Committee for Risk Assessment

RAC

Annex 1

Background document

to the Opinion proposing harmonised classification and labelling at EU level of

1*H*-benzotriazole

EC Number: 202-394-1
CAS Number: 95-14-7

CLN-O-0000007150-86-01/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

15 September 2022

CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

International Chemical Identification:
1H-Benzotriazole

EC Number: **202-394-1**

CAS Number: **95-14-7**

Index Number: **-**

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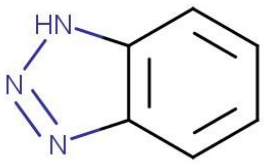
Version number: 2 **Date: August 2021**

CONTENTS

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	1H-benzotriazole
Other names (usual name, trade name, abbreviation)	Benzotriazole BTA
ISO common name (if available and appropriate)	-
EC number (if available and appropriate)	202-394-1
EC name (if available and appropriate)	1H-benzotriazole
CAS number (if available)	95-14-7
Other identity code (if available)	-
Molecular formula	C6H5N3
Structural formula	
SMILES notation (if available)	N1N=NC2=C1C=CC=C2
Molecular weight or molecular weight range	119.13 g/mol

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
1H-benzotriazole	> 99	-	

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling
-				

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
-					

Table 5: Test substances (non-confidential information) (this table is optional)

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)	Other information	The study(ies) in which the test substance is used
-				

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6: Proposed harmonised classification and labelling according to the CLP criteria

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	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	no entry										
Dossier submitters proposal	tba	1H-benzotriazole	202-394-1	95-14-7	Aquatic Chronic 2	H411	GHS09 Wng	H411			
Resulting Annex VI entry if agreed by RAC and COM					Aquatic Chronic 2	H411	GHS09 Wng	H411			

Table 7: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	hazard class not assessed in this dossier	No
Flammable gases (including chemically unstable gases)		
Oxidising gases		
Gases under pressure		
Flammable liquids		
Flammable solids		
Self-reactive substances		
Pyrophoric liquids		
Pyrophoric solids		
Self-heating substances		
Substances which in contact with water emit flammable gases		
Oxidising liquids		
Oxidising solids		
Organic peroxides		
Corrosive to metals		
Acute toxicity via oral route		
Acute toxicity via dermal route		
Acute toxicity via inhalation route		
Skin corrosion/irritation		
Serious eye damage/eye irritation		
Respiratory sensitisation		
Skin sensitisation		
Germ cell mutagenicity		
Carcinogenicity		
Reproductive toxicity		
Specific target organ toxicity-single exposure		
Specific target organ toxicity-repeated exposure		
Aspiration hazard		
Hazardous to the aquatic environment	**harmonised classification proposed**	**Yes**
Hazardous to the ozone layer	hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

1H-benzotriazole is not listed in Annex VI of Regulation (EC) No. 1272/2008.There are 40 aggregated notifications on 1H-benzotriazole. All of them are shown in Table 8.

Table 8: Overview of self-classification and labelling based on the CLP Regulation criteria (retrieved from https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/36314 on the 22.07.2021**)**

Classification		Labelling			Number of Notifiers
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**	
Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 2	H302 H319 H411	H302 H319 H411		GHS07 GHS09 Wng	210 (Joint entry)
Skin Irrit. 2 Eye Irrit. 2A	H315 H319	H315 H319		GHS07 Wng	2 (Joint entry)
Acute Tox. 4 Eye Irrit. 2	H302 H319	H302 H319		GHS07 Wng	447
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	H302 H319 H332 H412		GHS07 Wng	374
Acute Tox. 4	H302	H302		GHS07 Wng	148
Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H312 H319 H332 H412	H302 H312 H319 H332 H412		GHS07 Wng	89
Flam. Sol. 1 Acute Tox. 4 Eye Dam. 1 Acute Tox. 4 Aquatic Chronic 3	H228 H302 H318 H332 H412	H228 H302 H318 H332 H412		GHS02 GHS05 GHS07 Dgr	83
Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 3	H302 H319 H412	H302 H319 H412		GHS07 Wng	63
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4	H302 H319 H332	H302 H319 H332		GHS07 Wng	62
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 2 STOT SE 3 Muta. 2	H302 H319 H330 H336 (Central nervous) H341	H302 H319 H330 H336 H341		GHS06 GHS08 Dgr	55
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	H302+H332 H319 H412		GHS07 Wng	38
Not classified					33
Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 3	H302 H312 H319 H412	H302 H312 H319 H412		GHS07 Wng	26

Classification		Labelling			Number of Notifiers
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**	
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 2 Aquatic Chronic 3	H302 H319 H330 H412	H302 H319 H330 H412		GHS06 Dgr	22
Acute Tox. 4 Acute Tox. 4 Aquatic Chronic 3	H302 H332 H412	H302 H332 H412		GHS07 Wng	22
Acute Tox. 3 Eye Irrit. 2 Acute Tox. 4	H301 H319 H332	H301 H319 H332		GHS06 Dgr	20
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 2	H302 H319 H332 H411	H302+H332 H319 H411		GHS09 GHS07 Wng	17
		H302		GHS07 Wng	7
Acute Tox. 4 Eye Dam. 1 Acute Tox. 4	H302 H318 H332	H302 H318 H332		GHS07 GHS05 Dgr	6
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 STOT SE 3 Aquatic Chronic 3	H302 H319 H332 H335 (Respiratory sys) H412	 H319 H335 H412		GHS07 Wng	6
		H302 H319 H332 H412		GHS07 Wng	5
Acute Tox. 4 Eye Dam. 1 Acute Tox. 4 Aquatic Chronic 3	H302 H318 H332 H412	H302 H318 H332 H412		GHS05 GHS07 Dgr	3
Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H315 H319 H332 H412	H302 H315 H319 H332 H412		GHS07 Wng	1
Acute Tox. 4 Acute Tox. 4 Aquatic Chronic 4	H302 H312 H413	H302 H12 H413		GHS07 Wng	1
Flam. Sol. 1 Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H228 H302 H319 H332 H412	H228 H302 H319 H332 H412		GHS02 GHS07 Dgr	1
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	H302 H319 H332 H412		GHS07 Wng	1
Flam. Sol. 1 Acute Tox. 4	H228 H302	H228 H302		Dgr	1

