BIT undergoes a thiazoline ring opening between sulphur and nitrogen atoms followed by the glucuronyl or methyl conjugation. The two remaining metabolites came from the mono or dioxidation of the sulphur atom in the previously formed methyl conjugated thioanisole.

Acute toxicity

Active substance

Acute oral toxicity was evaluated in rats with similar results in five independent studies. The lowest LD_{50} (combined for both sex) was 454 mg BIT/kg bw. It determined that BIT was classified as harmful and labelled with GHS07 + H302 (harmful if swallowed).

The dermal LD_{50} was higher than 2000 mg BIT/kg bw (confirmed in five independent studies).

Acute inhalation toxicity was evaluated in rats with similar results in two independent studies. The lowest LC_{50} (combined for both sex) was 0.25 mg BIT/L. It determined that BIT was classified as fatal and labelled with GHS06 + H330 (fatal if inhaled).

Representative products

[redacted] does not classify for this route of exposure according to Regulation (EC) No 1272/2008 because of their ATE_{mix} > 2000. [redacted], [redacted] and [redacted] should be classified as Acute Toxicity (Oral) 4 regarding the data obtained in their acute oral toxicity tests.

These products do not classify for dermal toxicity because their LD_{50} or their ATE_{mix} are higher than 2000.

[redacted], [redacted] and [redacted] should be classified as Acute Toxicity (Inhalation) 4 because of their ATE_{mix}. [redacted] should be classified as Acute Toxicity (Inhalation) 3 regarding the data obtained in an acute inhalation toxicity test.

Irritation and corrosion

Active substance

Five independent studies have showed that BIT is not able to induce skin irritation. The highest erythema and oedema scores were 1.33 and 0.33, respectively (both recorded 24 hours after exposure). All effects were reversible. Thus, BIT does not meet criteria to be classified for hazard of skin irritation and corrosion.

Six independent studies have showed that BIT induces severe non-reversible ocular lesions and therefore qualifies to be classified as Eye Damage 1 (H318: Causes serious eye damage).

Representative products

[redacted], [redacted], [redacted] and [redacted] should be classified as Skin Irritation 2 according to Regulation (EC) No 1272/2008 (Tables 3.2.3 and 3.2.4) for the first product and regarding the skin irritation studies for the other three products.

The four products should be classified as Eye Damage 1 by Regulation (EC) No 1272/2008 (Tables 3.3.3 and 3.3.4) ([redacted]) or regarding the eye irritation studies ([redacted], [redacted] and [redacted]).

Skin sensitisation

Active substance

Eight independent studies have showed that BIT induces skin sensitisation. The two LLNAs in the dossier showed that BIT was sensitizer at concentrations higher than 2%. One of them shows an $EC_3 < 2\%$ (Skin Sens. 1A) ([redacted]) and the other one shows an $EC_3 > 2\%$ (Skin Sens. 1B) ([redacted]). Other three BIT LLNAs can be found in RAC opinion about MBIT with four $EC_3 > 2\%$. Three of the four available GPMTs (OECD TG 406) showed that BIT was able to sensitise more than 30% of animals after challenges with intradermal doses higher than 1%. Thus, these seven studies showed that BIT must be classified as a Skin Sens. 1B. Taking into account information about human data ([redacted], 1999 and RAC opinion above mentioned (which contains information about BIT) this hazard category is supported. Also, regarding [redacted], 1999 (with sensitizing effects at 725 ppm) is appropriate to maintain the SCL ≥ 0.05% and labelled with the pictogram “Exclamation mark”, the word of danger “Warning” and the hazard statement H317 (May cause an allergic skin reaction).

The IVDK assessed concomitant reactions to BIT, MIT, and OIT. Less than 10 % of MIT-sensitised patients also reacted to BIT. This could be attributed to co-exposure rather than immunological cross-reactivity ([redacted], 2015). In another patch test series performed at the IVDK only 2 patients reacted simultaneously to C(M)IT/MIT and BIT and 1 patient reacted to BIT and OIT, but not to C(M)IT/MIT ([redacted], 1996). In general, the report submitted by the IVDK for this public consultation states that according to their data: “there is no relevant immunological cross-reactivity between BIT and other isothiazolinones” and co-reactivity to BIT and other isothiazolinones would be probably due to co-exposure.

[redacted], 2017 conducted a patch test series with C(M)IT/MIT, MIT, OIT, and BIT. Only 1 patient each reacted simultaneously to C(M)IT/MIT and BIT; C(M)IT/MIT, MIT and BIT; MIT, OIT and BIT or OIT and BIT, showing that positive reactions to BIT tended to occur in isolation.

In the FIOH, of 647 patients who were patch tested during the period 2012–2017, only two had reactions to both OIT and MIT. The authors concluded, “Allergic reactions to OIT were strongly associated with extreme reactions to MIT, which suggests cross-sensitization. In contrast, BIT reactions were mostly independent” ([redacted], 2017). The FIOH had earlier reported that of 2264 patients tested during the period 1991–2005 with [redacted] (0.88%) gave a positive reaction. 4 of these 20 patients reacted to C(M)IT/MIT and 2 to OIT. BIT was not considered to cross react with C(M)IT/MIT or OIT and as per study authors, concomitant reactions to these isothiazolinones supported separate sensitization ([redacted]

[redacted], 2006). In another study ([redacted], 2007), BIT was patch tested in 5450 patients at the HUCH. None of the BIT allergic patients had patch test reactions to C(M)IT/MIT or to OIT.

A non-systematic patch testing of C(M)IT/MIT-positive Belgian patients during 2010–2012 revealed that 4 reacted to BIT and 8 reacted to both BIT and OIT. Direct exposure to BIT could be determined for only 7 of the 12 BIT-positive patients ([redacted], 2014).

[redacted], 1995 evaluated different chemicals in the LLNA. They identified that the heterocyclic sulphur in BIT might form disulphide bonds with thiol sulphurs in proteins. C(M)IT, however, was identified as an electrophilic aromatic alkylating agent. The chemical reactivity of C(M)IT would not apply to BIT.

Furthermore, products with a concentration of BIT greater than 0.005% may be labeled with EUH208. With this element the uncertain possibility that cross-reactivity is real is covered in view of the ambiguous results.

Representative products

[redacted] and [redacted] should be classified as Skin Sens. 1B according to Regulation (EC) No 1272/2008 (Tables 3.4.5 and 3.4.6). [redacted] and [redacted] should be classified as Skin Sens. 1B following a weight of evidence approach since the amount of BIT (20%) is 400 times higher than the SCL (0.05%).

Repeated dose toxicity

Active substance

Several subchronic studies (90 days) have showed a variety of haematological alterations, although the most repeated alterations were stomach alterations (hyperkeratosis, hyperplasia, erosions and others). It suggests that other effects on bodyweight, food consumption and blood might be secondary to the primary local toxicity observed. The lowest NOAEL and LOAEL were found in one of the two available 90-day oral toxicity studies in dog, with values of 5 and 20 mg/kg bw/day, respectively.

The dossier does not contain studies of chronic toxicity. Chronic toxicity studies were not presented based on the low human exposure expected from use of the product, the quick and extensive metabolism to less reactive molecules, no bioaccumulation of BIT metabolites, and especially on the absence of related organ toxicity in any of the 90 day studies.

Representative products

The dossier does not contain repeat dose toxicity studies with the representative products.

Genotoxicity

Active substance

Sixteen *in vitro* genotoxicity studies were run (7 bacterial reverse mutation tests, 4 mammalian chromosome aberration tests and 5 gene mutation tests in mammalian cells) in presence and absence of exogenous metabolic activation yielded negative results for both presence and absence of rat liver microsomes. Two positive results were obtained with mouse lymphoma L5178Y cells, a positive Ames and two positive chromosome aberration studies.

Six *in vivo* genotoxicity studies were run (4 mouse micronucleus test and 2 unscheduled DNA synthesis tests). All six tests yielded negative results.

Thus, taking into consideration all results there are strong evidence that BIT does not induce genotoxicity in any of the tested conditions.

Representative products

The dossier does not contain genotoxicity studies with the representative products.

Carcinogenicity

Active substance

There are no data, from studies conducted according to current guidelines, addressing the carcinogenicity endpoints for BIT. However, the compound has been tested for toxicity in a number of assays with repeat dose protocols, including 90-day studies in the rat and in the dog. In addition, there are genotoxicity data from a number of *in vivo* and *in vitro* test systems and its ADME has been studied. A common feature of the repeated dose study with BIT is that, irrespective of the species or the route of administration, the major toxicity observed is toxicity at the site of primary contact such as hyperplasia and hyperkeratosis (subsequently any clinical signs of toxicity or mortality are secondary to these effects). In none of the studies were there any histopathological effects in any tissues distant from the site of dosing.

The lack of mutagenicity *in vivo* for BIT, the similar toxicological profile observed for isothiazolinones following chronic exposure and the prediction that BIT would not be carcinogenic based on structure-activity relationship analyses, together provide significant weight of evidence support for the conclusion that this chemical is predicted not to be associated with carcinogenic potential and that a chronic toxicity test and a cancer bioassay are unnecessary to characterise its intrinsic health hazard.

Representative products

The dossier does not contain carcinogenicity studies with the representative products.

Reproductive toxicity

Active substance

The four teratogenicity studies (1 in rabbit and 3 in rats) showed no potential of BIT to induce developmental toxicity. The developmental NOAELs were always between 2.5 and 9 times higher than the maternal toxicity NOAELs. The lowest NOAEL were found in the rabbit study, with records of 6 and 25 mg/kg bw/day for maternal and developmental effects respectively, based on maternal effects including significant decrease body weight loss and a decreased food consumption.

Two studies (1- and 2-generation studies in rats) demonstrated no effects on fertility and reproduction because the NOAELs for reproductive parameters were always higher (both in F1 and P generations) than NOAELs for general toxicity. The lowest NOAEL were found in the 2-generation study, with records of 10 and 50 mg/kg bw/day for parental and reproductive effects respectively, based on the moribund condition of 2 P males in the 25 mg/kg bw/day group and mortality in both sexes in both generations in the 65/50 mg/kg bw/day group and adverse clinical signs in these animals prior to death.

Representative products

The dossier does not contain reproduction toxicity studies with the representative products.

Neurotoxicity

Active substance

There is no evidence in multiple-dose toxicity studies conducted with BIT (or other compounds within this chemical class) that suggests this compound is neurotoxic and therefore, no neurotoxicity studies have been performed.

Representative products

The dossier does not contain neurotoxicity studies with the representative products.

Human data

BIT has not caused serious health problems in workers of the BIT manufacturing plants. However, several case reports demonstrated that BIT is a mild skin sensitizer to humans.

2.2.1.2. Effects assessment

The AELs were set as follows:

Study	Critical NOAEL	Assessment factor	AEL
Teratogenicity study in rabbits (Thullen, 2007a)	6 mg/kg bw	100	$AEL_{short-term}$ = 0.06 mg/kg bw
90-day oral toxicity study in dogs (Allen, 1991)	5 mg/kg bw/day	100	$AEL_{medium-term}$ = 0.05 mg/kg bw/day
90-day oral toxicity study in dogs (Allen, 1991)	5 mg/kg bw/day	200	$AEL_{long-term}$ = 0.025 mg/kg bw/day

2.2.1.3. Exposure assessment

For the human exposure and risk characterisation of BIT four population groups which are potentially exposed, are relevant: industrial users, professional users, non-professional users and the general public *via* indirect exposure.

After evaluating the exposure and characterizing the risk to human health following the use of 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 googles/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 preserved product PPE: protective gloves and coated coverall 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
Paints			
Mixing & loading	**Primary exposure** Mixing and loading of spray equipment PPE: protective gloves (new gloves for each work shift) and impermeable coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Application	**Primary exposure** Spraying of paint	Professionals	Acceptable with PPE and RMM

Summary table: human health scenarios			
	PPE: protective gloves (new gloves for each work shift) and impermeable coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)		
Post - application	**Primary exposure** Cleaning of spray equipment PPE: protective gloves (new gloves for each work shift) and impermeable coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Mixing & loading	**Primary exposure** Mixing and loading of paint into a receiving vessel PPE: protective gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Application	**Primary exposure** Application of the paint using paint brush or a roller PPE: protective gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Post - application	**Primary exposure** Cleaning of the equipment (brush or a roller)	Professionals	Acceptable with PPE and RMM

Summary table: human health scenarios			
	PPE: protective gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)		
Mixing & loading	**Primary exposure** Loading the paint into a receiving vessel RMM for medium hazard class chemicals (labelling, instructions for use, child-proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Application	**Primary exposure** Application of paint using a brush or a roller RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Post - application	**Primary exposure** Cleaning of the equipment (brush or roller) RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
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	General public	Acceptable with RMM

Summary table: human health scenarios			
	the painted walls and ceilings are completely dry.'		
Detergent			
Mixing & loading	**Primary exposure** Loading a washing machine or a washing bowl PPE: gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Application	**Primary exposure** Hand washed laundry PPE: gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Application	**Primary exposure** Use of detergents for pre-treatment of clothes PPE: gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Mixing & loading	**Primary exposure** Loading detergent for dishwashing PPE: gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Professionals	Acceptable with PPE and RMM
Application	Primary exposure Manual dishwashing	Professionals	Acceptable with PPE

Summary table: human health scenarios			
	PPE: gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)		
Mixing & loading	**Primary exposure** Mixing and loading for hand washing laundry RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Application	**Primary exposure** Hand washing laundry RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Application	**Primary exposure** Use of detergents for spot treatment of clothes RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Mixing & loading	**Primary exposure** Mixing and loading for hand dishwashing RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)	Non-Professionals	Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Application	**Primary exposure** Hand dishwashing	Non-Professionals	Only acceptable if the BIT concentration is below the

Summary table: human health scenarios			
	RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use)		concentration triggering classification as skin sensitizer.
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. 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 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 minimising 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.').

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 concentration triggering classification as skin sensitizer.

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After evaluating the exposure and characterizing the risk to human health following the use of 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** Automatic loading of the biocidal product to prepare the MWF-concentrate PPE: protective gloves (new gloves for each work shift), impermeable coverall and goggles/face mask RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)	Industrial / professional workers	Acceptable with PPE and RMM
Loading	**Primary exposure** Manual loading of the biocidal product to prepare the MWF-concentrate PPE: protective gloves, impermeable coverall and goggles/face mask RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)	Industrial / professional workers	Acceptable with PPE and RMM
Mixing/loading	**Primary exposure** Mixing/loading of the MWF-concentrate	Industrial / professional workers	Acceptable with PPE and RMM

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
	PPE: protective gloves, impermeable coverall and goggles/face mask RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)		
Application	**Primary exposure** Metalworking fluids on turning machine PPE: impermeable coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)	Industrial / professional workers	Acceptable with PPE and RMM
Application	**Primary exposure** Handling of work pieces, tools outside the turning machine PPE: protective gloves (new gloves for each work shift) and impermeable coverall. RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)	Industrial / professional workers	Acceptable with PPE
Maintenance	**Primary exposure** Machine/sump maintenance PPE: protective gloves and coated coverall RMM for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure)	Industrial / professional workers	Acceptable with PPE

All scenarios resulted in acceptable risk.

The population groups expected to be exposed are industrial and professional users.

Secondary exposure is not relevant for the industrial use of BIT in MWF as the metals are further used by professionals or in industry when the processed metals were cleaned and risk assessment for consumers via residues in food and animal health is not foreseen.

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

Concerning local effects, and 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

Concerning local effects, a qualitative assessment for sensitization has been undertaken in accordance with current guidance. This identified acceptable risks for all scenarios as long as technical and organizational RMM adequate for medium hazard chemicals (labelling, instructions for use, child proof closure, packaging minimising risk for exposure) and appropriate PPE (Substance/task appropriate gloves, Skin coverage with appropriate barrier material based on potential for contact with chemicals and Eye protection) are used.

2.2.2. Environmental Risk Assessment

The environmental risk assessment has been performed with the parent substance BIT. Although as shown in the next sections BIT transforms rapidly in different environmental compartments to different metabolites eCA has analysed the relevance of these metabolites for risk assessment (see doc IIA, section 4.3 for further information). According to the EPISUITE 4.11 QSAR modelling results, all the listed degradation products of BIT are not likely to bioaccumulate. BIT metabolites are shown to have potential to quick primary degradation. Results of surface water simulation tests cast some doubts on the degradation potential of some metabolites such as 2-sulfobenzamide, 2-methylsulfinyl-benzamide or 2-methylthio-benzamide. However, these metabolites are much less toxic than parent and due to their low kow and koc they are expected to remain in the water fraction.

2-methylthio-benzamide is formed in the STP and water, it is expected to be transformed into 2-methylsulfinylbenzamide in water. Both metabolites are not expected to partition to a great extent to sludge in the STP and therefore to migrate to groundwater via sludge application to soil. Furthermore, both metabolites are not formed in soil.

In addition, studies with the parent found that these two metabolites, 2-methylsulfinyl-benzamide and 2-methylthio-benzamide, are identified in rats and therefore they are considered to have been assessed by the toxicology studies of the parent. BIT and these metabolites gave an alert considered irrelevant by the "Toxicity profiling according to OECD QSAR Toolbox". BIT has been demonstrated not to be genotoxic, hence, neither these metabolites. All BIT is rapidly excreted metabolized in rats. They are considered not to be toxic, therefore a risk to groundwater is not expected.

There is another metabolite, Met6, which originates in soil and reaches a peak of 40.41%. This metabolite is a potential concern due to the longer degradation time than BIT (94 days at 12ºC) and its estimated low koc = 10 L/kg. However, the amount of this metabolite reaching soil will be lower than the amount of BIT (40.41% formation fraction) and therefore a risk for the soil compartment is not expected, also because its PNECtwa is **0.267 mg/kg wwt**, much higher than BIT's value.

Regarding its potential risk for groundwater, QSAR estimates a low koc for this metabolite and also due to its degradation half-life, a possible concern to groundwater exists. This metabolite M6 had been adequately tested for two aspects of genotoxicity, resulting in a negative conclusion for *in vitro* genotoxicity (Ames, mammalian cell gene mutation) and *in vivo* bone marrow micronucleus (EFSA, 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance ethametsulfuron[2]). Anyway, this was not considered enough to confirm the non- toxicity of this metabolite. For this reason, this metabolite is further investigated in case of direct emissions to soil and the risk for soil and groundwater is calculated.

Hence, based on the above, it is not deemed necessary to carry out a risk assessment of BIT metabolites since BIT represents a worst case and the potential for adverse environmental effects in response to exposure to BIT metabolites is considered low, except for the risk of metabolite 6 to soil and groundwater.

2.2.2.1. Fate and distribution in the environment

Abiotic degradation

BIT rapidly photolyses in water (DT50 2 hours). Photodegradation in water of BIT involves cleavage of the isothiazolone ring, hydroxylation of the benzene ring, and/or oxidation of the sulphur, which resulted in a number of degradation products depending on the pH value of the medium, among others: 1,2-benzisothiazolin-2-one at pH 5; 2-sulfobenzoic acid and benzamide at pH 7; Saccharin, 2-sulfobenzamide and 2-sulfobenzoic acid at pH 8-9.