Classification		Labelling			Number of Notifiers
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**	
Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H319 H332 H412	H319 H332 H412			
		H412		GHS06 Dgr	1
Acute Tox. 4 Acute Tox. 4	H302 H332			GHS07 Wng	1
Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 3	H302 H312 H319 H412	H302 H319 H412 H332		GHS07 Wng	1
Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 2	H302 H319 H411	H302 H411		GHS07 GHS09 Wng	1
Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H312 H319 H332 H412	H302 H319 H332 H412		GHS07 Wng	1
		H302		Wng	1
		H302 H315 H319 H335		GHS07 Wng	
Acute Tox. 4 Acute Tox. 3	H302 H331	H302 H331		GHS07 GHS06 Dgr	1
Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2	H302 H315 H319	H302 H315 H319 H335		GHS07 Wng	1
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 2	H302 H319 H332 H411	H302 H319 H332		GHS07 Wng	1
Acute Tox. 4 Eye Irrit. 2A Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	H302 H319 H332 H412		GHS07 Wng	1
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	 H318		GHS05 Dgr	1
Flam. Sol. 1 Acute Tox. 4 Acute Tox. 4 Aquatic Chronic 3	H228 H302 H332 H412	H228 H302 H332 H412		GHS02 GHS07 Dgr	1

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

According to Article 36(3) of Regulation (EC) No. 1272/2008 a harmonized classification and labelling of a substance is possible even if it does not fall under the provisions of paragraph 1 and 2 of Article 36. Such additions to Annex VI are possible on a case-by-case if justification is provided that there is the need for such action at community level. According to the "Guidance on the preparation of CLH dossiers" such justification is inter alia given if

- "differences in self-classification between different notifiers in the C&L Inventory and/or between different registration dossiers are discovered, and notifiers are not able to agree;"
- "the dossier submitter disagrees with the current self-classification by the notifiers and/or registrants".

Table 8 clearly shows that the first mentioned justification is given for 1H-benzotriazole. Furthermore, there are self-classifications and labellings in Table 8 that have no or a lower classification and labelling with regard to aquatic toxicity. The dossier submitters do not agree with these entries.

5 IDENTIFIED USES

According to the registration dossier 1H-benzotriazole is used in all applications listed in Table 9.

Table 9: Identified uses of 1H-benzotriazole

Life cycle step	description of the use	chemical product category or Article category	Environmental release category
Formulation			
a)	Manufacturing of cleaning and maintenance products		ERC 2: Formulation of preparations
b)	Industrial Formulation of lubricant additives, lubricants and greases	PC 24: Lubricants, greases, release products	ERC 2: Formulation of preparations
c)	Formulation of coolant mixtures	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 2: Formulation of preparations
d)	Formulation/blending	PC 0: Other: n/a	ERC 2: Formulation of preparations
e)	Manufacturing of cleaning and maintenance products	PC 35: Washing and cleaning products (including solvent based products)	ERC 2: Formulation of preparations
Uses at industrial sites			
a)	Industrial use of Food beverage and pharmacos products	PC 35: Washing and cleaning products (including solvent based products)	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
b)	(Industrial) Use of lubricants and greases in open systems.	PC 24: Lubricants, greases, release products	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
c)	(Industrial) Use of lubricants in high energy open processes	PC 24: Lubricants, greases, release products	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
d)	(Industrial) Handling and dilution of metalworking fluid concentrates	PC 24: Lubricants, greases, release products	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles

Life cycle step	description of the use	chemical product category or Article category	Environmental release category
e)	General industrial use of lubricants and greases in vehicles or machinery	PC 24: Lubricants, greases, release products	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
f)	Use as metalworking fluid	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
g)	(Industrial) Use of lubricants in open high temperature processes		ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
h)	Adjuvant in water based formulations	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	ERC 7: Industrial use of substances in closed systems
i)	Water treatment Chemical	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 37: Water treatment chemicals	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 7: Industrial use of substances in closed systems
Uses by Professional Workers			
a)	(Professional) Use of lubricants and greases in open systems.	PC 24: Lubricants, greases, release products	ERC 8a: Wide dispersive indoor use of processing aids in open systems
b)	Use as heat transfer fluids	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 9b: Wide dispersive outdoor use of substances in closed systems ERC 9a: Wide dispersive indoor use of substances in closed systems
c)	Use as metalworking fluid	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 8a: Wide dispersive indoor use of processing aids in open systems
d)	(Professional) Use of lubricants in high energy open processes	PC 24: Lubricants, greases, release products	ERC 8a: Wide dispersive indoor use of processing aids in open systems
e)	Professional Use of Dishwash products	PC 35: Washing and cleaning products (including solvent based products)	ERC 8a: Wide dispersive indoor use of processing aids in open systems
f)	Professional Use of Medical Devices	PC 35: Washing and cleaning products (including solvent based products)	ERC 8a: Wide dispersive indoor use of processing aids in open systems
g)	Professional Use of General surface cleaning products	PC 35: Washing and cleaning products (including solvent based products)	ERC 8a: Wide dispersive indoor use of processing aids in open systems
h)	General professional use of lubricants and greases in vehicles or machinery.	PC 24: Lubricants, greases, release products	ERC 9a: Wide dispersive indoor use of substances in closed systems
i)	(Re)packing of mixture	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 9b: Wide dispersive outdoor use of substances in closed systems ERC 9a: Wide dispersive indoor use of substances in closed systems

Life cycle step	description of the use	chemical product category or Article category	Environmental release category
j)	Use as anti-icing of roads & parking lots	PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 8d: Wide dispersive outdoor use of processing aids in open systems
Consumer uses			
a)	Use of Dishwash products	PC 35: Washing and cleaning products (including solvent based products)	ERC 8a: Wide dispersive indoor use of processing aids in open systems
b)	use in functional fluids	PC 9a: Coatings and paints, thinners, paint removes PC 24: Lubricants, greases, release products PC 16: Heat transfer fluids PC 4: Anti-freeze and de-icing products	ERC 9b: Wide dispersive outdoor use of substances in closed systems ERC 9a: Wide dispersive indoor use of substances in closed systems
c)	(Consumer) Use of lubricants and greases in open systems.	PC 24: Lubricants, greases, release products	ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8a: Wide dispersive indoor use of processing aids in open systems
d)	General consumer use of lubricants and greases in vehicles or machinery.	PC 24: Lubricants, greases, release products	ERC 9a: Wide dispersive indoor use of substances in closed systems

6 DATA SOURCES

Registration dossiers

7 PHYSICOCHEMICAL PROPERTIES

Table 10: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20 °C and 101,3 kPa	solid	visual inspection	
Melting/freezing point	100 °C	CRC_Handbook of Chemistry and Physics, CRC-Press, 91st Edition, Section 3-40	Handbook data
Boiling point	204 °C at 20 hPa	CRC-Handbook of Chemistry and Physics, W.M. Haynes, 91st Edition, 2010-2011, CRC Press, Section 3-40	Handbook data
Relative density	1.36 at 20 °C	GESTIS data base	Handbook data
Vapour pressure	0.007 kPa at 25 °C		EPI Suite (version 4.11) using MPBPVPWIN, estimation
Surface tension	n.a.		In accordance with Regulation

Property	Value	Reference	Comment (e.g. measured or estimated)
			(EC) No 1907/2006 Annex VII, section 7.6, Column 2, a study to determine the surface tension needs not to be conducted. Due to chemical structure, the substance is not expected to be surface-active.
Water solubility	19 g/l at 20 °C	GESTIS data base	Handbook data
Partition coefficient n-octanol/water	1.34 at 22.7 °C	OECD Guideline 117 (Partition Coefficient (n-octanol / water), HPLC Method)	measured
Granulometry	D10 ca. 849 µm D50 ca. 1256 µm D90 ca. 2132.9 µm	ISO13320-1	measured by Laser Diffraction method
Stability in organic solvents and identity of relevant degradation products	n.a.		In accordance with Regulation (EC) No 1907/2006 Annex IX, section 7.15, Column 1, a study needs not to be conducted, because the stability of the substance in organic solvents is not considered critical.
Dissociation constant	pKa 8.37 for 5-methyl-1H-benzotriazole at 20 °C;	International Union of Pure and Applied Chemistry (IUPAC), IUPAC Chemical Data Series, 23, 159 (1979).	Handbook data
Viscosity	n.a.		The substance is a solid.

8 EVALUATION OF PHYSICAL HAZARDS

Not assessed in this dossier.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not assessed in this dossier.

10 EVALUATION OF HEALTH HAZARDS

Not assessed in this dossier.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Table 11: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
Hydrolysis OECD 111	Temperature: 50 °C 5 days incubation pH 4: Hydrolytically stable pH 7: Hydrolytically stable pH 9: Hydrolytically stable	Reliability 1 Test material: CAS 95-14-7 purity > 99%	Registration dossier (Anonymous, 2013)
Ready biodegradability OECD 301D	Temperature: 20 °C Inoculum: activated sludge (two test series: adapted and non-adapted) Initial concentration: 0.6, 2.0, 6.0 and 20 mg/L 0 % biodegradation (O2 consumption) after 28 days (adapted and non-adapted)	Reliability 2 Test material: CAS 95-14-7 purity > 99%	Registration dossier (Anonymous, 1991a)
Ready biodegradability OECD 301B	Temperature: 20-25 °C Inoculum: activated sludge (adapted, from SCAS Test) Initial Concentration: 10 mg/L (based on Carbon) 0 % biodegradation (CO2 production) after 28 days	Reliability 2 Test material: CAS 95-14-7 purity > 99%	Registration dossier (Anonymous, 1994a)

11.1.1 Ready biodegradability

The biodegradation potential of 1H-benzotriazol was studied in compliance with the OECD Guideline 301 D (Anonymous, 1991a). The substance (initial concentration 0.6, 2.0, 6.0 and 20 mg/L) was tested with adapted (14 days pre-exposure to benzotriazole solution (50-100 mg/L)) and non-adapted inoculum. After 28 days no biodegradation was observed in both inocula.

This result was confirmed by a study according to OECD Guideline OECD 301B (Anonymous, 1994a). Adapted activated sludge (freshly from a SCAS Test) was used for this study. After 28 days 0 % biodegradation (CO_2 production) was observed. The reference substance reached the pass level after 5 days. The toxicity test shows > 25 % degradation within 14 days (41.6 %).

In conclusion 1H-benzotriazole is considered to be not readily biodegradable.

11.1.2 BOD_5/COD

No data available

11.1.3 Hydrolysis

Hydrolysis was tested according to the OECD Guideline 111 at three different pH-Values (4, 7 and 9) in an incubation chamber at 50 °C for 5 days (Anonymous, 2013). It was found that 1H-benzotriazole was stable at all three pH-values (concentration of the test substance after 5 days ~ 100 % of the started concentrations).

11.1.4 Other convincing scientific evidence

11.1.4.1 Field investigations and monitoring data (if relevant for C&L)

No data available.

11.1.4.2 Inherent and enhanced ready biodegradability tests

In the registration dossier an inherent biodegradability tests according to OECD guideline 302A is available (Anonymous, 1994b). Predominantly domestic sewage (adapted) was used as inoculum. Degradation of 0.8 % (DOC removal) was observed after 30 days. Some adsorption of test substance has been observed, but only during day 1 to 4.

Furthermore, a test according to OECD guideline 302B is available (Anonymous, 1988). Degradation, based on test material analysis, of 83 % (in the dark) and 90 % (illuminated by daylight) after 28 days was observed, but 7-day pass level has been missed (50 and 55 %, respectively). 95 % of the reference substance aniline was degraded after 7 days. As the adaption of the inoculum was not stated, the study should not be considered for classification.

11.1.4.3 Water, water-sediment and soil degradation data (including simulation studies)

No data available.

11.1.4.4 Photochemical degradation

An atmospheric half-life of 10.7 days was calculated (AOPWIN v1.91) for the reaction of 1H-benzotriazole with OH radicals.

Regarding phototransformation in water, two studies are available, which provide clear indication of relevant photodegradation processes of 1H-Benzotriazole in aqueous solutions under acidic and neutral pH conditions (Andreozzi et al., 1999; Hem et al., 2003). Under basic conditions, the ionic form of 1H-Benzotriazole has been dominant, showing a reduced reactivity to UV light. Aniline, phenazine and supposable an oxidation product of phenazine were identified as relevant transformation products of 1H-Benzotriazole. Based on these findings it is concluded that phototransformation in water may enhance the detoxification and biodegradability of 1H-Benzotriazole.