2 EFSA Journal2014;12(7):3787, 96 pp. doi:10.2903/j.efsa.2014.3787

BIT is stable to hydrolysis at pH 4, 7 and 9 with a half-life greater than 1 year. Since the degradation was less than 10% in the tests, relevant metabolites were not measured nor considered significant in the risk assessment.

Given the low VP and slight water solubility, the concentration of BIT in the air is expected to be low. Nevertheless, indirect photolysis through reaction with OH-radicals would lead to the degradation of BIT in < 2 days. Potential metabolites of BIT are also reactive towards photodegradation with half-lives < 2 days.

Biotic degradation

BIT did not fulfil the strict conditions of ready biodegradability tests to be considered readily biodegradable. On inherent biodegradability tests, BIT was also not considered inherently biodegradable. However, biodegradation of BIT was achieved when more favourable conditions were set in the inherent tests (ca. 40-50% was degraded).

There were also simulation studies on degradation in soil, water and sewage treatment. They showed very short half-lives of BIT in the different environmental compartments. In aquatic systems with estuarine and sea water, BIT degraded rapidly with half-lives at 12ºC of 0.95-1.2 days in estuarine water and 5-12 days in sea water. In a simulated STP the half-life of BIT was estimated to be 2.2 hours or 3.6 hours at 15ºC. In another study, it showed 80% biodegradation in STP. For risk assessment, taking into account the two studies provided, fractions released from STP to each compartment will be estimated with EUSES based on the k obtained from the STP degradation study ($k = 0.19\ h^{-1}$) at 15ºC.

BIT disappeared very rapidly from soil irrespective of the soil type with DT50s ranging from 0.01 to 0.27 days at test temperature depending on the soil type. The value 0.54 days at 12ºC, as a worst case, will be taken for risk assessment whereas a DT50 = 62.14 d will be considered for metabolite 6. The results in the simulation studies correlate with the results observed for other isothiazolone biocides demonstrating that BIT is not persistent in the environment.

Several degradation products were formed in the different tests:

- In ready biodegradability studies two metabolites were identified, 2-methylthiobenzamide (ca. 61%) and 2-methylsulfinylbenzamide (ca. 16%) both evolving from the cleavage of the isothiazolone ring.

- In surface water simulation studies, 2-methylthiobenzamide (ca. 54%) and 2-methylsulfinylbenazamide (ca. 24%) were also identified. Two additional metabolites, 2-sulfobenzamide (ca. 29%) and 2-methylthiobenzoic acid methyl ester (ca. 12%) were also detected.

- In STP and according to eCA's proposed degradation pathway, relevant metabolites formed were 2-methylsulfinylbenzamide (45.53%), 2-methylthiobenzamide (39%) M5 (2-sunfanylbenzoic acid) (15%), and 2-carbamoylbenzenesulfonic acid and sulfobenzoic acid with a probable photolysis origin and accounting for 11%.

-In soil, major degradation products include 1,2-benzisothiazolin-3-one-1-oxide (met 2, max average 23.1% of AR across the 4 soils). MET-2 is an intermediate metabolite with unclear structure, but it degrades rapidly to saccharin. Saccharin (7.8% AR across the three soils where it was found), 2-sulphanyl benzamide (M8) (10.52%), 2-aminosulphinylbenzoic acid (M9) (14.1%), Metabolite 6 (whose chemical structure could not be identified, 40.55% AR including M6b). Metabolite M19 did not exceed 5% in the non-sterile soils and reached the maximum of 4.9% AR. M9 is a transient metabolite which is further rapidly degraded to M6. M8 also degraded very fast, as well as saccharin and 1,2-benzisothiazolin-3-one-1-oxide.

Formation fractions of the different metabolites were: 0.31 for metabolite 2 (from parent), 0.88 for metabolite 6 (including M6b) (from parent and from met 2), 0.366 for met 5 or saccharin (from met 2) and 0.046 for M19. MET2 metabolite, which was shown to be rapidly formed from the parent compound, was very rapidly degraded in all soils with DT50 values ranging from 0.3 to maximum 2.3 (slow phase) days. Saccharin and M19 metabolites showed also acceptable fits and were degraded with DT50 values ranging from 6.3 (12.6) to 10.3 (20.6), and 2.0 (4) to 23.2 (46.4 at 12ºC) days, respectively. Due to the rapid degradation and the lack of sufficient data points, no kinetics can be calculated for metabolites M8 and M9. Only MET6 was considered for Risk Assessment.

Distribution

There were four studies available to show the adsorption/desorption potential from soil and sediment of BIT. Following Vol IV ENV Part B+C, 2017 Guidance and geometric mean, the koc value for BIT is 196.87 L/kg for soils. For sediments, a Koc value of 64 L/kg was available. It is expected that BIT is moderately mobile in soil according to the mobility classification of substances.

Regarding mobility, based upon slight water solubility of BIT (ca. 1.2 g/L at 20ºC and pH 7) and the low log Kow (0.7 at pH 7 and 20º C), any releases of BIT to the aquatic compartment are expected to remain in the water phase, with low adsorption onto suspended particles and sediment.

Based upon the physique-chemical properties of BIT and its low vapor pressure the release to the atmosphere will be negligible. Even if present in the air, the indirect tropospheric photolysis would lead to the degradation of BIT in ca. 23 hours.

Accumulation

BIT has a log Kow<<3 and its potential for bioaccumulation is very low. This is confirmed by the low estimated BCF for aquatic and terrestrial organisms (i.e. 0.7-3.162 and 0.9 L/Kgwwt respectively). The experimental (not normalized) BCF for fish of 6.9 L/Kgwwt led to similar conclusions, as supporting information.

2.2.2.2. Effects assessment

Aquatic compartment

Acute toxicity to fish

There are various valid acute test with different fish species. For *Oncorhynchus mykiss*, there are five studies available which justifies the use of the geometric mean LC50 for acute toxicity to fish = 1.41 mg/L (as indicated in the Guidance of the Biocidal Products Regulation).

Acute toxicity to aquatic invertebrates

For aquatic invertebrates there are seven studies available. For freshwaterthe geomean of *Daphnia magna* studies results in a EC50= 3.13 mg/L. For marine invertebrates, the 96-hour EC50 = 0.99 mg/L *Mysidopsis bahia* is the lowest value.

Chronic toxicity to fish

There are two studies available on fish chronic toxicity. The lowest and key endpoint considered for chronic fish toxicity corresponds to NOEC = 0.21 mg a.i./L *O. mykiss*.

Chronic toxicity to invertebrates

There are two studies available with *Daphnia magna* for the chronic toxicity of aquatic invertebrates. The lowest endpoint of 21-day NOEC of 0.91 mg a.s./L is selected as the key endpoint for chronic aquatic invertebrate toxicity, for freshwater and marine ecosystems.

Algae

Five studies were considered valid in the case of algae. Results show that for most of the test 24h is the most sensitive endpoint with values lying within the same order of magnitude and no difference in sensitivity between freshwater and marine species, thus values can be pooled. The lowest reliable 24h-ErC50 value for algae is 0.011 mg BIT/L and the 24h-ErC10 is 0.0029 mg BIT/L (*P. subcapitata*).

Since there are multiple data points for the same species (*P. subcapitata*), the geometric mean will be used for the risk assessment: ErC10 = 0.026 mg/L and ErC50 = 0.108 mg/L.

Sediment-dwelling organisms

Two studies are available for sediment dwelling organisms. The test with *Chironomus riparius*, 28-day exposure period resulted in a NOEC value of 11.7 mg a.s./kg.

Inhibition of aquatic microbial activity

There were five reliable tests performed. The values EC50 = 3.95 and EC10 = 0.55 mg/L, represent the most conservative approach and were selected for risk assessment.

Soil microflora

Three tests were performed to assess the effects of BIT on the carbon and nitrogen transformation activity of soil microorganisms during 28 days. The lowest values for the risk assessment were an EC50 (28days) >811.5 soil mg BIT/kg dry soil and a NOEC (based on CO2 production rates) = 100 mg BIT/kg.

Soil invertebrates

Three studies with *Eisenia fetida* are considered in the risk assessment. The acute 14-day LC50 value was 114 mg a.i./kg dry weight and the chronic 28-day NOEC was established at 20 mg a.s./kg dw.

Terrestrial plants

Two studies with different species showed that the most sensitive species was lettuce with a 21-day EC50 value of 18.4 mg a.s./kg dw and a NOEC of 3.7 mg a.s./kg dw. These values were considered the key values for the risk assessment.

2.2.2.3. PNEC Derivation

PNEC for aquatic organisms

A broad database of studies is available on the effects of BIT, comprising acute and long-term toxic endpoints in species of three trophic levels (fish, invertebrates and algae) both from the freshwater and the marine environment, being algae the most sensitive species. Guideline proposes to calculate the geometric mean if more than one L(E)C50 or long-term data (NOEC/EC10) value is available for the same species and endpoint. Based on this, the geomean value of the studies presented for *P.subcapitata* was used for PNEC derivation applying an AF of 10 resulting in:

$$\mathbf{PNEC_{water} = 0.0026\ mg\ a.s./L}$$

For marine organisms, the guidance proposes an AF of 100 for the same lowest endpoint as the one selected for freshwater ecosystems, resulting in:

$$\mathbf{PNEC_{marine} = 0.00026\ mg\ a.s./L}$$

PNEC for STP microorganisms

According to the guidance, when a NOEC/EC10 and an EC50 from a study compliant with OECD 209 are available and both values are derived from the same study, the PNEC for microorganisms in a sewage treatment plant should be derived by dividing the NOEC/EC10 by an assessment factor of 10. The lowest EC50 was 3.946 mg BIT/L and the lowest EC10 was 0.55. Accordingly, the predicted no effect concentration for microorganisms in a sewage treatment plant applying an AF of 10 over the lowest EC10 is:

$$\mathbf{PNEC_{stp} = 0.055\ mg\ a.s./L}$$

PNEC for sediment-dwelling organisms

Due to physico-chemical properties of BIT (log Kow of 0.7 and Koc 196.87 L/kg) and its rapid degradation in surface waters (with DT50 of 1.24 d at 12ºC) it may be expected that this active substance will not partition into sediment to a significant extent. However, PNECsediment values are provided following:

- Assessment factor approach taking into account the tests available. The tests were done using spiked sediment but sediment might not be the main exposure pathway as mentioned above, so this is not considered the best approach.

Toxic endpoints both from an acute and a long-term test with the sediment-dwelling midge *Chironomus tentans* and *Chironomus riparius*, respectively, are available, resulting in the lowest 28-day NOEC for *Chironomus riparius* = 11.7 mg a.s./kgdwt.

According to the guidance, when only one long-term test is available, the AF of 100 applies:

$PNEC_{sediment}$ (dry weight) = 11.7 mg a.s./kgdw / 100 = 0.117 mg/kg dw

- Equilibrium Partitioning Method (EPM): this is considered the best approach, which takes into account only uptake via the water phase, so $PNEC_{sed}$ is derived from $PNEC_{water.}$

$PNEC_{sed} = (K_{susp\text{-}water}/RHO_{susp}) * PNEC_{water} * 1000 = 0.0132$ mg/kg ww (this value will be chosen as the PNEC to be used for risk assessment).

$PNEC_{sediment}$ = 0.0132 mg/kg ww

<u>PNEC for soil organisms</u>

BIT has a log Kow = 0.7 indicating low adsorption to soil and high mobility. Therefore, its bioavailability will not be driven by soil organic matter and the correction to standard organic matter recommended in the guidance should not be done in this case (as concluded in WGV 2015 and the ad-hoc working group for BIT).

The hazard to soil has been assessed for the three trophic levels (earthworm, plants and microorganisms) both in acute and long-term toxicity tests, being the lowest 21-d NOEC plants (lettuce) = 3.7 mg/kg_{dwt}. Taking into account the AF of 10 and conversion factor to wet weight:

$PNEC_{soil}$ = 0.33 mg/kg_{ww}

Given the short half live of BIT in soil DT50 values of 0.01-0.27 days at 20.9 ºC it can be considered that soil metabolites were exposed to BIT metabolites rather than BIT.

For this reason, in case of non-continous exposure (indirect exposure via sludge application) and direct exposure where degradation was not taken into account $PNEC_{nominal}$ = 0.33 mg/kg_{ww} should be compared with $PEC_{initial}$. But in case of continuous exposure (direct emission to soil), where degradation in soil is taken into account $PNEC_{TWA}$ should be compared with $PEC_{plateau}$. This PNEC value is a worstcase since with a half live <1 it results in very low concentrations of BIT. This approach has already been followed for other isothiazolinones such as MBIT and CMIT/MIT:

$PNEC_{soil\_TWA} = PNEC_{nominal\ ww} \cdot ftwa$ = 0.0043 mg/kg (wet weight)

For metabolite M6, as for parent, PNEC is first estimated considering no degradation and based on nominal concentrations. In this case, it is assumed that toxicity found in the soil studies is due to the metabolite. Thus, PNECnominal soil for metabolite 6 is **0.33 mg/kg wwt.** This value should be compared with PECinitials.

In case of continuous exposure and direct emission to soil and taking into account degradation $PNEC_{TWA}$ for metabolite 6 is calculated taking into account DT50 for this metabolite obtained in the soil degradation study. This value should be compared to PECplateau for the metabolite.

$PNEC_{TWA}$= PNEC nominal ww x f_{twa} = 0.24 mg/kg wwt

<u>PNEC oral for predators (birds and mammals)</u>

Exposure of higher mammals to BIT via the food chain is expected to be negligible as the proposed use patterns are not expected to result in extensive exposure of the aquatic or terrestrial environment. BIT has an estimated log Kow of 0.7, so it is unlikely to bioaccumulate, indicating little or no risk of secondary poisoning in the food chain.

2.2.2.4. PBT assessment

According to the PBT assessment in the Annex XIII from the REACH regulation, substances are classified when they fulfil the criteria for all three inherent properties Persistent, Bioaccumulable, Toxic.

<u>Persistence</u>

BIT rapidly degrades in fresh and marine water and has a DT50 < 1 day in soil. Considering these data, the active substance BIT does not fulfil the P criteria. Relevant metabolites are shown to be either readily biodegradable, transient or potentially degradable and are not expected to be persistent.

<u>Bioaccumulation</u>

The potential for bioaccumulation of BIT measured from a study conducted in fish (*Lepomis macrochirus*) is considered as very low with a BCF = 6.96 L/kg (much lower than limit value of 2000). BIT log kow = 0.7 is also low. Considering these data, the active substance BIT is no selected according to the B criteria.

Neither BIT metabolites are expected to have a BCF value > 2000 L/kg

<u>Toxicity</u>

According to the PBT assessment in the Annex XIII from the REACH regulation, the toxicity criterion is fulfilled when the chronic value for aquatic organism is less than 0.01 mg/L or when the substance is toxic to mammals and classified as Very Toxic or Toxic after oral dosing.

The lowest EC10 obtained for BIT was 0.0029 mg/l (algae test *P. subcapitata*). Since the cut off value given by the TGD corresponds to 0.01 mg/L, the substance meets the T criterion, and therefore BIT can be regarded as potentially toxic substance. Nevertheless, there are multiple tests available for *P. subcapitata* and the geometric value 0.026 > 0.01mg/L was considered for risk assessment.

Summarizing, BIT does not fulfil the requirements to be classified as PBT or vPvB.

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

<u>Assessment of Endocrine Disruption (ED)</u>

In order to carry out the ED assessment according to the endocrine disruption regulation and EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, the applicant submitted a report on June 2019, that included:

- Evaluation of literature search and a search on ToxCast/EDSP21 database1, OECD (Q) SAR Toolbox v4.32, Endocrine disrptome3, Danish (Q)SAR Database4, VEGA v1.1.45,
- Annex E contained in EFSA/ECHA Guidance for the identification of endocrine disruptors.

This report has been taken into consideration in this CA evaluation.

The analysis of the lines of evidence for EATS regarding non-target organisms shows:

- There are no available guideline studies carried out to assess BIT effects on EATS mediated parameters in non-target organisms. No relevant scientific articles were found either.

- There are some available studies not designed to assess EATS-mediated parameters, but they can include some parameters sensitive to but not diagnostic of EATS modalities: FELS test has no endocrine-specific endpoints, but there is limited evidence to suggest that some thyroid system disrupters are able to interfere with metamorphosis of the fish embryo to the larva. This test does not provide information on Estrogenic, Androgenic and Steroidogenic modalities. There were statistically significant decreases in survival at highest concentrations and statistically significantly difference from the pooled control in total length and dry weight. The observed adverse effects could be related to the onset of systemic toxicity.
- ***In vitro*** mechanistic data are provided in the available studies carried out by US EPA as a part of the Endocrine Screening Program (EDSP). The ToxCast findings supported a lack of EATS related signals that would indicate EATS-mediated adversity in non-mammalian vertebrates at the population level. Only specific data on estrogen were available, QSAR rtER Expert System – USEPA predicted a relative binding affinity for BIT on the rainbow trout estrogen receptor of <0.00001%.
- There are not ***in vivo*** mechanistic data available for non-target organisms.

As mentioned in the Guidance for the Identification of endocrine disruptors, the minimum necessary data package to consider EATS modalities for non-target organisms other than mammals sufficiently investigated includes a Fish short term reproduction assay (FSTRA; OECD TG 229) or a 21-dayfish assay (OECD TG 230) for EAS modalities and additionally a Amphibians metamorphosis assay (AMA; OECD TG 231) for T-modality. None of these tests are currently available in the dossier.

No adverse effects were seen in the fish ELS other than a reduction in growth near to the MATC which could be related to the onset of systemic toxicity. Further, no reports of adverse effects were evident in the open literature.

The information provided by the screening, mammalian toxicology data, and scientific literature does not suggest any endocrine activity.

According to the current information available, it is not possible to conclude about the ED properties due to the lack of data as it is mentioned in EFSA/ECHA Guidance. However, using a weight of evidence (WoE) approach, we consider it is highly unlikely that BIT fulfils the ED properties.

Hence, according to the information currently available, we consider that the ED is not sufficiently investigated.

Additional studies should be performed to assess adequately the endocrine disruption properties. The eCA cannot request such assays due to the BPR legal restrictions about the backlog dossiers.

Several publications listed in "References" deal with endocrine disruption in non-target organisms other than mammals related to another member of the isothiazolinone family (DCOIT). Reviewing the results on endocrine disruption of these isothiazolinone family members should be explored.

2.2.2.5. Exposure assessment

For PT6 BIT can be used as in can preservative for various uses: washing and cleaning fluids, paints and coatings, in the production of paper, textiles and leather, fuels, in glues and adhesives and in other products to be preserved during storage. Furthermore, in-can preservatives are widely used in plant protection products. However, this use is within the scope of Regulation (EC) No 1107/2009.

For each of the uses, emissions have been calculated following both the consumption-based and the tonnage-based approaches and the worst case has been chosen for risk characterization. In addition, metabolite 6 has been evaluated for the case of direct emission to soil in paints and coatings scenario.

The following table summarises the uses evaluated for each applicant.