11.2 Environmental distribution

11.2.1 Adsorption/Desorption

According to a study by Breedveld et al. (2003) conducted in accordance to OECD guideline 106 1H-benzotriazole is showing a high mobility in soils containing low organic matter content. While there is significant adsorption in soils of high organic matter content even in these matrices the mobility remains high.

The sorption behaviour of 5-methyl-benzotrizaole and 1H-benzotriazole was investigated (test method: ASTM D4319-93) on four different soil matrices with organic carbon contents between 0.27 and 1.72% (Hard et al. 2004). Batch systems facilitated the equilibrium sorption with analysis by HPLC. Results from the experiment have been fitted by Langmuir, Freundlich and linear isotherms, giving indications on different factors affecting the sorption behaviour of both substances. As all members of the benzotriazole group have shown a strong dipole moment (polar character), binding to soil is a complex combination of molecular driving forces with different binding sites for adsorption, absorption and hydrogen bonding. Maximum log Koc values of 1.89 (1H-benzotriazole) and 2.04 (5-methyl-benzotrizaole) have been determined.

QSAR calculations made by the registrant and using KOCWIN (v.2.00) of EPI Suite on 1H-benzotriazole estimated the log K_{OC} to be in the range of 1.724 (MCI method) to 1.795 (KOW method). In a further QSAR calculation according to Schüürmann et al. (2006) a log Koc of 1.69 has been estimated.

11.2.2 Volatilisation

The registrant calculated the vapour pressure of Methyl-1H-benzotriazole with EPI Suite (version 4.11) using MPBPVPWIN. According to this calculation, the substance has a vapour pressure of 0.007 kPa at 25 °C.

A Henry`s Law constant of 0 Pa m³/mol (25 °C) has been calculated by the registrant using equation R.16-4 (ECHA Guidance on information requirements and chemical safety assessment).

11.3 Bioaccumulation

Table 12: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
Log Kow OECD 117	Log Kow = 1.34	Reliability 2	Registration dossier (Anonymous, 1991b)

11.3.1 Estimated bioaccumulation

No data relevant for classification is available.

11.3.2 Measured partition coefficient and bioaccumulation test data

The registrant performed a study according to OECD 117 to estimate the log K_{OW}. According to the study, the log K_{OW} is 1.34. This low log K_{OW} predicts a low aquatic bioaccumulation potential.

11.4 Aquatic acute toxicity

All tests summarised in the following tables were evaluated according to Klimisch et al. (1997). All tests published in Seeland et al. (2012) were evaluated with reliability 1 according to Klimisch et al. (1997) as they were conducted according to OECD Guidelines without deviations. In addition, the test concentrations were analytically verified by demonstrating the stability of the test substance in a separate stability test. The deviation from nominal concentrations was only 6.3 to 7.0 %.

Table 13: Summary of relevant information on acute aquatic toxicity

Species	Substance	Results [mg/L]	Test method and experimental conditions	Reliability	Reference
Brachydanio rerio (new name: *Danio rerio*)	1*H*-BT CAS 95-14-7	96h-LC_{50}= 180	OECD 203; semi-static; conc.: 32 – 56 – 100 – 180 – 320 mg/L; 10 fishes (1 replicate); length: 2.7 ± 0.2 cm; temp.: 24.3 – 25.4 °C; pH 7.2-8.2	1	Registration dossier: (Anonymous, 1993a)
Brachydanio rerio (new name: Danio rerio)	1H-BT CAS 95-14-7	96h-LC_{50}> 100	Verfahrensvorschlag (F.1.1) "Letale Wirkung beim Zebrabärbling Brachydario rerio" (LC0, LC 50, LC 100; 48-96 Stunden) des Umweltbundesamtes, Stand 01.06.83; static; conc.: 100 mg/L (Limit-test); 10 fishes (1 replicate); length: 30 ± 5 mm; temp.: 23 ± 2 °C; pH 6.4 – 7.0	2 – deficiencies in reporting	Registration dossier: (Anonymous, 1985)
Daphnia magna	1H-BT CAS 95-14-7	48h-EC_{50}= 137	OECD 202; static; conc.: 32 – 56 – 100 – 180 – 320 – 560 – 1000 mg/L; 4 replicates with 5 daphnids each; 19.9 – 20.3 °C, pH 7.0 – 8.1; 16 h light/d	1	Registration dossier: (Anonymous, 1993b)
Daphnia magna	1H-BT CAS 95-14-7	48h-EC_{50}= 91	"Bestimmung der Schwimmunfähigkeit beim Wasserfloh - Daphnia magna-" (EC0, EC50, EC100; 24 Stunden; statisches System) Verfahrensvorschlag: Umweltbundesamt Berlin, Stand Mai 1984; static; nominal: 63 – 88 – 125 – 177 – 250 – 354 and 500 mg/L; 10 replicates with 1 daphnid each; 21 ± 0.5 °C; pH 7.6-7.7;	2	Registration dossier: (Anonymous, 1991c)
Daphnia magna	1H-BT CAS 95-14-7	48h-EC_{50}= 107	OECD 202; static; conc.: 3.0 – 4.5 – 4.5 – 6.7 – 10.1 – 15.1 – 22.8 – 34.2 – 51.3 – 76.9 – 115 mg/L; 4 replicates with 5 daphnids each; age: < 24h; 20 °C; 16h light per day; no feeding	1	(Seeland et al., 2012)
Daphnia galeata	1H-BT CAS 95-14-7	48h-EC_{50}= 15.8	OECD 202; static; conc.: 3.0 – 4.5 – 4.5 – 6.7 – 10.1 – 15.1 – 22.8 – 34.2 – 51.3 – 76.9 – 115 mg/L; 4 replicates with 5 daphnids each; age: < 24h; 20 °C; 16h light per day; no feeding	1	(Seeland et al., 2012)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	1H-BT CAS 95-14-7	72h-E_rC_{50} =not reported	OECD 201; static; concentrations: 0.3 – 0.6 – 1.2 – 2.5 5.0 mg/L; temp.: 23 ± 1 °C; photoperiod 24h with 6,500 to 10,000 lux; start cell number: $5*10^4$ cells/mL; 5 control replicates and 3 for the test substance;	1	(Seeland et al., 2012)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	1H-BT CAS 95-14-7	72h-E_rC_{50} =231	DIN 38412-9; static; conc.: nominal: 1 - 3.2 – 10 – 32 – 100 - 320 and 1000 mg/L	4 – Reporting deficiencies: replicates unknown…	Registration dossier: (Anonymous, 1991d)
Pseudokirchneriella subcapitata (reported as Selenastrum capricornutum)	1H-BT CAS 95-14-7	72h-E_rC_{50}= 75	OECD 201; static; conc.: 6.4 – 20 – 36 – 64 – 112 – 200 – 640 mg/L; 23 ± 1 °C; pH 8.0 – 8.4; 4 control replicates; 2 replicates per test concentration	2 – reduced replicates + some deficiencies in reporting	Registration dossier: (Anonymous, 1994c)