Preservation Use	LANXESS	N&B	EBITTF	Troy
Detergents and cleaning fluids	x	x	x	x
Paints and Coatings	x	x	x	x
Additives used in paper, textile and leather production	x			x
Fuels	x			
Glues and Adhesives	x		x	x
Others: Polymer Emulsions	x		x	

In addition, the same applicants have applied for the authorization of BIT as a Biocide for Metal Working Fluids: PT13

For PEC calculations several assumptions have been followed in case of indirect emissions via STP or direct emissions to soil or water which are only relevant for PT6. The concentrations of the active substance assessed have been selected according to the data presented by the applicants considering the worst case, that is, the maximum concentration applied.

Due to 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 PECsediment is not included in the following assessment as agreed in BIT RCOM and taking into account BPR Guidance Parts B+C, Vol IV, 2017, section 3.5.2.

<u>Indirect emission via STP:</u>

In all scenarios with release via STP fractions released from STP to each compartment were estimated with EUSES 2.2.0 based on the k obtained from STP degradation study IIIA7.1.2.1.1/01/2/3 (k = 0.19 h^{-1} at 15ºC). This is a worst-case approach where EUSES calculates emissions fractions taking into account K_{OC} and K_{OW} values harmonised across applicants.

Nevertheless, eCA notes that the new TAB entry 182 indicates that Equation 28 has been used outside of its original applicability domain in allowing temperature corrections other than from 20 to 10°C. A wider applicability is however incorrect, since equation 28 effectively entails multiplication by Q10. Moreover, the equation is inaccurate due to rounding of the value contained in the exponent. It was agreed in the TAB to use the Arrhenius equation in the form below to correct biodegradation rates in the temperature range of 0 to 30°C:

or

$DT50_{T_1} =$

The WG II 2021 agreed that calculations performed by the eCA using equation 28 were appropriate and did not need correction since the overall outcome of the risk assessment would not change when using the new agreed equation. However, the WG also indicated that the temperature correction should have been done using the latest TAB agreed entry and requested eCA to include the distribution of BIT in the STP together with the DT50 value at 15 ºC. This has to be taken into account for product authorization. The next table show STP distribution with the two approaches as calculated by EUSES:

Fracctions to STP (%) from EUSES 2.2.0	***k = 0.19 h^{-1} (used in RA)***	***k = 0.18 h^{-1} (new TAB ENV 182)***
Degradation rate STP (hours)	3.6	3.8
Emission to water	30.88	32.04
Emission degraded in STP	67.14	65.98
Emission via prim. settler	1.74	1.73
Emission via surp. sludge	0.24	0.25

The next table shows the values used in the current risk assessment

Fractions and DT50s	**Values**
Fraction of emission directed to air by STP	1.04E-05
Fraction of emission directed to water by STP	30.88
Fraction of emission directed via primary settler	1.735
Fraction of emission via surplus sludge	0.238
Fraction of emission degraded in STP	67.14
Ready biodegradation	No
Hydrolysis	Stable
Degradation rate constant STP	k=0.19 h^{-1}
DT50 water (estuarine)	1.24 days
DT50 soil	0.54 d

The model **for STP** used corresponded to a STP with primary settler, effluent discharge rate of 2000.000 $l.d^{-1}$ (except for paper production where effluent discharge is 5E+06). Fraction of emission values are presented considering the results obtained from the “Elimination and Primary Biodegradation in Activated Sludge Simulation Test” (Document IIA IIIA7.1.2.1.1/01/ 2/ 3) and the results in the soil degradation test.

For the calculation of **$PEC_{surface\ water}$** a dilution factor of 10 was used.

Terrestrial endpoints for BIT are based on nominal concentrations (please refer to Doc. IIA). However, taking into account rapid degradation of BIT in soil (with the half-life less than 1 day) and duration of terrestrial studies it can be considered that terrestrial organisms were exposed to BIT`s metabolites rather than to BIT. Since in the effect and risk assessment nominal $PNEC_{soil}$ was considered the **$PEC_{initial,\ soil}$** was estimated. This approach is in agreement with guidance (BPR Guidance Vol. IV part B 2017). The same was also presented for CMIT/MIT and MBIT.

$PEC_{groundwater}$ values were derived on the basis of time weighted average concentration over 180 days considering agricultural soils according to BPR Guidance Vol. IV part B and EUSES.

Direct emissions (relevant for PT6):

Direct emissions to surface water occur in scenario 6.2-3 and 6.2-6.

The bridge over pond scenario is a worst-case scenario to cover direct emissions to surface water during application and service life. Brushing is the recommended method for application of paints and coatings on a bridge.

Two TIERs are considered in PEC calculations. TIER I calculates PECsurface water without considering degradation as in ESD PT6. For TIER 2 degradation is considered and the following formulas are applied. In this, case calculations follow the following approach according to the Item 4.6: Example calculations of a 3 phases pond-water system (NL) Follow up on WGII2018_ENV_7-3c_PT6-10_PECsediment_C (Agreed at at AHEE-3 (Sept 2019), where PECsurface water from a static pond-water system is calculated with the equations presented below:

Equation 10 AHEE-2 Item 4.6

$$Clocal_{diss,TIMEx} = \frac{}{[V_{water} \cdot (1}$$

Where intermediates calculation included:

$$Q_{water,\ brush} = AR$$

$$Clocal_{water,\ diss,b}$$

Mixed sewer system and separate sewer system

In urban areas, direct emissions to surface may occur due to bypass of STP (mixed sewer system) and direct rainwater discharge (separate sewer systems). The concentrations in surface water are calculated according to the guidance document to assess direct emissions to surface water in urban areas (2015). According to the TAB entry ENV 30 (TAB v. 2.1, Dec. 2019), emissions due to application are not relevant for direct emissions in urban areas. "The scenario for direct rainwater discharge[3] (bypass scenario) should not be used for the application since it is unrealistic to assume that application of paint will occur during or shortly before a storm event. However, the scenario discharge seems relevant."

Direct emissions to soil:

Direct emissions to soil occur in Scenarios 6.2-1 (spraying) and 6.2-2 (brush) for the application phase. For spraying two tiers are considered.

- Tier 1: emissions by runoff and drift
- Tier 2: emissions due to runoff are negligible thanks to the use of a tarpaulin on the ground, only drift is considered.

The concentration in groundwater was calculated according to EUSES outcome for the specific scenario where direct emissions to soil occur in the application phase.

For service life, scenario 6.2-5, two TIERs were considered:

- Tier 1: In all countryside scenarios PEC initial soil were calculated according to ESD for PT 6
- Tier 2: This approach represents the realistic Clocal of BIT in soil and reflects its rapid biodegradation in soil. Based on PT6 scenario PECplateau soil is:

$\mathbf{PEC_{pleateu\ soil} = Clocal_{soil,TIMEx}} = [E_{soil,leach,TIMEx}/(V_{soil} * RHO_{soil} * k)] - [E_{soil,leach,TIMEx}/(V_{soil} * RHO_{soil} * k)] * e^{-TIMEx*k}$

Considering this approach concentration of **BIT in groundwater** was calculated as follows:

$PEC_{grw} = PEC_{pleateu\ soil} \cdot RHOsoil/Ksoil\text{-}water \cdot 1000$,

In the case of the metabolites, groundwater assessment, eCA has performed a simplified approach where only metabolite 6 has been assessed. This approach was accepted by the Biocides WG-II-2021 for the case of BIT, since groundwater values are already above the

[3] It should read "mixed sewer system"

trigger value of 0.1µg/L. However, FOCUS PEARL provides the possibility to assess parent and metabolite(s) in one joint calculation step and it was agreed at TAB ENV10 entry that all relevant metabolites should be included in one transformation scheme, if possible. Hence, for product authorization, a full assessment of all relevant metabolites would be performed for groundwater, comparing the sum of the calculated PEC values with the trigger value of 0.5 µg/L for metabolites and active substance.

Metabolite 6 is assessed for direct emissions to soil since it only forms in soil. Based on the low DT50 of BIT in STP, low koc BIT values (BIT shall not accumulate in sewage sludge) and the fact that metabolite 6 only forms in soil, the eCA finds not necessary to analyse the risk of met 6 via STP.

The following sections summarise PEC values calculated based on the consumption-based approach (only higher TIER PECs are shown) both for PT6 and PT13. PEC values for PT6 based on the tonnage approach can be found on the corresponding confidential Appendix. In all uses, the consumption-based approach has been used for the proposed decision as the risk assessment resulted in a worst-case.

2.2.2.5.1. PEC values for PT6.

Nutrition & Biosciences (Switzerland)

Calculated PEC values (indirect emissions via STP) Detergents and cleaning fluids						
Scenario	**Elocal STP**	**PEC_{STP}**	**PEC_{water}**		**$PEC_{soil\ initial\ concentration}$**	**PEC_{GW}**
	kg/d]	mg/L	[mg/L		mg/kg ww	µg/L
Scenario 6.1.1 human hygienic products non pro	1.35E-02	2.08E-03	2.08E-04		4.87E-04	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	7.2E-02	0.011	1.11E-03		2.6E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	1E-03	1.54E-04	1.54E-05		3.61E-05	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	5.19E-02	8.01E-03	8.01E-04		1.87E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	7.25E-03	1.12E-03	1.12E-04		2.62E-04	3.11E-04

Scenario 6.1.2 B-3 Detergent Non pro - Surface	2.5E-02	3.86E-03	3.86E-04		9E-04	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	1.57E-01	2.42E-02	2.42E-03		5.66E-03	6.82E-03

Calculated PEC values Paints and Coatings Indirect emissions via STP.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-1 Façade Spray City	1.6E-02	2.47E-03	2.47E-04		5.77E-04	6.87E-04
6.2-2 City Façade with brush/roller (amateur)	2.67E-03	4.12E-04	4.12E-05		9.63E-05	1.15E-04
PT 6.2 Service Life						
6.2-4 City façade	3.9E-02	6.02E-03	6.02E-04		1.41E-03	1.67E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	**5.5E-02**	**8.49E-03**	**8.49E-04**		**1.99E-03**	2.36E-03
Calculated PEC values Paints and Coatings TIER I (direct release)						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**

PT 6.2: Paints Application						
6.2-3 Bridge over the pond			7.12E-05			
PT 6.2 Service Life Flowing Water						
6.2-6 Bridge over the pond Time 1			7.12E-04			
6.2-6 Bridge over the pond Time 2			1.1E-03			
6.2-6 Bridge over the pond Time 3			1.42E-03			
Urban area - Mixed sewer system						
Service life[1]			1.95E-03			
Urban area - Direct rainwater discharge						
Application brush [2]			4.45E-04			
Application spray [2]			2.67E-03			
Service-life[2]			6.5E-03			

Calculated PEC values Paints and Coatings TIER II BIT

Scenario		**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg$_{wwt}$]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			4.17E-05			
6.2-6 Bridge over the pond Time 2			5.3E-06			
6.2-6 Bridge over the pond Time 3			1.37E-06			

Calculated PEC values Paints and Coatings Direct emissions to soil.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed (mg/kg)**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray Countryside TIER I					0.242	**67.32**
6.2-1 Façade Spray Countryside TIER II					0.023	**6.418**
6.2-2 Countryside Façade with brush/roller (amateur)					0.0403	**12.79**
PT 6.2 Service Life tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.403	**112.1**
6.2-5 Clocalsoil, leach, time2					0.622	**173.2**
6.2-5 Clocalsoil, leach, time3					0.803	**223.6**
PT 6.2 Service Life tier II						
6.2-5 Concentration in local soil after the initial assessment period					0.0105	**2.912**
6.2-5 Clocalsoil,TIME2					1.33E-03	**0.37**
6.2-5 Clocalsoil,TIME3					3.44E-04	0.095

In the case of metabolite 6, PECs obtained are:

Calculated PEC values Paints and Coatings Direct emissions to soil Metabolite 6

Scenario	Elocal (kg/d)	PEC_{STP} [mg/L]	PEC_{water} [mg/L]	PECsed [mg/kg_{wwt}]	PEC_{soil} [mg/kg_{wwt}]	$PEC_{groundwater}$ [µg/L]
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					0.28	952.18
6.2-1 Façade Spray City TIER II					0.027	91.8
6.2-2 City Façade with brush/roller (amateur)					0.047	160
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.47	1600
6.2-5 Clocalsoil, leach, time2					0.73	2480
6.2-5 Clocalsoil, leach, time3					0.94	3200
PT 6.2 Service life Tier II						
6.2-5 Concentration in local soil after the initial assessment period					4E-01	1360
6.2-5 Clocalsoil,TIME2					1.77E-01	600
6.2-5 Clocalsoil,TIME3					4.6E-02	158

LANXESS

Calculated PEC values (indirect emissions via STP) Detergents and cleaning fluids						
Scenario	**Elocal STP**	**PEC_{STP}**	**PEC_{water}**		**$PEC_{soil\ initial\ concentration}$**	**PEC_{GW}**
	kg/d]	mg/L	[mg/L		mg/kg ww	µg/L
Scenario 6.1.1 human hygienic products non pro	1.35E-02	2.08E-03	2.08E-04		4.87E-04	5.79E-04

Scenario 6.1.2 A-1 – Detergents pro – Laundry	7.2E-02	0.011	1.11E-03		2.6E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	1E-03	1.54E-04	1.54E-05		3.61E-05	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	5.19E-02	8.01E-03	8.01E-04		1.87E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	7.25E-03	1.12E-03	1.12E-04		2.62E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	2.5E-02	3.86E-03	3.86E-04		9E-04	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	1.57E-01	2.42E-02	2.42E-03		5.66E-03	6.82E-03

Calculated PEC values Paints and Coatings Indirect emissions via STP.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-1 Façade Spray City	1.6E-02	2.47E-03	2.47E-04		5.77E-04	6.87E-04
6.2-2 City Façade with brush/roller (amateur)	2.67E-03	4.12E-04	4.12E-05		9.63E-05	1.15E-04

PT 6.2 Service Life						
6.2-4 City façade	3.9E-02	6.02E-03	6.02E-04		1.41E-03	1.67E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	5.50E-02	8.49E-03	8.49E-04		1.99E-03	2.36E-03

Calculated PEC values Paints and Coatings TIER I Surface water						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-3 Bridge over the pond			7.12E-05			
PT 6.2 Service Life Flowing Water						
6.2-6 Bridge over the pond Time 1			7.12E-04			
6.2-6 Bridge over the pond Time 2			1.1E-03			
6.2-6 Bridge over the pond Time 3			1.42E-03			
Urban area - Mixed sewer system						
Service life[1]			1.95E-03			
Urban area - Direct rainwater discharge						
Application brush [2]			4.45E-04			

Application spray [2]			2.67E-03			
Service-life[2]			6.5E-03			

Calculated PEC values Paints and Coatings TIER II BIT						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			4.17E-05			
6.2-6 Bridge over the pond Time 2			5.3E-06			
6.2-6 Bridge over the pond Time 3			1.37E-06			

Calculated PEC values Paints and Coatings Direct emissions to soil BIT.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed (mg/kg)**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray Countryside TIER I					0.242	**67.32**
6.2-1 Façade Spray Countryside TIER II					0.023	**6.418**
6.2-2 Countryside Façade with brush/roller (amateur)					0.0403	**12.79**
PT 6.2 Service Life						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.403	**112.1**

6.2-5 Clocalsoil, leach, time2					0.622	**173.2**
6.2-5 Clocalsoil, leach, time3					0.803	**223.6**
6.2-5 Concentration in local soil after the initial assessment period					0.0105	**2.912**
6.2-5 Clocalsoil,TIME2					1.33E-03	**0.37**
6.2-5 Clocalsoil,TIME3					3.44E-04	0.095

In the case of metabolite 6, PECs obtained are:

Calculated PEC values Paints and Coatings Direct emissions to soil Metabolite 6						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed [mg/kg_{wwt}]**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					0.28	952.18
6.2-1 Façade Spray City TIER II					0.027	91.8
6.2-2 City Façade with brush/roller (amateur)					0.047	160
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.47	1600
6.2-5 Clocalsoil, leach, time2					0.73	2480
6.2-5 Clocalsoil, leach, time3					0.94	3200
PT 6.2 Service life Tier II degradation considered						
6.2-5 Concentration in local soil after the					4E-01	1360

initial assessment period						
6.2-5 Clocalsoil,TIME2					1.77E-01	600
6.2-5 Clocalsoil,TIME3					4.6E-02	158

Summary table on calculated PEC values Paper (indirect emissions via STP)						
Scenario	**Elocal STP**	**PEC$_{STP}$**	**PEC$_{water}$**		**PEC$_{soil\ initial\ concentration}$**	**PEC$_{GW}$**
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]
Additives used in dry-end operations only						
Scenario 6.3.1-1 Newsprint	8.87E-01	5.48E-02	5.48E-03		0.015	0.015
Scenario 6.3.1-1 Tissues	7.89E-01	4.87E-02	4.87E-03		0.013	0.014
Scenario 6.3.1-1 Printing and writing papers	8.58E-01	0.053	5.3E-03		0.014	0.015
All additives						
Scenario 6.3.1-1 Newsprint	4.435	0.274	0.0274		7.5E-02	0.076
Scenario 6.3.1-1 Tissues	3.945	0.244	0.024		0.065	0.068
Scenario 6.3.1-1 Printing and writing papers	4.292	0.265	0.026		0.07	0.074
Recycling						
Refer to confidential Appendix						

PEC values for textile production (indirect emissions via STP)						
Scenario	**Elocal STP**	**PEC$_{STP}$**	**PEC$_{water}$**		**PEC$_{soil\ initial\ concentration}$**	**PEC$_{GW}$**
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]

Scenario 6.3.2-1 Textile production	0.868	0.134	0.0134		3.13E-02	0.037

PEC values for leather production (indirect emissions via STP)						
Scenario	Elocal STP	PEC_{STP}	PEC_{water}		$PEC_{soil\ initial\ concentration}$	PEC_{GW}
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]
Scenario 6.3.3-1 Leather production	7.69E-03	2.62E-01	2.62E-02		0.061	7.39E-02

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Calculated PEC values (indirect emissions via STP) Detergents and cleaning fluids						
Scenario	Elocal STP	PEC_{STP}	PEC_{water}		$PEC_{soil\ initial\ concentration}$	PEC_{GW}
	kg/d]	mg/L	[mg/L		mg/kg ww	µg/L
Scenario 6.1.1 human hygienic products non pro	1.35E-02	2.08E-03	2.08E-04		4.87E-04	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	7.2E-02	0.011	1.11E-03		2.6E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	1E-03	1.54E-04	1.54E-05		3.61E-05	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	5.19E-02	8.01E-03	8.01E-04		1.87E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	7.25E-03	1.12E-03	1.12E-04		2.62E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	2.5E-02	3.86E-03	3.86E-04		9E-04	1.07E-03
Scenario 6.1	1.57E-01	2.42E-02	2.42E-03		5.66E-03	6.82E-03

Detergent and cleaning fluids – Use - Aggregated						

Calculated PEC values Paints and Coatings Indirect emissions via STP.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-1 Façade Spray City	1.97E-02	3.04E-03	3.04E-04		7.11E-04	8.44E-04
6.2-2 City Façade with brush/roller (amateur)	3.28E-03	5.06E-04	5.06E-05		1.18E-04	1.41E-04
PT 6.2 Service Life						
6.2-4 City façade	4.8E-02	7.41E-03	7.41E-04		1.73E-03	2.06E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	6.7E-02	1.05E-02	1.05E-03		2.44E-03	2.90E-03