11.4.1 Acute (short-term) toxicity to fish

Two acute toxicity tests with fish (*Danio rerio*) are available from the registration dossier. The one conducted in 1993 with a reliability of 1 according to OECD Guideline 203 results in a 96h-LC_{50} of 180 mg/L. In the other acute toxicity test with *Danio rerio* conducted in 1985 (reliability 2 as there were reporting deficiencies), no effect occurred up to a concentration of 100 mg/L.

11.4.2 Acute (short-term) toxicity to aquatic invertebrates

Short-term toxicity tests with two aquatic invertebrate species are available: *Daphnia magna* and *Daphnia galeata.* All tests listed in Table 13 were conducted according to accepted guidelines.

The most sensitive result occurred in a short-term toxicity test with *Daphnia galeata* (Seeland et al. 2012) with a 48h-EC_{50} of 15.8 mg/L. *Daphnia magna* is less sensitive with a 48h-EC_{50} of 91 mg/L Anonymous (1991c).

11.4.3 Acute (short-term) toxicity to algae or other aquatic plants

There are three tests with algae (*Desmodesmus subspicatus* and *Pseudokirchneriella subcapitata*) available.

The lowest 72h-E_rC_{50} resulted from a test conducted by Anonymous (1994c) (registration dossier) with 75 mg/L for *Pseudokirchneriella subcapitata* (previous names: *Raphidocelis subcapitata, Selenastrum capricornutum).*

In the test conducted by Seeland et al. (2012) no 72h-E_rC_{50} was reported for *Desmodesmus subspicatus* (previous name: *Scenedesmus subspicatus*). The test conducted by Anonymous (1991d) will not be used for classification as there were reporting deficiencies and the test was assessed with Klimisch 4.

11.4.4 Acute (short-term) toxicity to other aquatic organisms

There are no tests for other aquatic organisms available.

11.5 Long-term aquatic hazard

All tests summarised in the following tables were evaluated according to Klimisch et al. (1997). All tests published in Seeland et al. (2012) were evaluated with reliability 1 according to Klimisch et al. (1997) as they were conducted according to OECD Guidelines without deviations. In addition, the test concentrations were analytically verified by demonstrating the stability of the test substance in a separate stability test. The deviation from nominal concentrations was only 6.3 to 7.0 %.

Table 14: Summary of relevant information on chronic aquatic toxicity

Species	Sub-stance	Results [mg/L]	Test method and experimental conditions	Reliability	Reference
Danio rerio	1H-BT CAS 95-14-7	35d-NOEC= 1.07 (post hatch survival)	OECD 234, exposure duration: 63d; flow-through, conc.: nominal: 0.10 0.32, 1.00, 3.20, 10.0 mg/L, measured: 0.104, 0.331, 1.07, 3.34, 11.0 mg/L; no vehicle; 30 fertilized eggs per replicate, 4 replicates; 27 ± 2 °C; pH: 6.24 – 7.24; 87-117% diss. Oxygen; 12h light per day; 1000 lumen	1	Registration dossier: (Anonymous, 2021)
Daphnia magna	1H-BT CAS 95-14-7	21d-NOEC= 25.9	"Daphnia Reproduction Test" of OECD Guideline 202, Part II (Draft 7/1993); semi-static; conc.: nominal: 0.7 - 2.2 - 7.0 - 22.1 and 70.0 mg/L; 20 ± 2 °C	2	Registration dossier: (Anonymous, 1995)
Daphnia magna	1H-BT CAS 95-14-7	21d-EC_{10}> 12.8	OECD 211; semi-static; conc.: 0.4 – 0.8 – 1.6 – 3.2 – 6.4 – 12.8 mg/L; 10 replicates with 1 daphnid each; age < 24h; 20 °C; 16h light per day; feeding: 0.2 mg C/ (daphnid and day)	1	(Seeland et al., 2012)
Daphnia galeata	1H-BT CAS 95-14-7	**21d-EC_{10}= 0.97**	OECD 211; semi-static; conc.: 0.4 – 0.8 – 1.6 – 3.2 – 6.4 – 12.8 mg/L; 10 replicates with 1 daphnid each; age < 24h; 20 °C; 16h light per day; feeding: 0.2 mg C/ (daphnid and day)	1	(Seeland et al., 2012)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	1H-BT CAS 95-14-7	72h-E_rC_{10} = 1.18	OECD 201; static; concentrations: 0.3 – 0.6 – 1.2 – 2.5 5.0 mg/L; temp.: 23 ± 1 °C; photoperiod 24h with 6,500 to 10,000 lux; start cell number: $5*10^4$ cells/mL; 5 control replicates and 3 for the test substance;	1	(Seeland et al., 2012)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	1H-BT CAS 95-14-7	72h-E_rC_{10} = 58	DIN 38412-9; static; conc.: nominal: 1 - 3.2 – 10 – 32 – 100 - 320 and 1000 mg/L	4 – Reporting deficiencies: replicates unknown…	Registration dossier: (Anonymous, 1991d)
Pseudokirchneriella subcapitata (reported as Selenastrum capricornutum)	1H-BT CAS 95-14-7	72h-E_rC_{10}= 10.5 72h-NOEC= 10	OECD 201; static; conc.: 6.4 – 20 – 36 – 64 – 112 – 200 – 640 mg/L; 23 ± 1 °C; pH 8.0 – 8.4; 4 control replicates; 2 replicates per test concentration	2 – reduced replicates + some deficiencies in reporting	Registration dossier: (Anonymous, 1994c)
Lemna minor	1H-BT CAS 95-14-7	7d-EC_{10}= 3.94	OECD 221; static; conc.: 1.0 – 2.5 – 5.0 – 10.0 – 20.0 mg/L; 12 healthy fonds in each glass beaker (250 mL, 10.5 cm Ø); 6 control replicates and 3 for the test substance;	1	(Seeland et al., 2012)