Calculated PEC values Paints and Coatings TIER I Surface water						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-3 Bridge over the pond			8.75E-05			
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			8.75E-04			
6.2-6 Bridge over the pond Time 2			1.31E-03			
6.2-6 Bridge over the pond Time 3			1.75E-03			
Urban area - Mixed sewer system (bypass STP)						

Service life[1]			2.4E-03			
Urban area - Direct rainwater discharge						
Application spray [2]			3.28E-03			
Application brush [2]			5.47E-04			
Service-life[2]			8E-03			

Calculated PEC values BIT - Paints and Coatings TIER II						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			5.12E-05			
6.2-6 Bridge over the pond Time 2			6.31E-06			
6.2-6 Bridge over the pond Time 3			1.68E-06			

Calculated PEC values Paints and Coatings Direct emissions to soil BIT.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed (mg/kg)**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray CountrysideTIER I					0.297	**82.67**
6.2-1 Façade Spray CountrysideTIER II					0.0283	**7.88**
6.2-2 Countryside Façade with brush/roller (amateur)					0.049	**13.78**
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment					0.495	**137.8**

period Clocalsoil, leach, time1						
6.2-5 Clocalsoil, leach, time2					0.741	**206.3**
6.2-5 Clocalsoil, leach, time3					0.99	**275.6**
PT 6.2 Service life Tier II						
6.2-5 Concentration in local soil after the initial assessment period					0.013	**3.58**
6.2-5 Clocalsoil,TIME2					1.58E-03	**0.44**
6.2-5 Clocalsoil,TIME3					4.23E-04	**0.118**

In the case of metabolite 6, PECs obtained are:

Calculated PEC values Paints and Coatings Direct emissions to soil Metabolite 6						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed [mg/kg$_{wwt}$]**	**PEC_{soil} [mg/kg$_{wwt}$]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					0.348	**1180**
6.2-1 Façade Spray City TIER II					0.033	**113**
6.2-2 City Façade with brush/roller (amateur)					0.0579	**197**
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.579	**1970**
6.2-5 Clocalsoil, leach, time2					0.867	**2950**
6.2-5 Clocalsoil, leach, time3					1,16	**3940**
PT 6.2 Service life Tier II (degradation considered)						

6.2-5 Concentration in local soil after the initial assessment period					0.49	**1670**
6.2-5 Clocalsoil,TIME2					0.21	**714**
6.2-5 Clocalsoil,TIME3					0.057	**194**

Troy

Calculated PEC values (indirect emissions via STP) Detergents and cleaning fluids						
Scenario	**Elocal STP**	**PEC_{STP}**	**PEC_{water}**		**$PEC_{soil\ initial\ concentration}$**	**PEC_{GW}**
	kg/d]	mg/L	[mg/L		mg/kg ww	µg/L
Scenario 6.1.1 human hygienic products non pro	1.35E-02	2.08E-03	2.08E-04		4.87E-04	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	7.2E-02	0.011	1.11E-03		2.6E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	1E-03	1.54E-04	1.54E-05		3.61E-05	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	5.19E-02	8.01E-03	8.01E-04		1.87E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	7.25E-03	1.12E-03	1.12E-04		2.62E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	2.5E-02	3.86E-03	3.86E-04		9E-04	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	1.57E-01	2.42E-02	2.42E-03		5.66E-03	6.82E-03

Calculated PEC values Paints and Coatings Indirect emissions via STP.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-1 Façade Spray City	1.97E-02	3.04E-03	3.04E-04		7.11E-04	8.44E-04
6.2-2 City Façade with brush/roller (amateur)	3.28E-03	5.06E-04	5.06E-05		1.18E-04	1.41E-04
PT 6.2 Service Life						
6.2-4 City façade	4.8E-02	7.41E-03	7.41E-04		1.73E-03	2.06E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	6.77E-02	1.05E-02	1.05E-03		2.44E-03	2.90E-03

Calculated PEC values Paints and Coatings TIER I Surface water						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2: Paints Application						
6.2-3 Bridge over the pond			8.75E-05			
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			8.75E-04			
6.2-6 Bridge over the pond Time 2			1.31E-03			
6.2-6 Bridge over the pond Time 3			1.75E-03			
Urban area - Mixed sewer system (bypass STP)						
Service life[1]			2.4E-03			
Urban area - Direct rainwater discharge						
Application spray [2]			3.28E-03			

Application brush [2]			5.47E-04			
Service-life[2]			8E-03			
Calculated PEC values Paints and Coatings TIER II Surface water						
Scenario	**Elocal [kg/d]**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**		**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Service Life						
6.2-6 Bridge over the pond Time 1			5.12E-05			
6.2-6 Bridge over the pond Time 2			6.31E-06			
6.2-6 Bridge over the pond Time 3			1.68E-06			
Calculated PEC values Paints and Coatings Direct emissions to soil BIT.						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed (mg/kg)**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray Countryside TIER I					0.297	**82.67**
6.2-1 Façade Spray Countryside TIER II					0.0283	**7.88**
6.2-2 Countryside Façade with brush/roller (amateur)					0.049	**13.78**
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.495	**137.8**
6.2-5 Clocalsoil, leach, time2					0.741	**206.3**
6.2-5 Clocalsoil, leach, time3					0.99	**275.6**

PT 6.2 Service life Tier II						
6.2-5 Concentration in local soil after the initial assessment period					0.013	**3.58**
6.2-5 Clocalsoil,TIME2					1.58E-03	**0.44**
6.2-5 Clocalsoil,TIME3					4.23E-04	**0.12**

In the case of metabolite 6, PECs obtained are:

Calculated PEC values Paints and Coatings Direct emissions to soil Metabolite 6						
Scenario	**Elocal (kg/d)**	**PEC_{STP} [mg/L]**	**PEC_{water} [mg/L]**	**PECsed [mg/kg_{wwt}]**	**PEC_{soil} [mg/kg_{wwt}]**	**$PEC_{groundwater}$ [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					0.348	1180
6.2-1 Façade Spray City TIER II					0.033	113
6.2-2 City Façade with brush/roller (amateur)					0.0579	197
PT 6.2 Service Life Tier I						
6.2-5 Concentration local soil at end of initial assessment period Clocalsoil, leach, time1					0.579	**1970**
6.2-5 Clocalsoil, leach, time2					0.867	**2950**
6.2-5 Clocalsoil, leach, time3					1.16	**3940**
PT 6.2 Service life Tier II (degradation considered)						
6.2-5 Concentration in local soil after the initial assessment period					0.49	**1670**
6.2-5 Clocalsoil,TIME2					0.21	**714**

6.2-5 Clocalsoil,TIME3					0.057	**194**

Summary table on calculated PEC values Paper (indirect emissions via STP)						
Scenario	**Elocal STP**	**PEC_{STP}**	**PEC_{water}**		**$PEC_{soil\ initial\ concentration}$**	**PEC_{GW}**
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]
Additives used in dry-end operations only						
Scenario 6.3.1-1 Newsprint	8.87E-01	5.48E-02	5.48E-03		0.015	0.015
Scenario 6.3.1-1 Tissues	7.89E-01	4.87E-02	4.87E-03		0.013	0.014
Scenario 6.3.1-1 Printing and writing papers	8.58E-01	0.053	5.3E-03		0.014	0.015
All additives						
Scenario 6.3.1-1 Newsprint	4.435	0.274	0.0274		7.5E-02	0.076
Scenario 6.3.1-1 Tissues	3.945	0.244	0.024		0.065	0.068
Scenario 6.3.1-1 Printing and writing papers	4.292	0.265	0.026		0.07	0.074
Recycling						
Refer to confidential Appendix						
PEC values for textile production (indirect emissions via STP)						
Scenario	**Elocal STP**	**PEC_{STP}**	**PEC_{water}**		**$PEC_{soil\ initial\ concentration}$**	**PEC_{GW}**
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]
Scenario 6.3.2-1 Textile production	0.868	0.134	0.0134		3.13E-02	0.037
PEC values for leather production (indirect emissions via STP)						

Scenario	Elocal STP	PEC_{STP}	PEC_{water}		$PEC_{soil\ initial\ concentration}$	PEC_{GW}
	[kg/d]	[mg/L]	[mg/L]		[mg/kg ww]	[µg/L]
Scenario 6.3.3-1 Leather production	1.7	2.62E-01	2.62E-02		0.061	7.39E-02

2.2.2.5.2. PEC VALUES FOR PT13

Nutrition & Biosciences (Switzerland)

	STP	Surface Water		Soil	Groundwater [µg/L]
Concentration 360 ppm	0.229	2.3E-02		5.35E-02	6.36E-02
Concentration 100 ppm	7.30E-02	7.27E-03		1.70E-02	2.02E-02

LANXESS

	STP	Surface Water		Soil	Groundwater [µg/L]
Concentration 360 ppm	0.229	2.3E-02		5.35E-02	6.36E-02
Concentration 100 ppm	7.30E-02	7.27E-03		1.70E-02	2.02E-02

Lonza, Thor and Lamirsa

	STP	Surface Water		Soil	Groundwater [µg/L]
Concentration 360 ppm	1.82E-01	1.8E-02		4.26E-02	5.07E-02
Concentration 100 ppm	7.10E-02	7.08E-03		1.65E-02	1.97E-02

Troy

	STP	Surface Water		Soil	Groundwater [µg/L]
Concentration 360 ppm	0.122	0.012		2.84E-02	3.38E-02
Concentration 100 ppm	6.80E-02	6.81E-03		1.59E-02	1.89E-02

2.2.2.6. Risk characterisation

For risk characterization calculated PEC values were divided by the following PNECs:

Environmental compartment	PNEC
Water	0.0026 mg/L (freshwater) 0.00026 mg/L (marine)
STP Microorganisms	0.055mg/L
Soil	0.33 mg/kg ww* 0.0043 mg/kg ww TWA**
Soil metabolite 6	0.33 mg/kg wwt* 0.24 mg/kg wwt TWA**

*Relevant for comparison with PECintial
**Relevant for direct emission to soil, where PECplateau was considered (countryside scenarios in PT 6.2 – Tier 2).

Concerning the atmosphere and the risk assessment of this compartment it is expected that in the event that BIT is released into the air it will be quickly photolysed (half-life <1day). Therefore the atmospheric compartment is not expected to be of concern also considering BIT's low vapour pressure.

2.2.2.6.1. PT6

For PT6 PEC/PNEC ratios for the different applicants based on highest TIER refinement are shown below:

In bold values >1 that indicate risk. The tonnage base approach is indicated in the headings of each table. Otherwise, values correspond to calculations based on the consumption approach.

Nutrition & Biosciences (Switzerland)

The summary calculated PEC/PNECs for [redacted] Tier II tonnage base approach can be found in the corresponding confidential appendix.

Calculated PEC/PNEC (indirect emissions via STP) Detergents and Cleaning Fluids					
Scenario	**STP**	**Water**		**Soil**	**GW** [µg/L]
Scenario 6.1.1 human hygienic products non pro	3.78E-02	8.00E-02		1.48E-03	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	2E-01	4.27E-01		7.88E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	2.80E-03	5.92E-03		1.09E-04	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	1.46E-01	3.08E-01		5.67E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	2.04E-02	4.31E-02		7.94E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	7.02E-02	1.48E-01		2.73E-03	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	4.40E-01	0.093		1.72E-02	6.82E-03

PEC/PNEC Paints and Coatings Indirect emissions via STP.					
Scenario	**STP**	**Water**		**Soil**	GW [µg/L]
PT 6.2: Paints Application					
6.2-1 Façade Spray City	4.49E-02	9.50E-02		1.75E-03	6.87E-04
6.2-2 City Façade with brush/roller (amateur)	7.49E-03	1.58E-02		2.92E-04	1.15E-04
PT 6.2 Service Life					
6.2-4 City façade	1.09E-01	2.32E-01		4.27E-03	1.67E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	1.54E-01	3.27E-01		6.02E-03	2.5E-03

PEC/PNEC Paints and Coatings TIER I Direct emissions to surface water					
Scenario	**STP**	**water**		Soil	GW [µg/L]
PT 6.2: Paints Application					
6.2-3 Bridge over the pond		2.74E-02			
PT 6.2 Service Life					
6.2-6 Bridge over the pond Time 1		2.74E-01			
6.2-6 Bridge over the pond Time 2		4.23E-01			
6.2-6 Bridge over the pond Time 3		5.46E-01			
Urban area - Mixed sewer system (bypass STP)					
Service life		7.50E-01			
Urban area - Direct rainwater discharge					
Application brush		1.71E-01			
Application spray		**1.03E+00**			
Service-life		**2.50E+00**			

Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the direct rainwater discharge application with spray and service life. Nevertheless, it is worth noting the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst-case values.

According to the conclusions of the WG-I-2020, additional refinements should be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, etc., to demonstrate acceptable risks for these emission pathways.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are not met for the use of paint considering the unacceptable risks via emission to direct rainwater discharge.

The same conclusions are applied for preserved polymer dispersions or any matrices introduced in paints.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil.					
Scenario	**STP**	**WATER**	**SED**	**SOIL**	**GW [µg/L]**
PT 6.2 Application phase					
6.2-1 Façade Spray Countryside TIER I				7.33E-01	**6.73E+01**
6.2-1 Façade Spray Countryside TIER II				6.97E-02	**6.42**
6.2-2 Countryside Façade with brush/roller (amateur)				1.22E-01	**1.28E+01**
PT6.2 Service life TIER II (compared with PNECsoil twa)					
6.2-5 Concentration in local soil after the initial assessment period $Clocal_{soil,TIME1}$				**2.44E+00**	**2.91**
6.2-5 $Clocal_{soil,TIME2}$				3.09E-01	**3.70E-01**
6.2-5 $Clocal_{soil,TIME3}$				8.00E-02	9.50E-02

In the case of application of paints and coatings there is no risk for soil but there is risk for the groundwater compartment.. FOCUS Pearl was used to refine brush PECgw = 12.8 µg/L as worst-case value.

The resulting groundwater concentrations are lower than the threshold value of 0.1 µg/L (see DocIIB+C).

For the Service life phase, for TIER II, based on a 50-75-100% approach, the PEC at day 30 (Time 1) exceeds the PNEC, but decreases below the PNEC within 365 days. Considering that BIT rapidly disappears from soils due to degradation, the PNEC will be exceeded, but only for a few days. Therefore, possible risks may only last a few days and considering the use, the total soil volume affected will be limited. Thus, no risk over time is foreseen for this use.

In the case of metabolite 6, as for parent, for PEC/PNEC calculations the initial PNECsoil was compared with PECs obtained during the application phase. PNECsoil TWA was used for comparison with PEC service-life TIER II.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil Met6					
Scenario	**STP**	**WATER**		**SOIL**	**GW [µg/L]**

PT 6.2 Application phase					
6.2-1 Façade Spray City TIER I				8.48E-01	952.18
6.2-1 Façade Spray City TIER II				8.18E-02	91.8
6.2-2 City Façade with brush/roller (amateur)				1.42E-01	160
P6.2 Service life TIER II (compared with PNECsoil TWA)					
6.2-5 Concentration in local soil after the initial assessment period $Clocal_{soil,TIME1}$ TIERII				1.76	**1360**
6.2-5 $Clocal_{soil,TIME2}$ TIER II				7.38E-01	**600**
6.2-5 $Clocal_{soil,TIME3}$ TIER II				1.92E-01	**158**

The resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L for scenarios 6.2-1, 6.2-2 and 6.2-5. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for the worst-case 6.2-5. The results of this refinement were values above the threshold value of 0.1 (see doc IIB+C).

There is no risk in any of the compartments because of BIT emissions to soil and groundwater considering the refinement performed with FOCUS Pearl. However, there is risk because of direct emissions to surface water and emissions of metabolite 6 to groundwater.

<u>Combined risk assessment</u>

Dispersive uses leading to emissions to the STP were considered in the combined exposure assessment as additional information and not for decision making. Aggregated uses include 6.1 (Detergents), 6.2 (Paints and coating).

Scenario	$Elocal_{STP}$ Aggregated (kg/d)	STP	Water		Soil	GW (µg/L)
6.1 + 6.2	2.25E-01	6.31E-01	**1.33**		2.46E-02	9.77E-03

The combined exposure of detergents and paint and coatings results in risk to surface water. Nevertheless, this combined exposure is included in the BPR guidance (vol IV, B+C) which contains only a decision tree on the need to estimate aggregated exposure (there is a draft guidance on aggregated exposure assessment and decision making under consultation).

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The summary calculated PEC/PNEC values for tonnage base approach can be found in the corresponding confidential appendix.

Calculated PEC/PNEC (indirect emissions via STP) Detergents and Cleaning Fluids					
Scenario	**STP**	**Water**		**Soil**	**GW** [µg/L]
Scenario 6.1.1 human hygienic products non pro	3.78E-02	8.00E-02		1.48E-03	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	2E-01	4.27E-01		7.88E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	2.80E-03	5.92E-03		1.09E-04	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	1.46E-01	3.08E-01		5.67E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	2.04E-02	4.31E-02		7.94E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	7.02E-02	1.48E-01		2.73E-03	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	4.40E-01	0.931		1.72E-02	6.82E-03

PEC/PNEC Paints and Coatings Indirect emissions via STP.					
Scenario	**STP**	**Water**		**Soil**	GW [µg/L]
PT 6.2: Paints Application					
6.2-1 Façade Spray City	4.49E-02	9.50E-02		1.75E-03	6.87E-04
6.2-2 City Façade with brush/roller (amateur)	7.49E-03	1.58E-02		2.92E-04	1.15E-04
PT 6.2 Service Life					
6.2-4 City façade	1.09E-01	2.32E-01		4.27E-03	1.67E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	1.54E-01	3.27E-01		6.02E-03	2.5E-03

PEC/PNEC Paints and Coatings TIER I Direct emissions to surface water					
Scenario	**STP**	**water**		Soil	GW [µg/L]
PT 6.2: Paints Application					
6.2-3 Bridge over the pond		2.74E-02			
PT 6.2 Service Life					
6.2-6 Bridge over the pond Time 1		2.74E-01			
6.2-6 Bridge over the pond Time 2		4.23E-01			
6.2-6 Bridge over the pond Time 3		5.46E-01			
Urban area - Mixed sewer system (bypass STP)					
Service life		7.50E-01			
Urban area - Direct rainwater discharge					
Application brush		1.71E-01			
Application spray		**1.03E+00**			
Service-life		**2.50E+00**			

Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the direct rainwater discharge application with spray and service life. Nevertheless, it is worth noting the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst-case values.

According to the conclusions of the WG-I-2020, additional refinements should be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, etc. to demonstrate acceptable risks for these emission pathways.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are not met for the use of paint considering the unacceptable risks via emission to direct rainwater discharge.