11.5.1 Chronic toxicity to fish

There is one long-term test for fish available. Anonymous (2021) conducted a Fish Sexual Development Test according to OECD TG 234 for 63 days. Post-hatch survival rates at 35 dpf varied between 83.3 % and 92.5 %. Statistical significant differences occurred between control and the two highest treatments with a monotonous concentration-response relationship. Therefore, the 35d-NOEC was 1.07 mg/L (post hatch survival during early-life-stage). Three days before test termination (60dpf), mortality occurred in two vessels of the control and the first treatment level. In total, 21 fish in controls and 20 fish at a treatment level of 0.10 mg benzotriazole/L (mean measured) were found dead. The remaining fish did not show any signs of disease. A statistical analysis of the post-hatch survival at 63 dpf could not be performed as the increased mortality in the controls 3 days before test termination occurred.

11.5.2 Chronic toxicity to aquatic invertebrates

Three long-term toxicity tests with aquatic invertebrates (*Daphnia magna* and *Daphnia galeata*) are available.

The most sensitive organism was again *Daphnia galeata* with a 21d-EC_{10} of 0.91 mg/L. *Daphnia magna* was less sensitive with a 21d-EC_{10} of 12.8 mg/L (both: Seeland et al. 2012).

11.5.3 Chronic toxicity to algae or other aquatic plants

There are three tests with algae (*Desmodesmus subspicatus* and *Pseudokirchneriella subcapitata*) and one with the aquatic plant *Lemna minor* available.

The lowest 72h-E_rC_{10} resulted from a test conducted by Anonymous (1994c) (registration dossier) with 10.5 mg/L for *Pseudokirchneriella subcapitata* (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum).* The 72h-NOE_rC from this test was 10 mg/L.

The test conducted by Seeland et al. (2012) resulted in a 72h-E_rC_{10} of 1.18 mg/L for *Desmodesmus subspicatus* (previous name: *Scenedesmus subspicatus*).

The test conducted by Anonymous (1991d) will not be used for classification as there were reporting deficiencies and the test was assessed with Klimisch 4.

The test carried out with *Lemna minor* reported in Seeland et al. (2012) results in a 7d-EC_{10} of 3.94 mg/L.

11.5.4 Chronic toxicity to other aquatic organisms

There are no tests for other aquatic organisms available.

11.6 Comparison with the CLP criteria

11.6.1 Acute aquatic hazard

Table 15: Comparison with criteria for acute aquatic hazards

	Criteria for acute environmental hazards	1H-benzotriazole	Conclusion
Acute Aquatic Toxicity	Cat. 1: $LC_{50}/EC_{50}/ErC_{50} \leq 1$ mg/L	Fish: *Danio rerio* 96h-LC_{50} > 100 mg/L (nominal) Invertebrates: *Daphnia galeata* 48h-EC_{50} = 15.8 mg/L (nominal) Algae: *Pseudokirchnerella subcapitata* 72h-E_rC_{50} = 75 mg/L (nominal)	**No classification**

11.6.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Table 16: Comparison with criteria for environmental hazards

	Criteria for environmental hazards	1H-benzotriazole	Conclusion
Rapid Degradation	Half-life hydrolysis < 16 days Readily biodegradable in a 28-day test for ready biodegradability	Hydrolytically stable 0 % after 28 days (O_2 consumption)	**Not rapidly degradable**
Bioaccumulation	BCF ≥ 500 Log K_{ow} ≥ 4	Experimental determined BCF not available Log K_{ow} = 1.34	**Not bioaccumulative** (low potential for bioconcentration in the aquatic environment)
Aquatic Toxicity	Non-rapidly degradable substances: Cat. 1: NOEC/EC_{10} ≤ 0.1 mg/L Cat. 2: NOEC/EC_{10} > 0.1 to ≤ 1 mg/L (based on Table 4.1.0 (b) (i) of the CLP Regulation)	Fish: *Danio rerio* 35d-NOEC = 1.07 mg/L (measured) Invertebrates: *Daphnia galeata* 21d-EC_{10} = 0.97 mg/L (nominal) Algae: *Desmodesmus subspicatus* 72h-E_rC_{10} = 1.18 mg/L (nominal) Aquatic plant: *Lemna minor* 7d-EC_{10} = 3.94 mg/L (nominal)	**Aquatic Chronic 2** (based on 21d-EC_{10}=0.97 mg/L)

11.7 Conclusion on classification and labelling for environmental hazards

Acute aquatic hazard:

All valid short-term toxicity E/LC_{50}-values are > 1 mg/L. Therefore, no acute aquatic classification is proposed.

Chronic aquatic hazard:

1H-benzotriazole is not rapidly degradable and has a low potential for bioaccumulation in the aquatic environment.

Chronic toxicity data is available for all three trophic levels. The most sensitive valid long-term toxicity value is EC_{10} = 0.97 mg/L (*Daphnia galeata*). This results in a classification of 1H-benzotriazole as Aquatic Chronic 2 based on the criteria given in Table 4.1.0(b)(i) of the CLP Regulation.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

1*H*-benzotriazole has no entry in Annex VI of the CLP Regulation. The Dossier Submitter (DS) proposed to classify the substance with Aquatic Chronic 2, H411 based on a 21-day EC_{10} of 0.97 mg/L for *Daphnia galeata.*

Degradation

In a ready biodegradation study performed according to the OECD TG 301 D (GLP), no degradation was observed after 28 days either with adapted of non-adapted activated sludge. In addition, no degradation after 28 days was observed in an OECD TG 301 B

study (GLP) with adapted activated sludge. The DS concluded that 1*H*-benzotriazole was not readily biodegradable.

1*H*-benzotriazole was hydrolytically stable at pH4, pH 7 and pH 9 in the OECD TG 111 (GLP) study. After 5 days the concentration of the test substance was about 100 % of the starting concentrations.

In the OECD TG 302A inherent biodegradability test (GLP), 0.8% degradation was observed after 30 days.

An atmospheric half-life of 10.7 days was calculated for the reaction of 1*H*-benzotriazole with OH radicals (AOPWIN v1.91).