The same conclusion is applied for preserved polymer dispersions or any matrices introduced in paints.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil BIT.					
Scenario	**STP**	**WATER**	**SED**	**SOIL**	**GW [µg/L]**
PT 6.2 Application phase					
6.2-1 Façade Spray Countryside TIER I				7.33E-01	**6.73E+01**
6.2-1 Façade Spray Countryside TIER II				6.97E-02	**6.48**
6.2-2 Countryside Façade with brush/roller (amateur)				1.22E-01	**1.28E+01**
PT6.2 Service life TIER II (compared with PNECsoil twa)					
6.2-5 Concentration in local soil after the initial assessment period $Clocal_{soil,TIME1}$				**2.44E+00**	**2.91**
6.2-5 $Clocal_{soil,TIME2}$				3.09E-01	**3.70E-01**
6.2-5 $Clocal_{soil,TIME3}$				8.00E-02	9.50E-02

For the Service life phase, for TIER II, based on a 50-75-100% approach, the PEC at day 30 (Time 1) exceeds the PNEC, but decreases below the PNEC within 365 days. Considering that BIT rapidly disappears from soils due to degradation, the PNEC will be exceeded, but only for a few days. Therefore, possible risks may only last a few days and considering the use, the total soil volume affected will be limited. Thus, no risk over time is foreseen for this use. The same would apply to the groundwater compartment.

In the case of metabolite 6, as for parent, for PEC/PNEC calculations the initial PNECsoil was compared with PECs obtained during the application phase. PNECsoil TWA was used for comparison with PEC service-life TIER II.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil Met6					
Scenario	**STP**	**WATER**	**SED**	**SOIL**	**GW [µg/L]**
PT 6.2 Application phase					
6.2-1 Façade Spray City TIER I				8.48E-01	952.18
6.2-1 Façade Spray City TIER II				8.18E-02	91.8

6.2-2 City Façade with brush/roller (amateur)				1.42E-01	160
P6.2 Service life TIER II (compared with PNECsoil TWA)					
6.2-5 Concentration in local soil after the initial assessment period $Clocal_{soil,TIME1}$ TIERII				**1.67**	**1360**
6.2-5 $Clocal_{soil,TIME2}$ TIER II				7.38E-01	**600**
6.2-5 $Clocal_{soil,TIME3}$ TIER II				1.92E-01	**158**

There is no risk because of BIT emissions to soil and groundwater considering the refinement performed with FOCUS Pearl. However, there is risk because of direct emissions to surface water and emissions of metabolite 6 to groundwater.

PEC/PNEC Paper production					
Scenario	**STP**	**Surface water**		**Soil**	**GW [µg/L]**
Additives used in dry-end operations only					
Scenario 6.3.1-1 Newsprint	9.96E-01	**2.11**		0.05	0.015
Scenario 6.3.1-1 Tissues	8.85E-01	**1.87**		0.04	0.014
Scenario 6.3.1-1 Printing and writing papers	9.64E-01	**2.04**		0.04	0.015
All additives					
Scenario 6.3.1-1 Newsprint	**4.98**	**1.05E+01**		0.23	0.076
Scenario 6.3.1-1 Tissues	**4.44**	**9.23**		0.20	0.068
Scenario 6.3.1-1 Printing and writing papers	**4.82**	**1.00E+01**		0.21	0.074

PEC/PNEC values for textile production (indirect emissions via STP)					
Scenario	**STP**	**Surface water**		**Soil**	**GW [µg/L]**
Scenario 6.3.2-1 Textile production	**2.44**	**5.15**		9.48E-02	0.037

PEC/PNEC values for leather production (indirect emissions via STP)						
Scenario	**Elocal STP**	**STP**	**Surface water**	**Sediment**	**Soil**	**GW [µg/L]**
Scenario 6.3.3-1 Leather production	1.7	**4.76**	**1.01E+01**		1.85E-01	7.39E-02

Combined risk assessment

Dispersive uses leading to emissions to the STP were considered in the combined exposure assessment as additional information and not for decision making. Aggregated uses include 6.1 (Detergents), 6.2 (Paints and coating).

Scenario	$Elocal_{STP}$ Aggregated (kg/d)	STP	Water		Soil	GW (µg/L)
6.1 + 6.2	2.25E-01	6.31E-01	**1.33**		2.46E-02	9.77E-03

The combined risk of detergents and paint and coatings results in risk to surface water. Nevertheless, this combined exposure is included in the BPR guidance (vol IV, B+C) which contains only a decision tree on the need to estimate aggregated exposure (there is a draft guidance on aggregated exposure assessment and decision making under consultation).

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The summary calculated PEC/PNEC values for tonnage base approach can be found in the corresponding confidential appendix.

Calculated PEC/PNEC Detergents (indirect emissions via STP)					
Scenario	**STP**	**Water**		**Soil**	**GW** [µg/L]
Scenario 6.1.1 human hygienic products non pro	3.78E-02	8.00E-02		1.48E-03	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	2E-01	4.27E-01		7.88E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	2.80E-03	5.92E-03		1.09E-04	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	1.46E-01	3.08E-01		5.67E-03	2.22E-03

Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	2.04E-02	4.31E-02		7.94E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	7.02E-02	1.48E-01		2.73E-03	1.07E-03
Scenario 6.1 Detergent and cleaning fluids – Use - Aggregated	4.40E-01	0.931		1.72E-02	6.82E-03

PEC/PNEC Paints and Coatings Indirect emissions via STP.					
Scenario	**STP**	**Water**		**Soil**	GW
PT 6.2: Paints Application					
6.2-1 Façade Spray City	5.53E-02	1.17E-01		2.15E-03	8.44E-04
6.2-2 City Façade with brush/roller (amateur)	9.20E-03	1.95E-02		3.58E-04	1.41E-04
PT 6.2 Service Life					
6.2-4 City façade	1.35E-01	2.85E-01		5.24E-03	2.06E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	1.90E-01	4.02E-01		7.39E-03	2.36E-03

PEC/PNEC Paints and Coatings TIER I Surface water					
Scenario	**STP**	**Surface Water**		**Soil**	**GW [µg/L]**
PT 6.2: Paints Application					
6.2-3 Bridge over the pond		3.37E-02			
PT 6.2 Service Life					
6.2-6 Bridge over the pond Time 1		3.37E-01			
6.2-6 Bridge over the pond Time 2		5.04E-01			
6.2-6 Bridge over the pond Time 3		6.73E-01			
Urban area - Mixed sewer system					
Service life		9.23E-01			

Urban area - Direct rainwater discharge					
Application brush		2.10E-01			
Application spray		**1.26**			
Service-life		**3.08**			

Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the direct rainwater discharge application with spray and service life. Nevertheless, it is worth noting the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst-case values.

According to the conclusions of the WG-I-2020, additional refinements should be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, etc., to demonstrate acceptable risks for these emission pathways.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are not met for the use of paint considering the unacceptable risks via emissions in Urban area-direct rainwater discharge.

For terrestrial PEC/PNEC calculations, the initial $PNEC_{soil}$ was compared with PECs obtained during the application phase. $PNEC_{soil}$ TWA was used for comparison with PEC service-life TIER II, which represents the realistic case

PEC/PNEC values Paints and Coatings Direct emissions to soil BIT.					
Scenario	**STP**	**Surface Water**	**Sediment**	**Soil**	**GW [µg/L]**
PT 6.2 Application phase					
6.2-1 Façade Spray Countryside TIER I				9.00E-01	**8.27E+01**
6.2-1 Façade Spray Countryside TIER II				8.58E-02	**7.88**
6.2-2 Countryside Façade with brush/roller (amateur)				1.50E-01	**1.38E+01**
P6.2 Service life TIER II (compared with PNECsoil TWA)					
6.2-5 $Clocal_{soil,TIME1}$ TIERII				**3.02**	**3.58**
6.2-5 $Clocal_{soil,TIME2}$ TIER II				3.67E-01	**4.40E-01**
6.2-5 $Clocal_{soil,TIME3}$ TIER II				9.84E-02	**1.18E-01**

According to the above table there is risk for groundwater in each of the scenarios assessed. For groundwater the case of brush represents a worst case with PEC_{gw} = 13.8 µg/L.

In this case the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for the worst case 6.2-2, being the resulting groundwater concentrations lower than the threshold value of 0.1 µg/L (see DocIIB+C). In case of metabolite 6, as for parent, for PEC/PNEC calculations the initial PNECsoil was compared with PECs obtained during the application phase. PNECsoil twa was used for comparison with PEC service-life TIER II.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil Met6						
Scenario	**Elocal (kg/d)**	**STP**	**WATER**	**SED**	**SOIL**	**GW [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					1.05	1180
6.2-1 Façade Spray City TIER II					0.1	113
6.2-2 City Façade with brush/roller (amateur)					0.176	197
PT 6.2 Service life Tier II (degradation considered)						
6.2-5 Concentration in local soil after the initial assessment period					2.05	**1670**
6.2-5 Clocalsoil,TIME2					8.76E-01	**714**
6.2-5 Clocalsoil,TIME3					2.38E-01	**194**

When considering degradation, there is risk in soil for time 1 and the resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for the worst-case 6.2-5.

There is not risk in any of the compartments because of BIT emissions to soil and groundwater considering the refinement performed with FOCUS Pearl. However, BIT transforms very rapidly in soil to metabolite 6. Calculations with this metabolite show risk to groundwater in all scenarios and risk to soil for time 1, even if considering degradation of this metabolite in soil. For time 2 and 3 there is no risk.

It is concluded that preservation of paints and coatings is acceptable provided that BIT is limited to products for interior use due to the risk of BIT because of direct emissions to surface water and of metabolite 6 to groundwater.

Polymer emulsions:

The requirements for acceptable risk according to the Guidance for BPR are met for the use of polymer emulsions, with concentrations of BIT up to 300 ppm for indoor use. This decision is based on risk ratios calculated for paints and coatings at 500 ppm which resulted in a safe use. A lower concentration of active substance under the same scenario will also result in a safe use.

In the case of outdoor applications eCA has calculated PEC/PNEC ratios for polymer emulsions at 300 ppm for surface water (for BIT) and for soil (metabolite 6), as in those cases there was risk at 500 ppm in the paints and coating scenarios.

PEC/PNEC Polymer emulsions TIER I Surface water BIT					
Scenario	**STP**	**Surface Water**		**Soil**	**GW [µg/L]**
PT 6.2: Paints Application					
6.2-3 Bridge over the pond		2E-02			
PT 6.2 Service Life					
6.2-6 Bridge over the pond Time 1		2E-01			
6.2-6 Bridge over the pond Time 2		0.3E-01			
6.2-6 Bridge over the pond Time 3		0.4E-01			
Urban area - Mixed sewer system					
Service life		0.55E-01			
Urban area - Direct rainwater discharge					
Application spray		0.76			
Application brush		0.13			
Service-life		**1.8**			

According to the table above, there is no risk to surface water in the bridge over the pond scenario as a result of application of polymer emulsion in TIER I (hence, there will be no risk in TIER II). Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the direct rainwater discharge service life. Nevertheless, it is worth noting the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst-case values. Yet, according to the conclusions of the WG-I-2020, additional refinements should be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, etc., to demonstrate acceptable risks for these emission pathways.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are not met for the use of BIT in polymers considering the unacceptable risks via emission to direct rainwater discharge.

For soil, as mentioned above, only the risk ratios at 300 ppm for which a risk at 500 ppm was found, are calculated here. This is the case of metabolite 6 and direct emissions to soil:

Calculated PEC/PNEC values Polymer Emulsions Direct emissions to soil Met6						
Scenario	**Elocal (kg/d)**	**STP**	**WATER**		**SOIL**	**GW [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					0.63	**708**
6.2-1 Façade Spray City TIER II					0.061	**67.8**
6.2-2 City Façade with brush/roller (amateur)					0.11	**118.2**
PT 6.2 Service life Tier II (degradation considered)						
6.2-5 Concentration in local soil after the initial assessment period					**1.22**	**1002**
6.2-5 Clocalsoil,TIME2					0.525	**428.4**
6.2-5 Clocalsoil,TIME3					1.42E-01	**116.4**

According to the table above, when considering degradation there is risk of metabolite 6 in soil for time 1 but not for time 2 and 3. Further, the resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for the worst-case 6.2-5.

<u>Conclusion:</u> There is no risk because of BIT emissions to soil and groundwater at 300ppm since there was no risk at 500 ppm. However, there is risk to groundwater and to soil for time 1 due to metabolite 6 emissions.

<u>Hence,</u> the use of BIT in Polymer emulsions is acceptable provided that BIT is limited to products for interior use due to the risk of BIT in direct emissions to surface water in the service life scenario "Urban area - Direct rainwater discharge" and the risk associated to emissions of metabolite 6 to groundwater.

<u>Combined risk assessment</u>

Dispersive uses leading to emissions to the STP were considered in the combined exposure assessment as additional information and not for decision making. Aggregated uses include 6.1 (Detergents), 6.2 (Paints and coating).

Scenario	$Elocal_{STP}$ (kg/d)	STP	WATER		SOIL	GW (µg/L)
Scenario 6.1 + 6.2	2.39E-01	6.71E-01	**1.42**		2.61E-02	1E-02

The combined exposure of detergents and paints and coatings results in risk to surface water. Nevertheless, this combined exposure is included in the BPR guidance (vol IV, B+C) which contains only a decision tree on the need to estimate aggregated exposure (there is a draft guidance on aggregated exposure assessment and decision making under consultation).

Troy

The summary calculated PEC/PNEC values for [redacted] for tonnage base approach can be found in the corresponding confidential appendix.

Calculated PEC/PNEC Detergents and cleaning fluids (indirect emissions via STP) BIT					
Scenario	**STP**	**Water**		**Soil**	**GW** [µg/L]
Scenario 6.1.1 human hygienic products non pro	3.78E-02	8.00E-02		1.48E-03	5.79E-04
Scenario 6.1.2 A-1 – Detergents pro – Laundry	2E-01	4.27E-01		7.88E-03	3.09E-03
Scenario 6.1.2 A-2 Detergent pro – Surface	2.80E-03	5.92E-03		1.09E-04	4.29E-05
Scenario 6.1.2 – B-1 Detergent Non Pro – Fabric washing	1.46E-01	3.08E-01		5.67E-03	2.22E-03
Scenario 6.1.2 B-2 Detergent Non pro – Dish washing	2.04E-02	4.31E-02		7.94E-04	3.11E-04
Scenario 6.1.2 B-3 Detergent Non pro - Surface	7.02E-02	1.48E-01		2.73E-03	1.07E-03
Scenario 6.1.2 Detergent and cleaning fluids – Use - Aggregated	4.40E-01	9.31E-01		1.72E-02	6.82E-03
PEC/PNEC Paints and Coatings Indirect emissions via STP.					
Scenario	**STP**	**Water**		**Soil**	GW
PT 6.2: Paints Application					
6.2-1 Façade Spray City	5.53E-02	1.17E-01		2.15E-03	8.44E-04

6.2-2 City Façade with brush/roller (amateur)	9.20E-03	1.95E-02		3.58E-04	1.41E-04
PT 6.2 Service Life					
6.2-4 City façade	1.35E-01	2.85E-01		5.24E-03	2.06E-03
Aggregated emissions – worst case City scenario sprayer - Application + Service life	1.9E-01	4.02E-01		7.39E-03	2.90E-03

PEC/PNEC Paints and Coatings TIER I Surface water					
Scenario	**STP**	**Surface Water**		**Soil**	**GW [µg/L]**
PT 6.2: Paints Application					
6.2-3 Bridge over the pond		3.37E-02			
PT 6.2 Service Life					
6.2-6 Bridge over the pond Time 1		3.37E-01			
6.2-6 Bridge over the pond Time 2		5.04E-01			
6.2-6 Bridge over the pond Time 3		6.73E-01			
Urban area - Mixed sewer system					
Service life		9.23E-01			
Urban area - Direct rainwater discharge					
Application brush		2.10E-01			
Application spray		**1.26**			
Service-life		**3.08**			

Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the direct rain water discharge application with spray and service life. Nevertheless, it is worth noting the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst case values.

According to the conclusions of the WG-I-2020, additional refinements should be provided at the product authorization stage, such as stability studies of the active substance in preserved products, leaching studies, etc., to demonstrate acceptable risks for these emission pathways.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are not met for the use of paint considering the unacceptable risks via emissions Urban area-direct rainwater discharge.

The same conclusions are applied for preserved polymer dispersions or any matrices introduced in paints.

PEC/PNEC values Paints and Coatings Direct emissions to soil.					
Scenario	**STP**	**Surface Water**	**Sediment**	**Soil**	**GW [µg/L]**
PT 6.2 Application phase					
6.2-1 Façade Spray Countryside TIER I				9.00E-01	**8.27E+01**
6.2-1 Façade Spray Countryside TIER II				8.58E-02	**7.88**
6.2-2 Countryside Façade with brush/roller (amateur)				1.50E-01	**1.38E+01**
PT 6.2 Service Life					
PT 6.2 Service life TIER II (compared with PNECsoil TWA)					
6.2-5 $Clocal_{soil,TIME1}$ TIERII				**3.02**	**3.58**
6.2-5 $Clocal_{soil,TIME2}$ TIER II				3.67E-01	**4.40E-01**
6.2-5 $Clocal_{soil,TIME3}$ TIER II				9.84E-02	**1.18E-01**

According to the table above, when considering degradation in soil there is risk for time 1 but not for time 2 and 3. The resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for the worst-case 6.2-5.

Calculated PEC/PNEC values Paints and Coatings Direct emissions to soil Met6						
Scenario	**Elocal (kg/d)**	**STP**	**WATER**	**SED**	**SOIL**	**GW [µg/L]**
PT 6.2 Application phase						
6.2-1 Façade Spray City TIER I					1.05	1180
6.2-1 Façade Spray City TIER II					0.1	113
6.2-2 City Façade with brush/roller (amateur)					0.176	197

PT 6.2 Service life Tier II (degradation considered)						
6.2-5 Concentration in local soil after the initial assessment period					2.05	**1670**
6.2-5 Clocalsoil,TIME2					8.76E-01	**714**
6.2-5 Clocalsoil,TIME3					2.38E-01	**194**

There is not risk in any of the compartments because of BIT emissions to soil and groundwater considering the refinement performed with FOCUS Pearl.

However, BIT transforms very rapidly in soil to metabolite 6. Calculations with this metabolite show risk to groundwater in all scenarios in the case of direct emissions to soil and risk to soil for time 1 even if considering degradation of this metabolite in soil. For time 2 and 3 there is no risk.

It is concluded that preservation of paints and coatings is acceptable provided that BIT is limited to products for interior use due to the risk of BIT because of direct emissions to surface water and emissions of metabolite 6 to groundwater.

PEC/PNEC Paper production					
Scenario	**STP**	**Surface water**		**Soil**	**GW [µg/L]**
Additives used in dry-end operations only					
Scenario 6.3.1-1 Newsprint	9.96E-01	**2.11**		0.05	0.015
Scenario 6.3.1-1 Tissues	8.85E-01	**1.87**		0.04	0.014
Scenario 6.3.1-1 Printing and writing papers	9.64E-01	**2.04**		0.04	0.015
All additives					
Scenario 6.3.1-1 Newsprint	**4.98**	**1.05E+01**		0.23	0.076
Scenario 6.3.1-1 Tissues	**4.44**	**9.23**		0.20	0.068
Scenario 6.3.1-1 Printing and writing papers	**4.82**	**1.00E+01**		0.21	0.074

The use of BIT in paper production results in risks to the aquatic compartment for the all additives and dry-end operations scenarios.

PEC/PNEC values for textile production (indirect emissions via STP)					
Scenario	**STP**	**Surface water**		**Soil**	**GW [µg/L]**

Scenario 6.3.2-1 Textile production	**2.44**	**5.15**		9.48E-02	0.037

For textile production there are unacceptable risks to the environment for various compartments associated to the use of BIT at a concentration of 500 ppm.

Scenario	STP	Surface water		Soil	GW [µg/L]
Scenario 6.3.3-1 Leather production	4.76	1.01E+01		1.85E-01	7.39E-02

The requirements for acceptable risk according to the Guidance for BPR are not met for the use of BIT for preserved leather production, with a concentration of pure BIT of 500 ppm in the end-product.

Further, there are risks for the aquatic compartment for application based on the tonnage approach.

Combined risk assessment

Dispersive uses leading to emissions to the STP were considered in the combined exposure assessment as additional information and not for decision making. Aggregated uses include 6.1 (Detergents), 6.2 (Paints and coatings).

Scenario	$Elocal_{STP}$ (kg/d)	STP	WATER	SOIL	GW (µg/L)
Scenario 6.1 + 6.2	2.39E-01	6.71E-01	**1.42E+00**	2.61E-02	1E-02

The combined exposure of detergents and paints and coatings results in risk to surface water.

Nevertheless, this combined exposure is included in the BPR guidance (vol IV, B+C) which contains only a decision tree on the need to estimate aggregated exposure (there is a draft guidance on aggregated exposure assessment and decision making under consultation).

Combined Risk Assessment for all Applicants

In addition to the combined risk assessment calculated for each of the applicants the WGII2021 (ENV6.3, discussion point 5) agreed to perform a risk assessment considering the uses 6.1 (Detergents), 6.2 (Paints and coatings) from all the four applicants. The combined risk assessment is based on the worst-case approach, which is in this case the consumption-based approach.

Scenario	STP	WATER	SOIL	GW (µg/L)
Scenario 6.1 + 6.2	2.604	5.5	0.101	0.039

The combined exposure results in risk to the STP and surface water. These results will be used for additional information and not for decision making, as this combined exposure is included in the BPR guidance (vol IV, B+C), which contains only a decision tree on the need to estimate aggregated exposure (there is a draft guidance on aggregated exposure assessment and decision making under consultation).

Tonnage sum-up for PT6

The calculations for the summing-up of the tonnages for all applicants, according to WG-II-2021, have been included in the confidential annex. It results in a safe use for all uses, with a PEC/PNEC below 1, except for the use as "Preservative in leather production".

2.2.2.6.2. PT13

The PEC/PNECs ratios for the different applicants for PT13 are shown in the next table.

Nutrition & Biosciences (Switzerland)

	STP	Surface Water		Soil	Groundwater [µg/L]
360 ppm	**4.16**	**8.85**		1.62E-01	6.36E-02
100 ppm	**1.33**	**2.8**		5.15E-02	2.02E-02

LANXESS

	STP	Surface Water		Soil	Groundwater [µg/L]
360 ppm	**4.16**	**8.85**		1.62E-01	6.36E-02
100 ppm	**1.33**	**2.8**		5.15E-02	2.02E-02

Lonza, Thor and Lamirsa

	STP	Surface Water		Soil	Groundwater [µg/L]
300 ppm	**3.31**	**6.92**		1.29E-01	5.07E-02
100 ppm	**1.29**	**2.72**		1.97E-01	1.97E-02

Troy

	STP	Surface Water		Soil	Groundwater [µg/L]
200 ppm	**2.22**	**4.62**		8.61E-02	3.38E-02
100 ppm	**1.24**	**2.62**		4.81E-02	1.89E-02

Risk assessment for PT 13 was calculated assuming, as suggested in the ESD PT 13 refinement, that the emissions will take place via STP and the treatment wastewater in external waste treatment companies.

2.2.3. Endocrine Disruption Risk Assessment

To evaluate a potential concern for endocrine disruption effects induced by BIT all available data were assessed for all levels of the OECD Conceptual Framework (Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009).

These data include experimental data generated by LANXESS Deutschland GmbH, Lonza Cologne GmbH, Nutrition & Biosciences (Switzerland) GmbH, Thor GmbH, Troy Chemical Company B.V., Laboratorios Miret S.A. as well as public available information (from an updated literature research performed in Feb. 2019).

Toxicological and ecotoxicological studies have been performed with the active substance (BIT).

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. For Human Health no endocrine disrupting properties are evident and BIT was not found to be an endocrine disruptor for Human Health. 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, 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.

However, despite the fact that a clear conclusion cannot be reached at present about endocrine disruption properties, it is highly unlikely that BIT has such properties.

3. DECISION

3.1. Background to the Proposed Decision

This Document I has been developed and finalised in support of the decision to include 1,2-Benzisothiazolin-3-(2*H*)-one (BIT) in the list mentioned in Art. 1.2 to Regulation (EU) 528/2012 for Product-types 6 and 13. The aim of the document I is to facilitate the authorisation in Member States of individual biocidal products in different Product-types (6 and 13) that contain 1,2-Benzisothiazolin-3-one (BIT). In their evaluation, Member States shall apply the provisions of Regulations (EU) No 528/2012, particularly the provisions of Article 5 as well as the common principles laid down in Annex VI.

BIT is an off-white fine, non-free-flowing crystalline powder that tends to form clumps. It is not readily degradable but slightly soluble in water (pH dependent: 0.98 g/L at pH 5 to 9.33 g/L at pH 8 at 20°C). The partition coefficient of BIT also varies with pH and temperature. The vapour pressure (1.1 x 10^{-4} Pa at 20°C) and Henry's Law constant is low. BIT is not highly flammable and has no explosive and oxidising properties.

Regarding **efficacy**, the assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against bacteria and fungi and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

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.

The overall conclusion from the **human health** evaluation is that it was demonstrated that the handling and use of the biocidal product containing BIT as active substance is safe. The assessment is based on realistic worst-case scenarios as well as previous evaluations by other scientific bodies[4,5,6]. No unacceptable risk is indicated for humans when the product containing BIT is handled and used as recommended.

Handling the biocidal product by industrial users may require the use of personal protection due to its classification as a contact sensitizer, serious eye damaging and acutely toxic. Technical measures should be implemented otherwise to reduce exposure via the dermal and inhalation routes.

For PT6:

1. Exposure level for professional and no professional users is considered to be within the acceptable range for all uses.
2. Adequate protection during spray painting is required due to the high degree of operator's contamination during this task, (protective gloves -new gloves for each work shift-, impermeable coverall and respiratory protection may be considered).
3. The indirect exposure for children and infants is considered to be within the acceptable range.
4. Exposure from eating with utensils and dishware that have been washed with detergent is estimated to be acceptable.
5. 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 concentration triggering classification, in order to take into account, the sensitizing properties of BIT.

For PT13:

1. Exposure level for industrial workers is considered to be within the acceptable range for all tasks.
2. Adequate protection during MWF tasks are required due to the high degree of operator's contamination during this task, (protective gloves -new gloves for each work shift-, impermeable coverall and/or respiratory protection may be considered).

The results of the **environmental** risk assessment for BIT indicate that there is no risk to the environmental compartments for all uses assessed, except for:

- PT6 - Preservation of additives used in leather production (concentration 500 ppm) - unacceptable risk for STP and surface water.

4 RAC Opinion proposing harmonised classification and labelling at EU level of 2-methyl-1,2-benzothiazol-3(2H)-one [MBIT]; CLH-O-0000001412-86-209/F

5 SCCS opinion on Benzisothiazolinone COLIPA n° P96

6 US EPA RED for BIT

    - PT6 - Preservation of additives used in paper production (concentration of 500 ppm) unacceptable risk for the aquatic compartment.
- PT6 - Preservation of additives used in textile production (concentration of 500 ppm): unacceptable risk to the aquatic compartment.
- PT6 - Preservation of paints and coatings in outdoor use: unacceptable risk to groundwater and direct emission to surface water.
- PT6 - Preservation of polymer emulsions used for paints and coatings in outdoor use: unacceptable risk to groundwater and direct emission to surface water.
- PT13: BIT has shown unacceptable risk for PT13 use for the environmental compartments STP and surface water. Nevertheless, the applicants have submitted several documents that prove the possibility to stablish some risk mitigation measures to reduce BIT content in the MWF waste:
    - First of all, the oil fraction should be separated from the water fraction to be treated by an external waste management company.
    - The water phase should be treated to achieve chemical deactivation/degradation of BIT to reduce its content (it has been achieved a percentage above 85%):
        - Isothiazolinones can be deactivated by an organic thiol[7] or by a neutralising/ inactivation agent such as sodium glycolate[8].
        - Degradation of BIT by sodium thiosulphate or potassium mono persulplahte and potassium peroxydisulphate has been analysed by one of the applicants with a BIT degradation above 85% in water[9].
        - Photodegradation of BIT under UVC irradiation achieves more than 90% BIT degradation[10].
        - BIT was rapidly degraded by ozonation effect, and ozonation markedly decreased the toxic effects of BIT to zebrafish embryos, hence the oxidized products are far less toxic than BIT[11].
        - The concentration of BIT in the waste of MWFs collected in a metalworking shop was below the limit of detection (0.67 mg/L) in all samples, from an initial BIT concentration of around 100 ppm (Thor[12]).

[7] 1996-06-24_Patent_US_5641411_Deactivation_Isothiazolinones

[8] 2021-06-30_VDI_2047-2_BIT_Removal_via_chemicals_(see_p_59ff)_DE__EN

[9] 2021-06-29_BIT_degradation_in_MWF_via_chemicals_-_Interim_Results

[10] 2017-08-16_Lit_Hu_et_al_Photodegradation_of_BIT

[11] 2016-04-09_Lit_Ang_Li_et_al_BIT-_removal_via_ozonation

[12] Monitoring BIT in MWF by Thor

- Various MWF mixtures were treated with a range of concentrations of hydrogen peroxide to achieve the degradation of BIT still present in used systems. The observed degradation rates ranged from 10 to 100% at the highest oxidant concentration, the best results obtained with boron- and amine- free MWF concentrates[13].

3.2. Proposed Decision regarding Inclusion in Annex I

It is recommended that 1,2-benzisothiazolin-3-one (BIT) is included in Union List of active substances under Regulation (EU) No 528/2012 as an active substance for use in different Product-types 6 and 13, subject to the following specific provisions:

A. The active substance BIT, as manufactured, shall have a minimum purity of 965.2 g/kg dry matter, corresponding to 821.4 g/kg wet matter for EBITTF (Lonza Cologne GmbH, Laboratorios Miret S.A. and Thor GmmbH), 982.7 g/kg dry matter, corresponding to 841.5 g/kg wet matter for LANXESS Deutchsland GmbH and 976.9 g/kg dry matter, corresponding to 799.4 g/kg for Troy Chemical Company B.V..
B. The identity and maximum content of impurities can be found in the "Confidential Section".
C. BIT may be used as active substance for the following uses:
PT6 - Preservation of Detergents and cleaning fluids
PT6 - Preservation of Paints and Coatings: indoor use
PT6 - Formulation phase of functional fluids
PT6 - Preservation of Glues and adhesives
PT6 - Preservation of polymer emulsions: indoor use
PT13 - Working metal fluids: although this use has not proven to be safe, it should be authorized if the MFW waste containing BIT can be processed in such a way that little or no exposure to the aquatic compartment is expected, with a BIT reduction in the water phase of such waste above 85%, by applying some risk mitigation measures (see section 3.1), provided a RCR below 1 is obtained.

No safe use of BIT has been proven for the following uses:

- PT6 Preservation of paints and coatings in outdoor. Nevertheless, 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, etc., to prove the use to be safe for surface water, soil and groundwater.

[13] Elimination_of_BIT_in_MWF_-_oxidation_Thor_5719

- LANXESS and Task Force: PT6 Preservation of polymer emulsions used for paints and coatings in outdoor use. Nevertheless, 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, etc., to prove the use to be safe for surface water, soil and groundwater.
- LANXESS and Troy: PT6 Preservation of additives used textile and leather production. Nevertheless, additional data and/or refinements could be provided on product authorization stage to prove the use to be safe for the STP and surface water.
- LANXESS and Troy: PT6 Preservation of additives used in paper production. Nevertheless, additional data and/or refinements could be provided on product authorization stage to prove the use to be safe for the STP and surface water.

	Proven safe uses			
Intended Use	LANXESS	N&B	Task Force	Troy
PT6 - Preservation of Detergents and cleaning fluids	Safe use	Safe use	Safe use	Safe use
PT6 - Preservation of Paints and Coatings	Only safe for indoor use. Possible refinement for outdoor use.	Only safe for indoor use. Possible refinement for outdoor use.	Only safe for indoor use. Possible refinement for outdoor use.	Only safe for indoor use. Possible refinement for outdoor use.
PT6 - Preservation of additives used in Paper production	No safe use proven. Possible refinement.			No safe use proven. Possible refinement.
PT6 - Preservation of additives used in Textile production	No safe use proven. Possible refinement.			No safe use proven. Possible refinement.
PT6 – Preservation of additives used in leather production	No safe use proven. Possible refinement.			No safe use proven. Possible refinement.
PT6 - Formulation phase of functional fluids	Safe use			
PT6 - Preservation of Glues and adhesives	Safe use		Safe use	Safe use
PT6 - Preservation of polymer emulsions	Only safe for indoor use. Possible refinement for outdoor use.		Only safe for indoor use. Possible refinement for outdoor use.	

PT13 – Preservation of metal working fluids	No safe use proven. Possible RMMs	No safe use proven. Possible RMMs	No safe use proven. Possible RMMs	No safe use proven. Possible RMMs

D. Technical measures appropriated to reduce dermal exposure to a minimum should be in place.
E. Spray application of paints containing BIT requires the operators to use adequate personal protection due to the high degree of contamination.

3.3. Factors to be taken into account by Member States when authorising products

- A) and B) are general requirements that will be obligatory specifications demands for the active substance for all Annex I entries.
- All the efficacy of the product has to be demonstrated for all the intended uses and all the target organisms claimed.
- Although it is difficult for cells to become resistant to BIT, since microbial resistance to BIT has been described in the literature, before authorizing products Member States should pay attention to possible occurrence of resistance.
- If product containing the active substance is intended to come directly or not, in contact with food, a dietary assessment would be necessary. This should be taken into account at product authorisation.
- Risk mitigation measures are necessary to ensure acceptable risks at the application phase of the preserved paints and coatings:
  - The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:
    - For application by spraying of paints and coatings, the following must be stated: “The ground must be covered during in-situ application of the treated articles (paints and coatings) and any spillage should be collected”.
    - For application by brush, the following must be stated: “The ground must be covered during in-situ application of the treated articles and any spillage should be collected.
- Risk mitigation measures are necessary to ensure acceptable risks at the application phase of the product in polymer emulsions:
  - The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:
    - For application by spraying of polymer emulsions, the following must be stated: “The ground must be covered during in-situ application of the treated articles (polymer emulsions) and any spillage should be collected”.
    - For application by brush, the following must be stated: “The ground must be covered during in-situ application of the treated articles and any spillage should be collected”.
- Risk mitigation measures are necessary to ensure acceptable risks at PT13 use. A BIT reduction in the water phase of the waste above 85% should be achieved and the RCR should be below 1.

Additional data to be submitted at product authorisation stage:

- Additional data such as stability studies of the active substance in preserved products, leaching studies, monitoring data, etc., should be submitted for a refinement to prove a safe use.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of 1,2-benzisothiazolin-3-(2*H*)-one (BIT) in accordance with Article 9 of Regulation No 528/2012.

Hence, no additional information is required.

3.5. Updating this Document I

This Document I may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of 1,2-benzisothiazolin-3-(2*H*)-one (BIT).

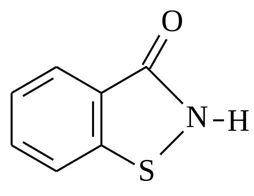
APPENDIX I: LISTING OF END POINTS

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	1,2-Benzisothiazol-3-(2*H*)-one
Function (Product-type)	Preservative for products during storage, (PT 6) Working or cutting fluid preservatives (PT 13)

Rapporteur Member State	Spain

Identity

Chemical name (IUPAC)	1,2-Benzisothiazol-3-(2*H*)-one
Chemical name (CA)	1,2-Benzisothiazolin-3-one
CAS No	2634-33-5
EC No	220-120-9
Other substance No.	Not applicable
Minimum purity of the active substance as manufactured (g/kg or g/L)	**EBITTF (Lonza Cologne GmbH, Laboratorios Miret S.A., and Thor GmbH):** ≥ 965.2 **LANXESS Deutschland GmbH:** ≥ 982.7 **Troy Chemical Company B.V.:** ≥ 976.9
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	C_7H_5NOS
Molecular mass	151.19 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.**

	157.1 ± 0.4ºC (99.8%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 157 ± 0.5 ºC (100.1%) **Troy Chemical Company B.V.** 159.5-160ºC (> 97%)
Boiling point (state purity)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** BIT decomposed above 300°C (> 99%) 328.7°C (> 99%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Test substance is a solid at ambient temperature. Also, DSC Thermogram does not exhibit a boiling point below 340ºC. Not Applicable. **Troy Chemical Company B.V.** 249.5 ± 0.6 ºC
Temperature of decomposition	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** > 300ºC (98%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Not available **Troy Chemical Company B.V.** Not relevant
Appearance (state purity)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Solid white powder at ambient temperature (99.8%) Damp brown powder at ambient temperature (73.2%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** White to off-white fine, non free-flowing crystalline powder with a few large hard clumps (at 22.0 ± 0.5ºC) (Purity: 100.1%) Off-white fine, non free-flowing crystalline powder that tends to form clumps, which are easily broken, with a few large hard clumps (at 22.0 ± 0.5ºC) (89.8%) **Troy Chemical Company B.V.** Off-white crystalline solid (97%) Solid Powder, Ivory (purity > 85%)