Regarding photo-transformation in water, two studies were available. Under acidic and neutral pH conditions clear indications of relevant photochemical processes were observed. Under basic conditions, the ionic form of 1*H*-Benzotriazole (pKa 8.4) was dominant, showing a reduced reactivity to UV light. Aniline, phenazine and supposable an oxidation product of phenazine were identified as relevant transformation products of 1*H*-Benzotriazole.

Based on all available information, the DS concluded 1*H*-benzotriazole as not being rapidly degradable.

Bioaccumulation

There was no bioconcentration study available for fish. In an OECD TG 117 study (GLP) a log P_{ow} of 1.34 was determined. The DS concluded that the log P_{ow} predicts low potential for bioaccumulation.

Aquatic toxicity

Acute

Table Summary of relevant information on acute aquatic toxicity

Species	**Results [mg/L]**	**Test method and experimental conditions**	**Reliability**	**Reference**
Fish				
Brachydanio rerio (new name: *Danio rerio*)	96h-LC_{50}= 180 (nom.)	OECD TG 203 (GLP); semi-static; no analytical monitoring, >80% assumed based on stability data of the substance	1	Registration dossier: (Anonymous, 1993a)
Brachydanio rerio (new name: Danio rerio)	96h-LC_{50}> 100 (nom.)	Verfahrensvorschlag (F.1.1) "Letale Wirkung beim Zebrabärbling Brachydario rerio" static; no analytical monitoring	2	Registration dossier: (Anonymous, 1985)
Invertebrates				
Daphnia magna	48h-EC_{50}= 137 (nom.)	OECD TG 202 (GLP); static; no analytical monitoring.	1	Registration dossier: (Anonymous, 1993b)

Daphnia magna	48h-EC_{50}= 91 (nom.)	"Bestimmung der Schwimmunfähigkeit beim Wasserfloh - Daphnia magna-" (EC0, EC50, EC100; 24 Stunden; statisches System) Verfahrensvorschlag: Umweltbundesamt Berlin, Stand Mai 1984 (GLP); static; analytical monitoring.	2	Registration dossier: (Anonymous, 1991c)
Daphnia magna	48h-EC_{50}= 107 (nom.)	OECD TG 202; static; analytical monitoring (*	1	(Seeland et al., 2012)
Daphnia galeata	48h-EC_{50}= 15.8 (nom.)	OECD TG 202; static; analytical monitoring (*	1	(Seeland et al., 2012)
Algae				
Pseudokirchneriella subcapitata (reported as Selenastrum capricornutum)	72h-E_rC_{50}= 75 (nom.)	OECD TG 201 (GLP); static; pH 8.0-8.4; no analytical monitoring	2	Registration dossier: (Anonymous, 1994c)

(*the test concentrations were analytically verified in a separate stability test. The deviation from nominal concentrations was only 6.3 to 7.0 %.

The DS presented information for fish, *Daphnia* and algae. For fish, the 96-hour LC_{50} was above 100 mg/L. The most sensitive result for invertebrates was a 48-hour EC_{50} of 15.8 mg/L for *Daphnia galeata*. For algae there was a 72-hour E_rC_{50} of 75 mg/L for *Pseudokirchneriella subcapitata*. Thus, the DS concluded that acute aquatic classification is not warranted for 1*H*-benzotriazole.

Chronic

Table Summary of relevant information on chronic aquatic toxicity

Species	**Results [mg/L]**	**Test method and experimental conditions**	**Reliability**	**Reference**
Fish				
Danio rerio	35d-NOEC= 1.07 (arithmetic mean) (post hatch survival)	OECD TG 234 (GLP), exposure duration: 63d; flow-through; analytical monitoring	1	Registration dossier: (Anonymous, 2021)
Invertebrates				
Daphnia magna	21d-NOEC= 25.9 (nom.)	"Daphnia Reproduction Test" of OECD TG 202, Part II (Draft 7/1993) (GLP); semi-static; analytical monitoring	2	Registration dossier: (Anonymous, 1995)

Daphnia magna	21d-EC_{10}> 12.8 (nom.)	OECD TG 211; semi-static; analytical monitoring	1	(Seeland et al., 2012) (*
Daphnia galeata	**21d-EC_{10}= 0.97 (nom.)** 21d-NOEC=1.0 (nom.)	OECD TG 211; semi-static; analytical monitoring	1	(Seeland et al., 2012) (*
Algae and aquatic plants				
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	72h-E_rC_{10} = 1.18 (nom.)	OECD TG 201; static; analytical monitoring	1	(Seeland et al., 2012) (*
Pseudokirchneriella subcapitata (reported as Selenastrum capricornutum)	72h-E_rC_{10}= 10.5	OECD TG 201 (GLP); static; no analytical monitoring	2	Registration dossier: (Anonymous, 1994c)
Lemna minor	7d-EC_{10}= 3.94	OECD TG 221; static; analytical monitoring	1	(Seeland et al., 2012) (*

(*the test concentrations were analytically verified in a separate stability test. The deviation from nominal concentrations was only 6.3 to 7.0 %.

There were reliable chronic aquatic toxicity tests available for fish, *Daphnia*, algae and aquatic plants. The 35-day NOEC for the fish *Danio rerio* was 1.07 mg/L. The lowest value for invertebrates was a 21-day EC_{10} of 0.97 mg/L for *Daphnia galeata*. For algae and aquatic plants, the most sensitive effect values were a 72-hour E_rC_{10} of 1.18 mg/L and a 7-day EC_{10} of 3.94 mg/L for *Desmodesmus subspicatus* and *Lemna minor*, respectively. Thus, based on the EC_{10} of 0.97 mg/L to *Daphnia galeata,* the Dossier Submitter proposed to classify 1*H*-benzotriazole as **Aquatic Chronic 2, H411** for a not rapidly degradable substance (0.1 mg/L<EC_{10}≤ 1 mg/L).

Comments received during consultation

Comments were received from 3 Member States (MS) and one National Authority (NA). The Member States agreed with the DS proposal. The NA wanted more information to consider the reliability and relevance for hazard classification regarding the key study on non-validated species *Daphnia galeata* in an OECD TG 211 test design.

In addition, the NA asked for clarifications on the appropriateness of the use of data performed on *Daphnia galeata* for aquatic hazard classification. According to the NA, OECD TG 211 states: 'Other daphnids may be used provided they meet the validity criteria as appropriate (the validity criterion relating to the reproductive output in the controls should be relevant for all species)'.

- The NA asked the Dossier Submitter for a confirmation of the test protocol validity criterion regarding 'the mortality of the parent animals (female *Daphnia*) does not exceed 20% at the end of the test'.
- According to NA, the second validity criterion of the test protocol regarding 'the mean number of living offspring produced per parent animal surviving at the end

of the test above 60' was not met. NA however, considered that the *Daphnia galeata* brood size may be smaller than that of *Daphnia magna* given the smaller physical size of the organism. Therefore, they were unclear whether this cut off is appropriate to assess the reproductive output of this species.

- The NA noted also that the percentage or number of dead offspring are also not reported. If this information would be available, it would be useful to calculate the coefficient of variation (CoV) of living offspring as an indicator of experimental reliability.

The DS confirmed that the *Daphnia galeata* species is smaller than *Daphnia magna*. Seeland et al 2021 describes that the difference in brood size was coherent with different body length for the species. Another publication[1] compared both species, e.g. in their life span, first brood, total number of offspring.

Table 2. Life span, first brood, total number of offspring per adult, and the number of offspring per broods of *Daphnia galeata* and *Daphnia magna*.

	Daphnia galeata[a]	*Daphnia magna*[29]
Life span (days)	28±8	50,1±10,9
First brood (days)	9±2	9,0±0,0
Total number of offspring per adult	29±23	357,8±104,7
Number of offspring per brood	4±2	13,3±3,7

[a] Data from this study

The mean number of juveniles in the control was 37 for *Daphnia galeata* in Seeland et al., 2012 in comparison with 99 for *Daphnia magna.* Taking into account the findings in Cui et al. 2016 this reproductive output of *Daphnia galeata* seems to be normal and appropriate for the assessment for toxicity testing.

In their comments, the NA argued that the NOEC might be a preferable key endpoint for *Daphnia galeata* for hazard classification regarding that the 21-day EC_{10} of 0.97 mg/L is below the 21-day NOEC of 1 mg/L and has confidence intervals of 0.35 – 2.7 mg/L which span the CLH classification band.

The DS did not, however, consider using the NOEC value necessary, as EC_{10} values are generally preferred over NOECs.

The NA also asked if the chronic Fish Sexual Development Test (OECD TG 234) had already been reviewed under Substance evaluation and if it could be used for aquatic hazard classification. The DS informed that the study is currently reviewed under Substance Evaluation. As the post-hatch survival of the control group at 35 days post fertilization (dpf) was very high (mean: 95.8 %), the post-hatch survival of 86.7 % at 3.34 mg/L was statistically significant. Therefore, the post-hatch survival at 1.07 mg/L (95.8 %) constitutes the 35-day NOEC for this endpoint. All the post-hatch survival rates in this test were above the validity criterion of 75 % of OECD TG 234.

[1] Cui, R., Kwak, J.I., & An, Y. (2016). Characteristics and Toxicity Sensitivity of Korean Dominant Species Daphnia galeata for Ecotoxicity Testing: Comparative Study with Daphnia magna. Journal of Korean Society of Environmental Engineers, 38, 193-200. https://doi.org/10.4491/KSEE.2016.38.4.193

Assessment and comparison with the classification criteria

Degradation

RAC agrees with the DS conclusion that 1*H*-benzotriazole is not rapidly degradable based on:

- No degradation observed after 28 days in an OECD TG 301 D test with non-adapted activated sludge.
- No surface water simulation test available.
- 1*H*-benzotriazole being hydrolytically stable at pH 4, pH 7 and pH 9.

No degradation after 28 days in two ready biodegradation tests (OECD TG 301 D and OECD TG 301 B) with adapted activated sludge and 0.8% degradation in an OECD TG 302A inherent test supported the conclusion.

Bioaccumulation

RAC agrees with the DS conclusion that 1*H*-benzotriazole has low potential for bioaccumulation even in the absence of an experimental fish bioconcentration study, as the measured low Pow of 1.34 was below the classification cut-off value of 4.

Aquatic toxicity

<u>*Daphnia magna* vs *Daphnia galeata*</u>

RAC notes that regarding the use of daphnids other than *Daphnia magna* in the OECD TG 211 study the validity criteria of the test guideline should be met. RAC recognises however that the fulfilment of the validity criteria in the control(s) 'the mortality of the parent animals (female *Daphnia*) does not exceed 20% at the end of the test' was not explicitly mentioned in the Seeland et al (2012) article available for RAC.

RAC notes also that the test protocol validity criterion 'the mean number of living offspring produced per parent animal surviving at the end of the test is > 60' was not met. RAC, however, agrees that considering the findings from Seeland et al 2021 and Cui et al 2016 articles, presented by DS, the reproductive output of *Daphnia galeata* appears to be appropriate for the assessment of aquatic toxicity.

As indicated in ECHA's CLP Guidance (v5.0, July 2017) the EC_{10} values are preferred over NOEC values for chronic toxicity studies when both are available for the same endpoint, therefore RAC agrees to use EC_{10} of 0.97 mg/L with confidence limits of 0.35 – 2.70 mg/L as a key endpoint for *Daphnia galeata* but also recognises that the NOEC of 1 mg/L would lead to a same classification.

<u>Acute</u>

RAC agrees with the DS in concluding that acute aquatic classification is not warranted for 1*H*-benzotriazole. All reliable LC/EC_{50} values (fish, *Daphnia magna*, *Daphnia galeata* and algae) were over the cut-off value of 1 mg/L for classification, the lowest value being a 48-hour EC_{50} of 15.8 mg/L for *Daphnia galeata*.

Chronic

There were reliable chronic toxicity data available for fish, *Daphnia magna*, *Daphnia galeata*, algae and aquatic plant. The lowest value is a 21-day EC_{10} of 0.97 mg/L to *Daphnia galeata* which warrants an Aquatic Chronic 2, H411 classification for a not rapidly degradable substance (0.1 mg/L<EC_{10}≤ 1 mg/L).

RAC agrees with the Dossier Submitter proposal to classify 1*H*-benzotriazole as **Aquatic Chronic 2, H411.**

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13 ANNEXES

Annex I