Relative density (state purity)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** 1.483 at 20ºC (> 99%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 1.50 (at 22.0 ± 0.5ºC) (100.1%) **Troy Chemical Company B.V.** 1.361 ± 0.02 g/mL at 20 ± 1ºC (99.6%)
Surface tension	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** 72.6 mN/m at 20ºC (1 g/L) (98%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 71.5 mN/m at 21.6 ± 0.5 ºC (0.881 g/L) (100.1%) **Troy Chemical Company B.V.** 71.5 mN/m at 21.6 ± 0.5 ºC (0.881 g/L) (100%)
Vapour pressure (in Pa, state temperature)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** 6.3×10^{-5} Pa at 20°C (> 90%) 1.4×10^{-4} Pa at 25°C (> 90%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 1.1×10^{-4} Pa at 20.0°C (100.1%) 2.3×10^{-4} Pa at 25.0°C (100.1%) **Troy Chemical Company B.V.** 1.5×10^{-4} Pa at 25ºC (pure BIT) 3.02×10^{-3} Pa at 20ºC (purity > 97.42%) 8.91×10^{-3} Pa at 25ºC (purity > 97.42%)
Henry's law constant (Pa m^3 mol^{-1})	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** 7.40×10^{-6} Pa m^3 mol^{-1} at 20ºC (calculated) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 1.45×10^{-5} Pa m^3 mol^{-1} at 20ºC (100.1%) **Troy Chemical Company B.V.** 1.89×10^{-5} Pa m^3 mol^{-1} at 20ºC (calculated)
Solubility in water (g/L, state temperature)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.**

	pH 5 (4.8): 0.727 g/L at 10ºC, 0.938 g/L at 20ºC, 1.196 g/L at 30ºC (99%) pH 7 (6.7): 1.288 g/L at 20ºC (99%) pH 9 (9.1): 1.651 g/L at 20ºC (99%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** pH 5: 0.712 g/L at 10°C; 0.976 g/L at 20°C and 1.400 g/L at 30°C (100.1%) pH 7: 0.860 g/L at 10°C; 1.150 g/L at 20°C and 1.590 g/L at 30°C (100.1%) pH 9 (8): 8.840 g/L at 10°C; 9.330 g/L at 20°C and 9.880 g/L at 30°C (100.1%) **Troy Chemical Company B.V.** 1.118 g/L in deionised water at 20ºC (pH not documented) (purity > 97%)
Solubility in organic solvents (in g/L or mg/L, state temperature)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** (94.2%) Methanol: 67 g/L at 24°C Acetonitrile: 13 g/L at 23°C Acetone: 42 g/L at 24°C Dichloromethane: 31 g/L at 23°C Toluene: 5 g/L at 24°C Ethyl Acetate: 23 g/L at 23°C Hexane: 0.1 g/Lat 23°C **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** (100.1%) At 10.0 ± 0.5ºC: 3.96 x 10^{-2} g/L (*n*-hexane) 10.1 g/L (ethyl acetate) 28.9 – 33.7 g/L (methanol) At 20.0 ± 0.5ºC: 5.36 x 10^{-2} g/L (*n*-hexane) 14.9 g/L (ethyl acetate) 29.0 – 33.8 g/L (methanol) At 30.0 ± 0.5ºC: 8.98 x 10^{-2} g/L (*n*-hexane) 14.8 g/L (ethyl acetate) 40.4 – 50.5 g/L (methanol) **Troy Chemical Company B.V.** (purity > 97%) 135 mg/L in heptane at 20ºC

	11.6 g/L in ethyl acetate at 20ºC
Stability in organic solvents used in biocidal products including relevant breakdown products	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Active substance as manufactured does not contain any organic solvent. (94.2%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Active substance as manufactured does not contain any organic solvent. **Troy Chemical Company B.V.** Stable in deionised water, heptane, ethyl acetate and 1-octanol at ambient temperature for 24, 48 and 120 h was tested (purity > 97%)
Partition coefficient ($logK_{ow}$) (state temperature)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** pH 5: 0.99 at 20ºC (99%) pH 7: 0.63 at 10ºC (99%) pH 7: 0.70 at 20ºC (99%) pH 7: 0.76 at 30ºC (99%) pH 9: -0.90 at 20ºC (99%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** pH 5: 1.48 at 10°C and 1.43 at 30°C (100.1%) pH 7: 1.3 at 10°C and 1.24 at 30°C (100.1%) pH 9: 0.224 at 10°C and 2.78 x 10^{-2} at 30°C (100.1%) **Troy Chemical Company B.V.** 1.40 ± 0.06 at 21 ºC (pH not documented) (pure BIT)

Hydrolytic stability (DT_{50}) (state pH and temperature)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** pH 5 at 30 ± 2 ºC: > 30 days. Hydrolysis did not exceed 10% after 30 days (purity > 97%) pH 7 at 30 ± 2 ºC: > 30 days. Hydrolysis did not exceed 10% after 30 days (purity > 97%) pH 9 at 30 ± 2ºC: > 30 days. Hydrolysis did not exceed 10% after 30 days (purity > 97%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** No hydrolysis at 50°C, at pH 4, 7 and 9 (100.1%) **Troy Chemical Company B.V.** pH 4: 219 days at 50.8ºC pH 7: >200 days at 50.8ºC pH 9: 145 days at 50.8ºC
Dissociation constant	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** pKa of 7.2 at 25 °C (100%) pKa of 7.5 ± 0.1 at 25 °C (99.5%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** pKa = 7.17 (100.1%) **Troy Chemical Company B.V.** pKa = 7.04 (Pure BIT)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** > 99% pure water 4.29 at 224 nm, NaOH (0.1 mol/L) 4.07 at 222 nm, HCl (0.1 mol/L) 4.31 at 225 nm **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 100.1% pure λ_{max}(acidic) 226,2 36, 246, 261, 316 nm λ_{max}(neutral) 226, 236, 245, 262, 316 nm λ_{max}(alkaline) 222, 248, 287, 321 nm **Troy Chemical Company B.V.** 83.5 % pure

	pH < 2: 226 and 236 nm for low concentrations and 246, 261 and 316 nm for high concentrations. ε at 316 nm was 4590 $Lmol^{-1}cm^{-1}$. pH 7-8: 226 and 236 nm for low concentrations and 245, 262 and 316 nm for high concentrations. ε at 316 nm was 4610 $Lmol^{-1}cm^{-1}$. pH > 10: 222 and 248 nm for low concentrations and 287 and 321 nm for high concentrations. ε at 321 nm was 4100 $Lmol^{-1}cm^{-1}$.
Photostability (DT_{50}) and metabolites above 10% (point VII.7.6.2.2)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Half-life < 4 hours (aqueous, sunlight, pH not reported) (99%) **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH & Troy Chemical Company B.V.** Half-lives for aqueous photolysis: pH 5: 9 hours; pH 7 and 9: 0.7 hours (natural sunlight 30 - 50°N) (100.1%)
Quantum yield of direct phototransformation in water at > 290 nm (point VII.7.6.2.2)	Not determined
Oxidizing properties	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** No oxidizing properties were observed. (98%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** No oxidizing properties were observed. (89.8%) **Troy Chemical Company B.V.** The molecular structure of BIT indicates that the substance has no oxidising properties. Therefore, a study is not required
Reactivity towards containers material	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** No corrosion was observed for aluminium, carbon steel, stainless steel 304, stainless steel 316 or polypropylene. A purplish deposit was observed on the surface of the carbon steel samples and there was a small weight gain (mean value of 0.2% w/w). A slight surface deposit was also observed on one of the aluminium test samples, however no weight change was observed. A weight gain of 0.2% w/w was observed for one of the polypropylene samples. (76% and 80% of TGAI) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH**

	No degradation of container (HDPE) seen during two-week test at 54ºC. (89.8% of TGAI) **Troy Chemical Company B.V.** No signs of corrosion or discoloration were observed in a piece of polyethylene after being in contact with the test substance for approximately 14 days.
Flammability	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** No relative self-ignition temperature below its melting point. (83.5 and 89.8%) No self-ignition was observed up to the stop temperature of 400°C. (98%) **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** Not highly flammable. (83.5 and 89.8%)
Explosive properties	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Thermal Sensitivity: No Reaction; Mechanical Sensitivity (shock): No Reaction; Mechanical Sensitivity (friction): No Reaction; TGAI has no explosive properties. (98%) **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** No explosive properties were observed. (100.1%) **Troy Chemical Company B.V.** The molecular structure of BIT indicates that the substance has no explosive properties. Therefore, a study is not required.

Classification and proposed labelling

with regard to physical/chemical data	Not classified
with regard to toxicological data	Acute Toxicity 4, Acute Toxicity 2, Eye Damage 1, Skin sensitization 1B H302, H330, H318, H317
with regard to fate and behaviour data	Not classified
with regard to ecotoxicological data	Aquatic Acute 1, M-factor = 1 Aquatic Chronic 1, M-factor = 1 H400, H410

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC-UV
Impurities in technical active substance (principle of method)	Karl-Fischer (water) HPLC-UV (impurities)

Analytical methods for residues

Soil (principle of method and LOQ)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Justification for non-submission of analytical method for soil because the DT_{90} value of the active substance and relevant metabolites is 24 hours. **Troy Chemical Company B.V. Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** HPLC-MS/MS, LOQ = 0.05 mg/kg MS/MS transitions: precursor 152/152, product 105/109. **Troy Chemical Company B.V.** LC-MS/MS, LOQ = 0.05 mg/kg MS/MS transitions: precursor 152/152, product 105/109.
Air (principle of method and LOQ)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Justification for non-submission of analytical method for air because BIT has low vapour pressure. **Troy Chemical Company B.V. Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** HPLC-MS/MS, LOQ = 6.0 µg/m^3 MS/MS transitions: precursor 152/152, product 105/109. **Troy Chemical Company B.V.** HPLC-UV at λ = 274 nm, LOQ = 0.0168 mg/m^3
Water (principle of method and LOQ)	**Lonza Cologne GmbH, Thor GmbH and Laboratorios Miret S.A.** Drinking water: LC-MS/MS, LOQ = 0.1 µg/L MS/MS transitions: precursor 152/152, product 105/109.

	Troy Chemical Company B.V. Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH Drinking, surface and sea water: HPLC-MS/MS, LOQ = 0.05 µg/L MS/MS transitions: precursor 152/152, product 105/109.
Body fluids and tissues (principle of method and LOQ)	Required, BIT is classified as toxic or highly toxic according to acute mammalian toxicity studies.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	**Lonza Cologne GmbH, Thor GmbH, Laboratorios Miret S.A. and Troy Chemical Company B.V.** Justification for no submission because BIT is an in-can preservative and is not intended for spraying, aerosol use, etc. around food or feedstuffs. **Nutrition & Biosciences (Switzerland) GmbH** HPLC-MS/MS, LOQ = 0.01mg/L
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant, since BIT is not intended to come in any contact with food and feeding stuffs.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	100%, fast
Rate and extent of dermal absorption:	For BIT, 46% in 8 hours according to 2017 EFSA Guidance from an *in vitro* study with human skin. For the representative products and the dilutions, default values should be used according to the EFSA guidance. For the water based end-use products, 50 % was considered appropriate.
Distribution:	Adrenals, bone marrow, thyroids showed radioactivity after distribution, but without significant accumulation
Potential for accumulation:	Negligible
Rate and extent of excretion:	Mainly urinary (more than 80% in 24 hours)
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	Five independent studies of acute oral toxicity displayed a range of LD_{50} records between 454 and 1010 mg/kg bw. LD_{50} = 454 mg/kg bw = Acute Tox. 4 (H302).
Rats LD_{50} dermal	LD_{50} > 2000 mg/kg in five independent studies. Not classified.
Rat LC_{50} inhalation	Two independent studies of acute inhalation toxicity displayed a range of LC_{50} records between 0.21 and 0.57 mg BIT/L. LC_{50} = 0.25 mg BIT/L = Acute Tox. 2 (H330).
Skin irritation	Several independent studies have showed that BIT is not able to induce skin irritation. Not classified.
Eye irritation	Six independent studies have showed that BIT induces severe non-reversible ocular lesions. Eye Dam. 1 (H318).
Skin sensitization (test method used and result)	Several independent *in vivo* studies have showed that BIT induces skin sensitisation. Skin Sens. 1B (H317) (SCL ≥ 500 ppm). SCL for skin sensitisation agreed in the RAC will have to be taken into account at the product authorization stage.

Repeated dose toxicity

Species/ target / critical effect	Rat / 90 days / decreased body weight gain, decreased food consumption and differences in haematology and clinical chemistry Dog / 90 days / the gastrointestinal and hepatic effects

Oral NOAEL / LOAEL	NOAEL = 5 mg/kg bw/day (90 days oral study in dogs) LOAEL = 20 mg/kg bw/day (90 days oral study in dogs)
Dermal NOAEL / LOAEL	No available study.
Inhalation NOAEL / LOAEL	No available study.

Genotoxicity	4 mouse micronucleus test and 2 unscheduled DNA synthesis tests yielded negative results. Not classified.

Chronic Toxicity/Carcinogenicity

Species/ target / critical effect	No available study. Not classified.
Relevant NOAEL / NOEL	No available study.
Carcinogenicity	No available study.

Reproductive toxicity

Reproduction toxicity

Species/ Reproduction target / critical effect	2-generation study in rats/no reproductive effect reported at maternal toxic doses. Not classified.
Parental NOAEL / LOAEL	NOAEL = 10 mg/kg bw/day (↓ body weight, ↓ food consumption)
Reproductive NOAEL / LOAEL	NOAEL = 50 mg/kg bw/day (without critical effects)
Offspring NOAEL / LOAEL	NOAEL = 25 mg/kg bw/day (without critical effects)

Developmental toxicity

Developmental target / critical effect	Decrease in foetal body weight. Not classified.
Relevant maternal NOAEL	NOAEL = 6 mg/kg bw/day (↓ body weight gain, ↓food consumption)
Relevant developmental NOAEL	NOAEL = 25 mg/kg bw/day (without critical effects)

Neurotoxicity

Acute neurotoxicity	No available study but no signs of neurotoxicity on acute toxicity studies
Repeated neurotoxicity	No available study but no signs of neurotoxicity on subchronic toxicity studies
Delayed neurotoxicity	No available study.

Other toxicological studies

....	No available studies.

Medical data

....	No serious health problems in workers of the BIT manufacturing plants. Case reports of mild skin sensitizer.

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	0.025 mg/kg bw/day	90 days oral study in dog	200
AEL (Exposure Level, short term)	0.06 mg/kg	Rabbit developmental study	100
AEL (Exposure Level, medium term)	0.05 mg/kg bw/day	90 days oral study in dog	100
AEL (Exposure Level, long term)	0.025 mg/kg bw/day	90 days oral study in dog	200
Drinking water limit	0.025 mg/l	90 days oral study in dog	200
ARfD (acute reference dose)	0.06 mg/day	Rabbit developmental study	100

Acceptable exposure scenarios (including method of calculation)

Industrial users

PT 06

Automated loading of a liquid biocidal product into a final product to be preserved

RISKOFDERM Toolkit and follows Biocides Human Exposure Expert Group recommendations (HEEG Opinion1) for assessing exposure from automated transfer pumping

Filling of preserved product

RISKOFDERM Dermal Model Loading liquid, automated or semi-automated

NO RISK taking into account:

- gloves, coated coverall and goggles/face mask.
- RMMs for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use).

	PT 13 *Metalworking fluid dilution (automatic)* RISKOFDERM Toolkit - Loading liquid according to the recommendation no. 7. *Metalworking fluid dilution (manual)* Mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. *Metalworking on turning machine* Scenario included in the recommendation no. 7. *Handling of work pieces, tools outside the turning machine* Scenario included in the recommendation no. 7. *Machine/sump maintenance* Scenario included in the recommendation no. 7. NO RISK taking into account: • Protective gloves (new gloves for each work shift), impermeable coverall and/or goggles/face mask. • RMMs for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use).
Professional users	**PT 06** *Liquid detergents: hand laundry.* Loading a washing machine or a washing bowl from model included in ConsExpo Web. Hand washing laundry from model included in ConsExpo Web. Use of detergents for pre-treatment of clothes from model included in ConsExpo Web. *Liquid detergents: hand dishwashing.* Loading a washing machine or a washing bowl from model included in ConsExpo Web. Manual dishwashing from model included in ConsExpo Web. *Water based paint: spraying.* Mixing/Loading Model No.6 (loading antifouling paints for airless sprayer) Spraying model 3 (airless sprayer) from the TNsG 2007 Cleaning of spray equipment model from the data base BEAT *Water based paint: brushing* Mixing/Loading Model No.6 (loading antifouling paints for airless sprayer)

	Brushing from the scenario included in the recommendation no. 7. Cleaning of brush from the HEEG opinion 11. NO RISK taking into account: • Protective gloves (new gloves for each work shift), impermeable coverall and/or goggles/face mask. • RMMs for medium hazard class chemicals (labelling, instructions for use, child proof closure, packaging minimising risks for use).
Non-professional users	**<u>PT 06</u>** *Liquid detergents: hand laundry.* Loading a washing machine or a washing bowl from model included in ConsExpo Web. Hand washing laundry from model included in ConsExpo Web. Use of detergents for spot treatment of clothes from model included in ConsExpo Web. *Liquid detergents: hand dishwashing.* Loading a washing machine or a washing bowl from model included in ConsExpo Web. Manual dishwashing from model included in ConsExpo Web. *Water based paint: spraying.* Mixing/Loading Model No.6 (loading antifouling paints for airless sprayer) Spraying model 3 (airless sprayer) from the TNsG 2007 Cleaning of spray equipment model from the data base BEAT *Water based paint: brushing* Mixing/Loading Model No.6 (loading antifouling paints for airless sprayer) Brushing from the scenario included in the recommendation no. 7. Cleaning of brush from the HEEG opinion 11. NO RISK taking into account: • Only acceptable if the BIT concentration is below the concentration triggering classification as skin sensitizer.
Indirect exposure as a result of use	**<u>PT 06</u>** *Preserved Detergents and Cleaning Fluids* Dermal exposure towards residues of BIT on textiles.

	Dermal and oral exposure towards residues on cleaned surfaces. *Preserved Paints* Dermal exposure from contact with BIT in dried/wet paint and oral exposure from hand to mouth transfer using recommendation no. 5.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	**Lonza Cologne GmbH and Thor GmbH** pH 4: 219 days at 50.8ºC* pH 7: Not determined, stable at 50ºC pH 9: 145 days at 50.8ºC* **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutchsland GmbH** pH 4: Not determined; stable at 50°C pH 7: Not determined; stable at 50°C pH 9: Not determined; stable at 50°C **Troy Chemical Company B.V.** pH 4: > 1 year at 25ºC pH 7: > 1 year at 25ºC pH 9: > 1 year at 25ºC *Extrapolated far beyond study duration of 5 days
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites in water	**Lonza Cologne GmbH and Thor GmbH** Rapid photodegradation of BIT was observed. Due to this rapid rate of photodegradation an accurate photolytic half-life could not be calculated for BIT. Relevant metabolites: Saccharin 18.5% (pH = 8-9) 2-sulphobenzamide 29.6% (pH = 8-9) Sulphobenzoic acid 61.8% (pH = 7) Benzamide 34.2% (pH = 7) **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** DT_{50} at pH 5: 9 hours DT_{50} at pH 7: 0.7 hours DT_{50} at pH 9: 0.7 hours The photodegradation of BIT was rapid and involves cleavage of the isothiazolone ring and several photoproducts were obtained according to different photolytic pathways. 1,2-benzthiazolin-2-one 49.8% (pH = 5) Saccharin 13.2% (pH = 8 – 9)

	2-sulphobenzamide+Sulphobenzoic acid 56.4% (pH= 7) **Key endpoint (lowest and reliable)**: 2 hours **Troy Chemical Company B.V.** DT_{50}<< 1 hour of artificial irradiation and << 2 hours of natural sunlight **Key endpoint (lowest and reliable)**: 2 hours
Readily biodegradable (yes/no)	Not ready biodegradable
Inherent biodegradable (yes/no)	Not inherently biodegradable: **Lonza Cologne GmbH and Thor GmbH** Degree of degradation 40- 52 % in 91 days
Biodegradation in seawater	**Lonza Cologne GmbH and Thor GmbH** BIT was not mineralized in seawater at concentrations of 0.1 and 1.0 mg/L BIT. **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** Not available
Aerobic aquatic degradation in surface water	**Nutrition & Biosciences (Switzerland) GmbH** DT_{50} = 0.95 – 1.24 days (12ºC, estuarine water) DT_{50} = 5.3 – 12 days (12ºC, sea water) **Key endpoint: 1.24 d**
Biological sewage treatment	**Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH** DT_{50} = 2.2 h (STP system, test temperature) or 3.6 h at 15ºC (derived using eq.28 of the BPR) and 3.8h at 15ºC using equations specified in TAB ENV 182
Non-extractable residues	Not required
Distribution in water / sediment systems (active substance)	Not required
Distribution in water / sediment systems (metabolites)	**<u>2-methylthiobenzamide</u>:** 61.47% Ready biodegradation 54% Surface water biodegradation 11.57-39% Simulation in STP. **<u>2-methylsulfinylbenzamide:</u>** 45.53% Simulation in STP 16.34% Ready biodegradation

	24.9% Surface water biodegradation, **<u>2-sulphobenzamide:</u>** 30% Surface water biodegradation **<u>2-mercaptobenzoic acid</u> or 2-sulfanylbenzoic acid:** 15% Simulation in STP **<u>2-methylthiobenzoic acid methyl ester:</u>** 12.8% Surface water biodegradation

Route and rate of degradation in soil

Mineralization (aerobic)	**Nutrition & Biosciences (Switzerland) GmbH** DT_{50} 9.3 h (12ºC) (Sandy loam soil) (metabolites not completely identified) **New study (all applicants):** **Key endpoint: DT_{50} BIT = 0.54 day (12 ºC)** **DT50 Met6 = 62.14 days (12 ºC)** **DT50 M2 = 1.4 days (12ºC)** **DT50 saccharin (M5) = 13.84 days (12ºC)** **DT50 M19 = 10.86 days (12 ºC)**
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT50 values in between 0.01 and 0.27 days (20 ºC) depending on the soil type. Mineralization was 40 and 56% depending on the soil type.
Field studies (state location, range or median with number of measurements)	Not relevant
Anaerobic degradation	Not relevant
Soil photolysis	Not relevant
Non-extractable residues	48.6, 39.9, 43.2 and 41.9% AR respectively for 4 soils tested at the end of incubation period.
Relevant metabolites - name and/or code,% of applied a.i. (range and maximum)	**Nutrition & Biosciences (Switzerland) GmbH** *N*-(4-amino-4hydroxy-buta-1,3-dietyl)benzamide 20.7% Soil aerobic biodegradation **New study (all applicants):** 1,2-Benzisothiazolin-3-one-1-oxide (M2) 23.1% AR Soil aerobic biodegradation Saccharin (M5) 7.8% AR Soil aerobic degradation (M6)* one possible structure: 2-sulphamoylbenzoic acid

	40.55 % AR (including M6b) Soil aerobic biodegradation 2-sulphanylbenzamide (M8) 10.52% AR Soil aerobic biodegradation (M9)* 14.1% AR Soil biodegradation * chemical structure not confirmed Formation fractions: M2 = 0.31 from parent M6 (including M6b) = 0.88 from parent and Met2 Saccharin (M5) = 0.366 from Met2 M19 = 0.046 from parent
Soil accumulation and plateau concentration	BIT is not expected to accumulate in soil

Adsorption/desorption

K_a, K_d Ka_{oc}, Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	**Lonza Cologne GmbH and Thor GmbH** Loamy Sand: Average Ka_{oc} = 447 Loam: Average Ka_{oc} = 235 Silty Clay Loam: Average Ka_{oc} = 566 Silty Loam: Average Ka_{oc} = 348 No pH dependence observed **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Loamy Sand: Average Ka_{oc} = 117 Loam/Silt Loam: Average Ka_{oc} = 79 Silt Loam: Average Ka_{oc} = 200 Clay Loam: Average Ka_{oc} = 59 Loamy Sand Sediment Ka_{oc} = 64 No pH dependence observed **Troy Chemical Company B.V.** Ka_{oc} was 128.8 (neutral pH)
	Mean Koc = 196.87 L/kg (no pH dependence was observed)

Fate and behaviour in air

Direct photolysis in air	Not applicable

Quantum yield of direct photolysis	Not applicable
Photo-oxidative degradation in air	**Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** SaR Method: DT_{50} (OH) = 10.3 h and DT_{50} (NO3) = 15.7 h; Latitude: 40°N ; Season: Summer **Lonza Cologne GmbH, Thor GmbH, and Troy Chemical Company B.V.** AOPwin DT_{50}: 0.946 days (24-hour days)
Volatilization	Not required – based upon physical-chemical properties, volatilisation is not expected

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout, *Oncorhynchus mykiss*	96 h	Lethality (LC_{50})	**Lonza Cologne GmbH and Thor GmbH** 1.23 mg BIT L^{-1} **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 1.9 mg BIT L^{-1} **Troy Chemical Company B.V.** 0.74 mg BIT L^{-1}
Zebra danio (*Brachydanio rerio)*	96 h	Lethality (LC_{50})	**Troy Chemical Company B.V.** 4.9 mg BIT L^{-1}
Rainbow trout, *Oncorhynchus mykiss*	28 days	Growth (NOEC)	**Lonza Cologne GmbH and Thor GmbH** 0.21 mg BIT L^{-1}
Fathead minnow *(Pimephales promelas)*	33 d	Hatch, survival, growth; NOEC	**Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** 0.28 mg BIT L^{-1}
Marine			
Sheepshead minnow *(Cyprinodon variegatus)*	96 h	Lethality (LC_{50})	**Lonza Cologne GmbH and Thor GmbH** 9.47 mg BIT L^{-1} **Nutrition & Biosciences (Switzerland) GmbH** 19 mg BIT L^{-1}
Key endpoint: 28 d-NOEC = 0.21 mg BIT L^{-1}			
Invertebrates			
Freshwater			

Water flea (*Daphnia magna*)	48 h	Immobility (EC_{50}) (measured concentrations)	**Lonza Cologne GmbH and Thor GmbH** 2.94 mg BIT L^{-1} **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 3.7 mg BIT L^{-1} **Troy Chemical Company B.V.** 2.244 mg BIT L^{-1}
Water flea (*Daphnia magna*)	21 days	Growth/reproduction (NOEC)	**Lonza Cologne GmbH and Thor GmbH** 1.2 mg BIT L^{-1} **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** 0.91 mg BIT L^{-1}
Marine			
Mysid shrimp *(Americamysis bahia)*	96 h	Immobility (EC_{50})	**Lonza Cologne GmbH and Thor GmbH** 0.99 mg BIT L^{-1}
Mysid shrimp *(Americamysis bahia)*	96 h	Immobility (EC_{50})	**Nutrition & Biosciences (Switzerland) GmbH** 1.9 mg BIT L^{-1}
Key endpoint: 21d-NOEC = 0.91 mg L^{-1}			
Algae			
Freshwater			
P. subcapitata	72 h	Growth inhibition (24h-E_rC_{50})	**Lonza Cologne GmbH and Thor GmbH** 0.08 mg BIT L^{-1} **Troy Chemical Company B.V.** 0.011 mg BIT L^{-1}
	96 h		**Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 0.33 mg BIT L^{-1}

P. subcapitata	72 h	Growth inhibition (E_rC_{10})	**Lonza Cologne GmbH and Thor GmbH** 0.035 mg BIT L^{-1} **Troy Chemical Company B.V.** 0.16 mg BIT L^{-1} 0.0029 mg BIT L^{-1}
	96 h		**Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 0.032 mg BIT L^{-1}
Marine			
Phaeodactylum tricornutum	72 h	Growth inhibition (48h-E_rC_{50})	**Lonza Cologne GmbH and Thor GmbH** 0.165 mg BIT L^{-1}
Phaeodactylum tricornutum	72 h	Growth inhibition (48h-E_rC_{10})	**Lonza Cologne GmbH and Thor GmbH** 0.063 mg BIT L^{-1}
Key endpoint: 24 h-E_rC_{10} (geometric mean *P. subcapitata*) = 0.026mg L^{-1}			
Microorganisms			
Activated sludge	3 hours	Effect on respiration rate (EC_{50}/estimated EC_{10})	**Lonza Cologne GmbH and Thor GmbH** EC_{50} = 13 mg BIT L^{-1} Estimated EC_{10} = 1.7 mg BIT L^{-1} **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** EC_{50} = 28.5 mg BIT L^{-1} Estimated EC_{10} = 4.12 mg BIT L^{-1} **Troy Chemical Company B.V.** EC_{50} = 3.95 mg BIT L^{-1} Estimated EC_{10} = 0.55 mg BIT L^{-1}
Key endpoint: 3 h- EC_{10} = 0.55 mg BIT L^{-1}			
Sediment Dwelling Organisms			

Chironomus tentans	10 days	Mortality NOEC, EC_{50}	**Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** NOEC = 32.8 mg BIT/kg sediment EC_{50} > 45.9 mg BIT/kg sediment
Chironomus riparius	28 days	Mortality NOEC, EC_{50}	**Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** NOEC = 11.7 mg BIT/kg sediment *EC_{50} = 32.79 mg BIT/kg sediment*
Key endpoint: 28 d - NOEC = 11.7 mg BIT/kg sediment			

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia fetida*	**Lonza Cologne GmbH and Thor GmbH** 14 d-LC_{50} (*Eisenia fetida*): > 410.6 mg BIT/kg dry substrate **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V** 14 d-LC_{50} (*E. fetida*) = 114 mg BIT/kg soil dw **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 56 d-NOEC (*E. fetida*) = 20 mg BIT/kg soil dw
	Key endpoint: NOEC (56 d) = 20 mg a.s./kg soil dw

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	**Lonza Cologne GmbH and Thor GmbH** 28-day EC_{50}: > 811.5 mg BIT/kg dw soil **Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** 28-day NOEC (EC_{10}) = 833 mg a.s./kg dw soil 28-day EC_{50} > 1000 mg BIT/kg dw soil
Carbon mineralization	**Lonza Cologne GmbH and Thor GmbH** Not required **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** 28-day NOEC = 100 mg BIT/kg dw soil 28-day EC_{50} > 1000 mg BIT/kg dw soil
	Key endpoint: NOEC = 100 mg a.s./kg soil dw (based on CO_2 production rates)

Effects on terrestrial vertebrates

Acute toxicity to birds	**Lonza Cologne GmbH, Thor GmbH, Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Not required **Troy Chemical Company B.V.** LC_{50} = 790 mg BIT/kg bw

Dietary toxicity to birds	**Lonza Cologne GmbH, Thor GmbH, Nutrition & Biosciences (Switzerland) GmbH and LANXESS Deutschland GmbH** Not required **Troy Chemical Company B.V.** LC_{50} > 5000 mg BIT/kg feed (940 mg BIT/kg bw) NOEC = 156 mg BIT/kg feed (30 mg BIT/ kg bw)
Reproductive toxicity to birds	Not required

Effects on honeybees

Acute oral toxicity	Not evaluated
Acute contact toxicity	Not evaluated

Effects on other beneficial arthropods

Acute oral toxicity	Not required
Acute contact toxicity	Not required
Acute toxicity to	Not required

Bioconcentration

Bioconcentration factor (BCF)	**Lonza Cologne GmbH and Thor GmbH** Mean Steady State BCF (*L. macrochirus*) = 6.95 L/Kg$_{ww}$ (Rel. 3) **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** Not required QSAR-based BCF (fish): 0.78-3.162 L/Kg$_{ww}$ QSAR-based BCF (earthworm): 0.85 L/Kg$_{ww}$
Depuration time(DT_{50}) (DT_{90})	Not monitored
Level of metabolites (%) in organisms accounting for > 10% of residues	Not monitored

Chapter 6: Other End Points

Effects on terrestrial plants

Seedling emergence	**Lonza Cologne GmbH and Thor GmbH** EC_{50} (cabbage, 20 days): 166 mg BIT/kg dry soil **Nutrition & Biosciences (Switzerland) GmbH, LANXESS Deutschland GmbH and Troy Chemical Company B.V.** EC_{50} (lettuce, 21days): 18.4 mg BIT/kg dry soil
Reproductive toxicity to plants	Not required

APPENDIX II: LIST OF INTENDED USES

LANXESS Deutschland GmbH / Summary of intended uses:

Object and/or situation	Member State or Country	Product name	Organisms controlled (a)	Formulation		Application			Applied amount per treatment			Remarks: (e)
				Type (b)	Conc. of a.s.	method kind (c)	number min max (d)	interval between applications	Concen-tration min max	water L/m² min max	g as/m² min max	
PT 6: Pre-servation of aqueous systems (e.g., paints, detergents)	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	1	n.a.	100 - 500 ppm BIT in the preserved aqueous system	n.a.	n.a.	Industrial and professional use only. [redacted] is mixed into aqueous system during production, during storage or before canning.
PT13: Pre-servation of metalworking fluid concentrates	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	1	n.a.	1500 - 9000 ppm BIT in concentrate 100 - 360 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is formulated into metalworking fluid concentrates such that the use dilutions contain the desired use levels for microbial control.
PT13: Pre-servation of metalworking fluids, tank side addition	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	regular	weeks to months	100 - 360 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is dispensed as a tank side additive into the circulating use-dilution of the fluids using a metering pump or by manual pouring, at a suitable point to ensure rapid mixing and uniform dispersion throughout the system.

Lonza Cologne GmbH; Thor GmbH; Laboratorios Miret S.A. / Summary of intended uses:

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
			(a)	Type (b)	Conc. of a.s.	method kind (c)	number min max (d)	interval between applications	Concentration min max	water L/m^2 min max	g as/m^2 min max	(e)
PT06	EU	[redacted]	Fungi, molds	SL-Water soluble concentrate - formulation containing 80% water miscible solvent.	20%	Pouring / linking automatic transfer couplings	1 - 1	n.a	250-500 ppm	n.a.	n.a.	Primary exposure occurs during incorporation of the Biocidal Product into the End Use Product
PT13: Pre-servation of metal-working fluid concentrates	EU	[redacted]	Bacteria, fungi and yeast	SL	20 wt%	Mixing	1	n.a.	Max. 6000 ppm BIT in concentrate 100 - 300 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is formulated into metalworking fluid concentrates such that the use dilutions contain the desired use levels for microbial control.
PT13: Pre-servation of metal-working fluids, tank side addition	EU	[redacted]	Bacteria, fungi and yeast	SL	20 wt%	Mixing	regular	weeks to months	100 - 300 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is dispensed as a tank side additive into the circulating use-dilution of the fluids using a metering pump or by manual pouring, at a suitable point to ensure rapid mixing and uniform dispersion throughout the system.

Nutrition & Biosciences (Switzerland) GmbH / Summary of intended uses:

Object and/or situation	Member State or Country	Product name	Organisms controlled (a)	Formulation		Application			Applied amount per treatment			Remarks: (e)
				Type (b)	Conc. of a.s.	method kind (c)	number min max (d)	interval between applications (min)	Concen-tration min max	water L/m^2 min max	g as/m^2 min max	
PT 6: Pre-servation of aqueous systems (e.g., paints, detergents)	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	1	n.a.	100 - 500 ppm BIT in the preserved aqueous system	n.a.	n.a.	Industrial and professional use only. [redacted] is mixed into aqueous system during production, during storage or before canning.
PT13: Pre-servation of metal-working fluid concentrates	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	1	n.a.	1500 - 9000 ppm BIT in concentrate 100 - 360 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is formulated into metalworking fluid concentrates such that the use dilutions contain the desired use levels for microbial control.
PT13: Pre-servation of metal-working fluids, tank side addition	EU	[redacted]	Bacteria, fungi, yeasts	SL	20 wt%	Mixing	regular	weeks to months	100 - 360 ppm BIT in the metal-working fluid as used	n.a.	n.a.	Industrial and professional use only. [redacted] is dispensed as a tank side additive into the circulating use-dilution of the fluids using a metering pump or by manual pouring, at a suitable point to ensure rapid mixing and uniform dispersion throughout the system.

Troy Chemical Company BV; Dow Benelux BV / Summary of intended uses:

Object and/or situation	Member State or Country	Product name	Organisms controlled (a)	Formulation		Application			Applied amount per treatment			Remarks (e)
				Type (b)	Conc. of as	method kind (c)	number min/max (d)	interval between applications (min)	Concentration min max	water L/m^2 min max	g as/m^2 min max	
PT6 In-Can Preservative	Northern and Southern EU	[redacted]	Bacteria, fungi, yeasts	SL	20% w/w	Mixing	n.a.	n.a.	100-500 ppm	n.a.	n.a.	Industrial and professional use only. [redacted] is mixed to the end use product..
PT13: Pre-servation of metal-working fluid concentrates	Northern and Southern EU	[redacted]	Bacteria, fungi, yeasts	SL	20% w/w	Mixing	1	n.a.	2000-4000 ppm BIT in concentrate 100-200 ppm BIT in the metal-working fluid as used.	n.a.	n.a.	Industrial and professional use only. [redacted] is formulated into metalworking fluid such that the use dilutions contain the desired use levels for microbial control.
PT13: Pre-servation of metal-working fluids, tankside addition	Northern and Southern EU	[redacted]	Bacteria, fungi, yeasts	SL	20% w/w	Mixing	regular	Weeks to months	100-200 ppm BIT in the metal-working fluid as used.	n.a.	n.a.	Industrial and professional use only. [redacted] is dispensed as a tankside additive into the circulating use-dilution of the fluids using a metering pump or by manual pouring, at a suitable point to ensure rapid mixing and uniform dispersion system.

(a) *e.g.* biting and suckling insects, fungi, molds
(b) *e.g.* soluble (liquid) concentrate (SL), emulsifiable concentrate (EC), granule (GR) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4)
(c) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(d) Indicate the minimum and maximum number of application possible under practical conditions of use(
(e) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX III: LIST OF STANDARD TERMS AND ABBREVIATIONS

Stand. term / Abbreviation	**Explanation**
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AEL	acceptable exposure level
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor

Stand. term / Abbreviation	**Explanation**
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
b.p.	biocidal product
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval

Stand. term / Abbreviation	**Explanation**
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
Doc.	document
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake

Stand. term / Abbreviation	**Explanation**
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography

Stand. term / Abbreviation	**Explanation**
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested

Stand. term / Abbreviation	**Explanation**
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management

Stand. term / Abbreviation	**Explanation**
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry

Stand. term / Abbreviation	**Explanation**
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration

Stand. term / Abbreviation	**Explanation**
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level

Stand. term / Abbreviation	**Explanation**
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer

Stand. term / Abbreviation	**Explanation**
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit

Stand. term / Abbreviation	**Explanation**
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous

Stand. term / Abbreviation	**Explanation**
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals

Stand. term / Abbreviation	**Explanation**
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method

Stand. term / Abbreviation	**Explanation**
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

APPENDIX IV: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	**Explanation**
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd

Abbreviation	**Explanation**
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre

Abbreviation	**Explanation**
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System

Abbreviation	**Explanation**
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)

Abbreviation	**Explanation**
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network

Abbreviation	**Explanation**
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund