Committee for Risk Assessment

RAC

Annex 1
Background document
to the Opinion proposing harmonised classification and labelling at EU level of

methyl-1*H*-benzotriazole

EC Number: 249-596-6
CAS Number: 29385-43-1

CLH-O-0000007149-69-01/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: methyl-1H-benzotriazole

EC Number: **249-596-6**

CAS Number: **29385-43-1**

Index Number: **-**

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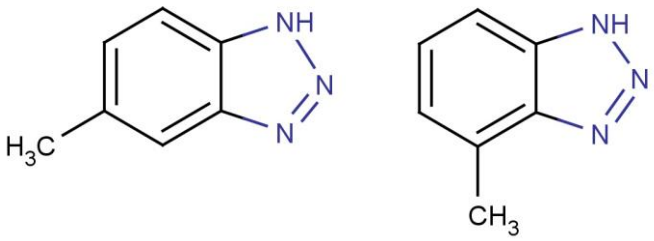
Version number: 2 **Date: August 2021**

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)	methyl-1H-benzotriazole
Other names (usual name, trade name, abbreviation)	Tolyltriazole TTA 1H-Benzotriazole, 4(or 5)-methyl-
ISO common name (if available and appropriate)	-
EC number (if available and appropriate)	249-596-6
EC name (if available and appropriate)	methyl-1H-benzotriazole
CAS number (if available)	29385-43-1
Other identity code (if available)	-
Molecular formula	C7H7N3
Structural formula	
SMILES notation (if available)	CC1=CC2=C(NN=N2)C=C1
Molecular weight or molecular weight range	133.15 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)
5-methyl-1H-benzotriazole	For typical concentration and concentration ranges see confidential annex		
4-methyl-1H-benzotriazole			

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:

	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	methyl-1H-benzotriazole	249-596-6	29385-43-1	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

Methyl-1H-benzotriazole is not listed in Annex VI of Regulation (EC) No. 1272/2008.There are 21 aggregated notifications on Methyl-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/15467 **on the 21.07.2021)**

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 Repr. 2 Aquatic Chronic 2	H302 H361 H411	H302 H361d H411		GHS09 GHS08 GHS07 Wng	12 (Joint entry)
Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 3	H302 H319 H412	H302 H319 H412		GHS07 Wng	2198
Acute Tox. 4 Eye Irrit. 2	H302 H319	H302 H319		GHS07 Wng	596
Acute Tox. 4 Aquatic Chronic 2	H302 H411	H302 H411		GHS09	519
Acute Tox. 4	H302	H302		GHS07 Wng	177
Acute Tox. 4 Aquatic Chronic 2	H302	H302		GHS09 GHS07 Wng	170
Acute Tox. 4 Aquatic Chronic 3	H302 H412	H302 H412		GHS09 GHS07	80
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4 Aquatic Chronic 3	H302 H319 H332 H412	H302 H319 H332 H412		GHS07 Wng	54
Not Classified					29
Acute Tox. 4 Eye Dam. 1 Aquatic Chronic 3	H302 H318 H412	H302 H318 H412		GHS05 GHS07 Dgr	14
Acute Tox. 4 Eye Irrit. 2 STOT SE 3	H302 H319 H335 (respiratory tract) (Inhalation)	H302 H319 H335		GHS07 Wng	13
Skin Irrit. 2 Skin Sens. 1 Aquatic Chronic 2	H315 H317 H411	H315 H317 H411		GHS09 GHS07 Wng	9
Eye Irrit. 2	H319	H319		GHS07 Wng	4
Aquatic Chronic 2	H411	H302 H411		GHS09	3

Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Acute Tox. 4 STOT SE 3	H302 H315 H319 H332 H335 (Repiratory tract) (Inhalation)	H302 H315 H319 H332 H335		GHS07	2
Acute Tox. 4 Aquatic Chronic 2	H302 H411	H302 H411		GHS07 Wng	1
		H302 H412		GHS07 Wng	1
Acute Tox. 4 Acute Tox. 4 Acute Tox. 4	H302 H312 H332	H302 H312 H332		GHS07 Wng	1
Acute Tox. 4 Acute Tox. 4 Aquatic Chronic 3	H302 H332 H412	H302 H332 H412		GHS07 Wng	1
Acute Tox. 4 Eye Irrit. 2 Acute Tox. 4	H302 H319 H332	H302+H332 (H319)		GHS07 Wng	1
Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 2	H302 H315 H319 H400 H411	 H315 H317 H319 H410		HGS09 GHS07 Wng	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 Methyl-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, Methyl-1H-benzotriazole is used in all applications listed in Table 9.

Table 9: Identified uses of Methyl-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
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 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
d)	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
e)	(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
f)	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
g)	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
h)	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
i)	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
j)	(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
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

7 *REGISTRATION DOSSIERS*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	Between 76 °C and 87 °C, depending on purity	The MAK Collection for Occupational Health and Safety	Handbook data
Boiling point	Decomposition at approx. 195 °C	EU Method A.2, method according to Siwoloboff	Measured
Relative density	1.266	OECD Guideline 109, EU Method A.3, pycnometer method	Measured
Vapour pressure	0.0143 kPa at 25 °C		EPI Suite (version 4.11) using MPBPVPWIN, estimation
Surface tension	n.a.		In accordance with Regulation (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	4049.4 mg/L at 20 °C and pH 5,65	OECD 105, EU A.6, flask method	measured
Partition coefficient n-octanol/water	1.081 at 25 °C	OECD 117, EU A.8, HPLC method	measured
Flash point	190 °C c.c.	DIN EN 22719	measured
Flammability	not highly flammable solid The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.	EU Method A.10 expert judgement	measured study scientifically not necessary
Explosive properties	non explosive (> 99 % w/w)	EU Method A.14	measured
Explosives according to the criteria given in section 2.1 of Annex I to Regulation (EC) No 1272/2008	non explosive OB = -210	expert judgement (according Recommendations on the TRANSPORT OF DANGEROUS GOODS - Manual of Tests and Criteria, 2009)	The calculated oxygen balance is less than -200 and hence, the classification procedure does not need to be applied.
Self-ignition temperature	n.a.		In accordance with Regulation (EC) No 1907/2006, Annex VII, section 7.12, column 2, the self-ignition temperature needs not to be

Property	Value	Reference	Comment (e.g. measured or estimated)
			conducted for solids, if the substance has a melting point ≤ 160 °C.
Oxidising properties	no oxidising properties	expert judgement	In accordance with the "Guidance on information requirements and chemical safety assessment", Chapter R.7a / Chapter R.7.1.13.3 (Version 4.1, October 2015) a study needs not to be conducted, because the substance has no chemical groups associated with oxidising properties.
Granulometry	D10 > 1400µm D50 > 1400 µm D90 > 1400 µm	DIN 66165	measured
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 to be critical.
Dissociation constant	pKa 8.85 for 5-methyl-1H-benzotriazole at 20 °C; pKa 9.15 for 4-methyl-1H-benzotriazole at 20 °C;		Estimated by SPARC
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

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th><th>Reference</th></tr>
<tr><td>Hydrolysis
OECD 111</td><td>Temperature: 50 °C
5 days incubation
pH 4: Hydrolytically stable
pH 7: Hydrolytically stable
pH 9: Hydrolytically stable</td><td>Reliability 1
Test material: CAS 29385-43-1 purity > 99%</td><td>Registration dossier
(Anonymous, 2013a)</td></tr>
<tr><td>Ready biodegradability
OECD 301F</td><td>Temperature: 20±1 °C
Adaptation: 33 days
Duration: 28 days
Continuous darkness
Initial Concentration: 100 mg/L
<table><tr><th>Day</th><th>Biodegradation (%)</th></tr><tr><td>4</td><td>1</td></tr><tr><td>6</td><td>0</td></tr><tr><td>8</td><td>0</td></tr><tr><td>12</td><td>2</td></tr><tr><td>14</td><td>2</td></tr><tr><td>18</td><td>2</td></tr><tr><td>20</td><td>2</td></tr><tr><td>22</td><td>2</td></tr><tr><td>26</td><td>2</td></tr><tr><td>28</td><td>4</td></tr></table></td><td>Reliability 2 (performed in accordance with OECD 301 F but with adapted inoculum)
Test material: CAS 29385-43-1 purity > 99.9 %</td><td>Registration dossier
(Anonymous, 1992)</td></tr>
<tr><td>ISO 7827
(Evaluation in an aqueous medium of the "ultimate" aerobic biodegradability of organic compounds -- Method by analysis of dissolved organic carbon (DOC))</td><td>5-methyl-benzotriazole:
100% degradation after 28 days (based on test substance)

Technical mixture:
5-methyl-benzotriazole:
100% degradation after 28 days (based on test substance)
4-methyl-benzotriazole: 25 % degradation after 28 days (based on test substance)</td><td>Reliability 2
Missing information on purity of substance
Test material: 5-methyl-benzotriazole, technical mixture of 5-methyl-benzotriazole and 4-methyl-benzotriazole</td><td>Registration dossier

(Weiss et al., 2006)</td></tr>
</table>

11.1.1 Ready biodegradability

The biodegradation potential of Methyl-1H-benzotriazol was studied in compliance with the OECD Guideline 301 F (Anonymous, 1992). The inoculum was adapted by using sludge fed with synthetic waste water containing 10 mg/L benzotriazole and 10 mg/L methyl-1H-benzotriazole. After 33 days of adaptation methyl-1H-benzotriazole was added in an initial concentration of 100 mg/L. The oxygen consumption was measured at 20±1 °C in the dark for 28 days. After 28 days, 4 % of the test substance has been degraded. In conclusion, Methyl-1H-benzotriazole is considered to be not readily biodegradable.

Weiss et al. (2006) investigated the biodegradability of 5-methyl-1H-benzotriazol and a technical mixture of 5-methyl-benzotriazole and 4-methyl-benzotriazole according to ISO 7827. The individual test substances were used as sole substrate with initial concentrations of 47.8 mg/L (DOC = 30 mg/L). The inoculum, fresh activated sludge, was taken from a lab-scale membrane bioreactor, which was fed with the effluent of the primary treatment of a wastewater treatment plant (mainly domestic wastewater, 30 % industrial input). Adaption of the inoculum was not specified. Complete removal of 5-methyl-benzotriazole was observed within 17 days (based on concentrations of test substance). The test with the technical mixture shows similar results for 5-methyl-benzotriazol. However, only 25 % (based on concentrations of test substance) of 4-methyl-benzotriazole degraded within 28 days. A sample taken after 42 days shows that degradation did not continue. No degradation of the test substance was observed in the sterile abiotic control confirming that all detected effects were due to microbial activity.

In conclusion, Methyl-1H-benzotriazol is not readily biodegradable.

11.1.2 BOD5/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, 2013a). It was found that Methyl-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

No data available.

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, two inherent biodegradability tests (OECD guideline 302 B) are available. The test performed with methyl-1H-benzotriazol showed that the substance is biodegradable (Anonymous, 1988). Degradation of 77 % (in the dark) and 59 % (illuminated by daylight) after 28 days was observed (7-day pass level: 70 and 59 %). 95 % of the reference substance aniline was degraded after 7 days. Nevertheless, as the adaption of the inoculum was not stated, the study should not be considered for classification. The other test was performed with 4-methylbenzotriazole (Anonymous, 1995a) at 20-25 °C in the dark. No degradation, based on DOC, was observed during 28 days (degradation of reference substance: 98 % within 14 days). Information on adaption of the inoculum was missing. Nevertheless, this study supports the observation of Weiss et al. that the constituent 4-methyl-benzotriazole is slowly biodegradable.

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 3.89 days was calculated (AOPWIN v1.91) for the reaction of Methyl-1H-benzotriazole with OH radicals.

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 the structurally similar substance 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 Methyl-1H-benzotriazole estimated the log K_{OC} to be in the range of 1.938 (MCI method) to 1.944 (KOW method) and support the transferability of the results of Breedveld et al. to methyl-1H-benzotriazole.

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 0.0143 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 K_{OW} OECD 117	Log K_{OW} = 1.081 ± 0.002	Reliability 1	Registration dossier (Anonymous, 2013b)

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 1.081. This low log K_{OW} predicts a low aquatic bioaccumulation potential.

11.4 Aquatic acute toxicity

The table 13 provides an overview over the most relevant test results on aquatic organisms with methyl-1*H*-benzotriazole. 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 %. All test conditions are listed in Table 13 and not additionally mentioned in the text below.

The registration dossier also contains read-across studies with 1H-benzotriazole (CAS 95-14-7). These are not included in the CLH dossier as for all endpoints recommended for classification and labelling purpose studies are available with the substance itself.

Table 13: Summary of relevant information on acute aquatic toxicity

Species	substance	Results [mg/L]	Test method and experimental conditions	Reliability	Reference
Cyprinodon variegatus	methyl-1H-benzotriazole CAS 29385-43-1	96h-LC_{50}= 55	PARCOM 1995 Part B Protocol for a Fish Acute Toxicity Test (modified OECD 203 Fish Acute Toxicity Test); no analytic; semi-static; saltwater; concentrations: 10 – 30 – 100 – 300 – 1000 mg/L; 10 juvenile fishes (1 replicate); length: 1.6-2.0 cm; 19.2 – 20.1 °C, pH 7.47-8.21;	1	Registration dossier: (Anonymous, 2003a)
Daphnia magna	5-methyl-benzotriazole CAS 136-85-6	48h-EC_{50}= 51.6	OECD 202; static; concentrations: 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	5-methyl-benzotriazole CAS 136-85-6	48h-EC_{50}= 8.58	OECD 202; static; concentrations: 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)
Arcatia tonsa	methyl-1H-benzotriazole CAS 29385-43-1	48h-EC_{50}= 55	ISO/CD 14669: "Determination of Acute Lethal Toxicity to Marine Copepads" and PARCOM Ring Test Protocol: "Acute Toxicity to the Marine Copepod Acartia tonsa."; static; saltwater; conc.: 30 – 100 – 300 – 1000 mg/L; 4 replicates with 5 organisms each; age: 16d; 19.3 – 20.5 °C	1	Registration dossier: (Anonymous, 2003b)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	5-methyl-benzotriazole CAS 136-85-6	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;	2 – deficiencies in reporting	(Seeland et al. 2012)

Skeletonema costatum	methyl-1H-benzotriazole CAS 29385-43-1	72h-E_rC_{50}= 53	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum); static; saltwater; conc.: 10 - -30 – 100 – 300 mg/L; 6 control replicates; 3 replicates per test conc.; 19.3-20.7 °C; pH 7.83 – 8.09; 6300-8400 lux; growth rate control: 1.6 per day	1	Registration dossier: (Anonymous, 2003c)

11.4.1 Acute (short-term) toxicity to fish

There is one acute toxicity test available from the registration dossier with sheepshead minnow (*Cyprinodon variegatus*). This is a reliable semi-static saltwater test over 96 hours. The test substance was homogenised. Water accommodated fractions (WAFs) were used to generate the test concentrations (nominal: 10, 30, 100, 300, and 1000 mg/L). The result is a 96h-LC_{50} of 55 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.* Here 5-methyl-1*H*-benzotriazole (5MBT CAS 136-85-6) was used as test substance.

All tests listed in Table 13 were conducted according to accepted guidelines and are considered reliable.

The lowest short-term result for aquatic invertebrates eventuated from the acute toxicity test with *Daphnia galeata* with a 48h-EC_{50} of 8.58 mg/L (Seeland et al. 2012).

Daphnia magna is less sensitive with a 48h-EC_{50} of 51.6 mg/L (Seeland et al. 2012).

The study reported in the registration dossier from 2003 with *Arcatia tonsa*, another aquatic invertebrate, resulted in a 48h-EC_{50} of 55 mg/L. The test was conducted with Methyl-1*H*-benzotriazole (MBT CAS 29385-43-1) according to ISO/CD 14669: "Determination of Acute Lethal Toxicity to Marine Copepads" and PARCOM Ring Test Protocol: "Acute Toxicity to the Marine Copepod Acartia tonsa.”.

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

There are two tests with algae (*Desmodesmus subspicatus* and *Skeletonema costatum*) available.

The test with *Skeletonema costatum* (registration dossier: Anonymous, 2003c) was conducted according to ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*). The test substance was Methyl-1H-benzotriazole (MBT CAS 29385-43-1). It resulted in a 72h-E_rC_{50}= 53 mg/L.

The two other tests were conducted by Seeland et al. (2012) and used 5-methyl-1H-benzotriazole (5MBT CAS 136-85-6) as the test substance. For the test with *Desmodesmus subspicatus* according to OECD Guideline 201 the E_rC_{50}-value was not reported.

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

The table 14 provides an overview over the most relevant test results on aquatic organisms with methyl-1*H*-benzotriazole. 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 %. All test conditions are listed in Table 14 and not additionally mentioned in the text below.

The registration dossier also contains a read-across study with 1H-benzotriazole (CAS 95-14-7) for the algae species. These are not included in the CLH dossier as for all endpoints recommended for classification and labelling purpose studies are available with the substance itself.

Table 14: Summary of relevant information on chronic aquatic toxicity

Species	substance	Results [mg/L]	Test method and experimental conditions	Reliability	Reference
Daphnia magna	methyl-1H-benzotriazole CAS 29385-43-1	21d-NOEC= 18.4	OECD Guideline 202, Part II (Draft 7/1993); semi-static; conc.: 2.0 – 4.0 – 8.0 – 16.0 – 32.0 mg/L; age: < 48h; 19.5 – 20.4 °C; pH 7.8-8.2; 16 h light/d about 500 lux	1	Registration dossier : (Anonymous, 1995b)
Daphnia magna	5-methyl-benzotriazole CAS 136-85-6	21d-EC_{10}= 5.93	OECD 211; semi-static; concentrations: 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)	2 – deficiencies in reporting	(Seeland et al., 2012)
Daphnia galeata	5-methyl-benzotriazole CAS 136-85-6	**21d-EC_{10}= 0.40**	OECD 211; semi-static; concentrations: 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)	2 – deficiencies in reporting	(Seeland et al., 2012)
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	5-methyl-benzotriazole CAS 136-85-6	72h-E_rC_{10} = 2.86	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;	2 – deficiencies in reporting	(Seeland et al., 2012)
Skeletonema costatum	methyl-1H-benzotriazole CAS 29385-43-1	72h-NOE_rC= 30	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum); static; saltwater; conc.: 10 - -30 – 100 – 300 mg/L; 6 control replicates; 3 replicates per test conc.; 19.3-20.7 °C; pH 7.83 – 8.09; 6300-8400 lux; growth rate control: 1.6 per day	1	Registration dossier: (Anonymous, 2003c)
Lemna minor	5-methyl-benzotriazole CAS 136-85-6	7d-EC_{10}= 2.11	OECD 221; static; concentrations: 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;	2 – deficiencies in reporting	(Seeland et al., 2012)

11.5.1 Chronic toxicity to fish

Long-term test results for fish are not available.

11.5.2 Chronic toxicity to aquatic invertebrates

Three long-term toxicity tests to aquatic invertebrates are available.

In the registration dossier a test according to OECD Guideline 202, Part II (Draft 7/1993), conducted in the year 1995, is mentioned. The test organism was *Daphnia magna* and the test substance Methyl-1H-benzotriazole (MBT CAS 29385-43-1). It resulted in a NOEC of 18.4 mg/L.

The test conducted by Seeland et al. (2012) according to OECD Guideline 211 used *Daphnia magna* and *Daphnia galeata.* Similar to the acute toxicity tests *Daphnia galeata* is more sensitive. The tests were carried out with 5-methyl-1H-benzotriazole (5MBT CAS 136-85-6). *D. galeata* showed an EC_{10} of 0.40 mg/L and *D. magna* an EC_{10} of 5.93 mg/L.

11.5.3 Chronic toxicity to algae or other aquatic plants

There are two tests with algae (*Desmodesmus subspicatus* and *Skeletonema costatum*) and one with the aquatic plant *Lemna minor* available.

The test with *Skeletonema costatum* (registration dossier: Anonymous, 2003c) was conducted according to ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*). The test substance was Methyl-1H-benzotriazole (MBT CAS 29385-43-1). It resulted in a 72h-NOE_rC of 30 mg/L.

The two other tests were conducted by Seeland et al. (2012) and used 5-methyl-1H-benzotriazole (5MBT CAS 136-85-6) as test substance. The test with *Desmodesmus subspicatus* according to OECD Guideline 201 resulted in a 72h-E_rC_{10} of 2.86 mg/L. The test carried out with *Lemna minor* according to OECD Guideline 221 resulted in a 7d-EC_{10}= 2.11 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	Methyl-1H-benzotriazole	Conclusion
Acute Aquatic Toxicity	Cat. 1: $LC_{50}/EC_{50}/ErC_{50} \leq 1$ mg/L	Fish: *Cyprinodon variegatus* 96h-LC_{50} = 55 mg/L (nominal) Invertebrates: *Daphnia galeata* 48h-EC_{50} = 8.58 mg/L (nominal) Algae: *Skeletonema costatum* 72h-E_rC_{50} = 53 mg/L (nominal)	**No classification**

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

Table 16: Comparison with criteria for long-term aquatic hazards

	Criteria for environmental hazards	Methyl-1H-benzotriazole	Conclusion
Rapid Degradation	Half-life hydrolysis < 16 days Readily biodegradable in a 28-day test for ready biodegradability	Hydrolytically stable 4 % after 28 days (O_2 consumption)	**Not rapidly degradable**
Bioaccumulation	BCF ≥ 500 Log K_{ow} ≥ 4	Experimental determined BCF not available Log K_{ow} = 1.081	**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)	Invertebrates: *Daphnia galeata* 21d-EC_{10} = 0.4 mg/L (nominal) Algae: *Desmodesmus subspicatus* 72h-E_rC_{10} = 2.86 mg/L (nominal) Aquatic plant: *Lemna minor* 7d-EC_{10} = 2.11 mg/L (nominal)	**Aquatic Chronic 2** (based on 21d-EC_{10}=0.4 mg/L)
	<u>Surrogate approach in absence of appropriate chronic toxicity reference data</u> (based on Table 4.1.0 (b) (iii) of the CLP Regulation)<u>:</u> Not rapidly degradable substances and/or bioaccumulative substances: Cat. 1: E/LC_{50} ≤ 1 mg/L Cat. 2: E/LC_{50} > 1 to ≤ 10 mg/L Cat. 3: E/LC_{50} > 10 to ≤ 100 mg/L	No long-term toxicity data for fish available. Fish: *Cyprinodon variegatus* 96h-LC_{50} = 55 mg/L (nominal)	(Not for all trophic levels adequate chronic data available: Classification based on Table 4.1.0(b)(iii): Aquatic Chronic 3)

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:

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

Chronic toxicity data is not available for all three trophic levels. Therefore, according to Figure 4.1.1 of the CLP Regulation the aquatic chronic classification is based on the most stringent outcome of the two assessments according to Table 4.1.0 (b) (i) and (iii).

The most sensitive valid long-term toxicity value is EC_{10} = 0.40 mg/L (*Daphnia galeata*). This results in a classification of methyl-1H-benzotriazole as Aquatic Chronic 2 based on the criteria given in Table 4.1.0(b)(i) of the CLP Regulation.

For fish, no long-term toxicity data is available. Therefore, the criteria according to Table 4.1.0 (b) (iii) are used for this trophic level. The acute toxicity data (96h-LC_{50}= 55 mg/L; not rapidly degradable) leads to a chronic classification Aquatic Chronic 3.

The most stringent outcome of the two assessments according to Table 4.1.0 (b) (i) and (iii) results in a classification of methyl-1H-benzotriazole as Aquatic Chronic 2, H411 (based on 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

Methyl-1*H*-benzotriazole (CAS 29385-43-1) is not listed in Annex VI of the CLP Regulation. It is is a multiconstituent substance containing two isomers, 5-methyl-1*H*-benzotriazole (CAS 136-85-6) and 4-methyl-1*H*-benzotriazole (CAS 29878-31-7)). The Dossier Submitter (DS) proposed to classify the substance with Aquatic Chronic 2, H411 based on a 21-day EC_{10} of 0.40 mg/L for *Daphnia galeata* derived with the isomer 5-methyl-1*H*-benzotriazole and the application of the scheme outlined in Figure 4.1.1 of the CLP Regulation.

Degradation

In a ready biodegradability test (OECD TG 301 F, GLP), methyl-1*H*-benzotriazole (>99.9%) only 4 % degraded in 28 days, even though the inoculum was adapted. The DS concluded that the substance is not readily biodegradable.

Methyl-1*H*-benzotriazole (>99%) was hydrolytically stable in an OECD TG 111 (GLP) hydrolysis test at pH4, pH7 and pH9. Concentration of the test substance after 5 days was approximately 100%.

The biodegradability of 5-methyl-1*H*-benzotriazole and a technical mixture of 5-methyl-1*H*-benzotriazole and 4-methyl-1*H*-benzotriazole were investigated according to ISO 7827. The individual test substances were used as sole substrate with initial concentrations of 47.8 mg/L (DOC = 30 mg/L). The inoculum, fresh activated sludge, was taken from a lab-scale membrane bioreactor, which was fed with the effluent of the primary treatment of a wastewater treatment plant (mainly domestic wastewater, 30 % industrial input). Adaption of the inoculum was not specified. Complete removal of 5-methyl-1*H*-benzotriazole was observed within 17 days (based on concentrations of test substance). The test with the technical mixture showed similar results for 5-methyl-1*H*-benzotriazole.

Regarding the biodegradability of 4-methyl-1*H*-benzotriazole isomer, the same test (ISO 7827) derived 25 % of degradation (based on concentrations of test substance) within 28 days. No degradation of the test substance was observed in the sterile abiotic control confirming that all detected effects were due to microbial activity. The DS considered that the reliability of the ISO 7827 study was restricted due to missing information on purity of the test substances.

Two inherent biodegradability tests (OECD TG 302B) were available. Methyl-1*H*-

benzotriazole degraded 77 % (in the dark) and 59 % (illuminated by daylight) after 28 days (7-day pass level: 70 and 59 %). Adaption of the inoculum was not stated. In the other test with 4-methyl-1*H*-benzotriazole no degradation, based on DOC, was observed during 28 days in the dark. Information on adaption of the inoculum was missing.

An atmospheric half-life of 3.89 days was calculated (AOPWIN v1.91) for the reaction of Methyl-1*H*-benzotriazole with OH radicals.

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

Bioaccumulation

There was no bioconcentration test data available for fish. The log K_{ow} of 1.08 ± 0.002 from an OECD TG 117 test showed low potential for bioaccumulation for methyl-1*H*-benzotriazole, according to the DS.

Aquatic toxicity

Acute

***Table**: Summary of reliable information on acute toxicity*

Species	Substance	Results [mg/L]	Test method	Reliability/Reference
Fish				
Cyprinodon variegatus	methyl-1*H*-benzotriazole CAS 29385-43-1	96h-LC_{50}= 55	PARCOM 1995 Part B Protocol for a Fish Acute Toxicity Test (modified OECD TG 203 Fish Acute Toxicity Test) (GLP); no analytical monitoring; WAF-test; semi-static; saltwater;	Reliability 1 Registration dossier: (Anonymous, 2003a)
Invertebrates				
Daphnia magna	5-methyl-1*H*-benzotriazole CAS 136-85-6	48h-EC_{50}= 51.6 (nom.)	OECD TG 202; static; analytical monitoring	Reliability 1 Seeland et al., 2012 (*
Daphnia galeata	5-methyl-1*H*-benzotriazole CAS 136-85-6	48h-EC_{50}= 8.58 (nom.)	OECD TG 202; static; analytical monitoring	Reliability 1 Seeland et al. 2012 (*

Acartia tonsa	methyl-1*H*-benzotriazole CAS 29385-43-1	48h-EC_{50}= 55	ISO/CD 14669: Determination of Acute Lethal Toxicity to Marine Copepads and PARCOM Ring Test Protocol: Acute Toxicity to the Marine Copepod Acartia tonsa. (GLP); no analytical monitoring; WAF-test; static; saltwater	Reliability 1 Registration dossier: (Anonymous, 2003b)
Algae				
Skeletonema costatum	methyl-1*H*-benzotriazole CAS 29385-43-1	72h-E_rC_{50}= 53	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum) (GLP); static; saltwater; no analytical monitoring; WAF-test.	Reliability 1 Registration dossier: (Anonymous, 2003c)

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

The only acute toxicity test available for fish gave a 96-hour LC_{50} of 55 mg/L for methyl-1*H*-benzotriazole.

For aquatic invertebrates, there were two studies available (*Daphnia magna, Daphnia galeata*) with 5-methyl-1*H*-benzotriazole. In addition, there was a study with *Acartia tonsa* with methyl-1*H*-benzotriazole. The lowest short-term result for aquatic invertebrates was derived from the test with *Daphnia galeata* (48h-EC_{50} of 8.58 mg/L). *Daphnia magna* was less sensitive with a 48h-EC_{50} of 51.6 mg/L.

The only acute result for algae was a 72-hour ErC_{50} of 53 mg/L for *Skeletonema costatum* with methyl-1*H*-benzotriazole.

The lowest short-term result was a 48-hour EC_{50} of 8.58 mg/L (5-methyl-1*H*-benzotriazole) for *Daphnia galeata*.

All aquatic acute toxicity values were above the classification cut-off 1 mg/L and thus no aquatic acute classification was proposed by the DS.

Chronic

Table: Summary of reliable data on chronic toxicity

Species	substance	Results [mg/L]	Test method	Reliability/Reference
Fish – no studies				
Invertebrates				
Daphnia magna	methyl-1*H*-benzotriazole CAS 29385-43-1	21d-NOEC= 18.4 (nom.)	OECD TG 202, Part II (Draft 7/1993) (GLP); semi-static; analytical monitoring	Reliability 1 Registration dossier: Anonymous, 1995b
Daphnia magna	5-methyl-1*H*-benzotriazole CAS 136-85-6	21d-EC_{10}= 5.93 (nom.)	OECD TG 211; semi-static; analytical monitoring	Reliability 2 Seeland et al., 2012
Daphnia galeata	5-methyl-1*H*-benzotriazole CAS 136-85-6	**21d-EC_{10}= 0.40 (nom.)** 21d-NOEC=1.0 (nom.)	OECD TG 211; semi-static; analytical monitoring	Reliability 2 Seeland et al., 2012
Algae and aquatic plants				
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*)	5-methyl-1*H*-benzotriazole CAS 136-85-6	72h-E_rC_{10} = 2.86 (nom.)	OECD TG 201; static; concentrations; analytical monitoring	Reliability 2 Seeland et al., 2012
Skeletonema costatum	methyl-1*H*-benzotriazole CAS 29385-43-1	72h-NOE_rC= 30	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum) (GLP); static; saltwater; no analytical monitoring; WAF-test	Reliability 1 Registration dossier: (Anonymous, 2003c)
Lemna minor	5-methyl-1*H*-benzotriazole CAS 136-85-6	7d-EC_{10}= 2.11	OECD TG 221; static; analytical monitoring	Reliability 2 Seeland et al., 2012

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

There were no chronic toxicity data on fish available for methyl-1*H*-benzotriazole.

For invertebrates there was one study available for methyl-1*H*-benzotriazole and two studies for 5-methyl-1*H*-benzotriazole. The lowest chronic toxicity value was a 21-day

EC_{10} of 0.40 mg/L for *Daphnia galeata* with 5-methyl-1*H*-benzotriazole.

There was one study on algae available for methyl-1*H*-benzotriazole, whilst for 5-methyl-1*H*-benzotriazole there were studies available for algae and aquatic plant. The lowest chronic toxicity value was a 7-day EC_{10} of 2.11 mg/L for *Lemna minor* with 5-methyl-1*H*-benzotriazole.

Based on Figure 4.1.1 of the CLP Regulation, the aquatic chronic classification is based on the most stringent outcome of the two assessments according to Table 4.1.0 (b) (i) and (iii). The lowest value available was a 21-day EC_{10} of 0.40 mg/L 5-methyl-1*H*-benzotriazole with *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, Table 4.1.0 (b)(i)).

Comments received during consultation

Two Member States supported the proposed classification. A National Authority (NA) asked for further information on the solubility of the test item in test media and actual tests concentrations in the acute Water Accommodated Fraction tests. The DS answered that no more data was available although the substance had a water solubility of 4049.4 mg/L in the OECD TG 105 solubility test.

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.

[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

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* appears 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 effects endpoint for *Daphnia galeata* for hazard classification regarding that the 21-day EC_{10} of 0.4 mg/L is below the 21-day NOEC of 1 mg/L and has confidence intervals of 0.08 – 1.95 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.

Finally, the NA wondered if the Fish Sexual Development Test (OECD TG 234) test for 1*H*-benzotriazole (CAS: 95-14-7) can be used for the purpose of aquatic hazard classification and noted that the study is currently undergoing review as part of the ongoing REACH Substance Evaluation.

The DS agreed that the study could be considered within the overall weight of evidence. RAC decided not to take this study into account for the reasons explained later in this document.

Assessment and comparison with the classification criteria

Comparison with the criteria

Methyl-1*H*-benzotriazole (29385-43-1) is a multiconstituent substance containing two isomers, 5-methyl-1*H*-benzotriazole (CAS 136-85-6) and 4-methyl-1*H*-benzotriazole (CAS 29878-31-7).

Degradation

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

- No ready biodegradation test available with non-adapted inoculum.
- 4 % degradation in 28 days in an OECD TG 301 F ready biodegradability test.
- No surface water simulation test available.
- Methyl-1*H*-benzotriazole being hydrolytically stable at pH 4, pH 7 and pH 9.
- 25% of 4-methyl-1*H*-benzotriazole was degraded within 28 days in a technical

mixture in ISO 7827 study.

- No degradation of 4-methyl-1*H*-benzotriazole in an OECD TG 302 B test.

Therefore, RAC agrees with the DS conclusion that methyl-1*H*-benzotriazole can be considered not rapidly degradable.

Bioaccumulation

RAC agrees with the DS conclusion that methyl-1*H*-benzotriazole has low potential for bioaccumulation even in the absence of an experimental fish bioconcentration study, as the measured low Pow of 1.081 ± 0.002 was below the classification cut-off value of 4.

Aquatic toxicity

Daphnia magna vs Daphnia galeata

RAC notes that regarding the use of other daphnids 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 criterion 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 regarding the mean number of living offspring produced per parent animal surviving at the end of the test being above 60 was not met. RAC, however, agrees that considering the findings from Seeland et al 2021 and Cui et al 2016 articles as presented by the DS, the reproductive output of *Daphnia galeata* appears to be appropriate for the assessment for toxicity testing.

As indicated in the 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 0.40 mg/L with confidence limits of 0.08 – 1.95 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.

Classification approach used by RAC

There were data available both for methyl-1*H*-benzotriazole and one of its ingredients 5-methyl-1*H*-benzotriazole. RAC agrees with the DS that data on 5-methyl-1*H*-benzotriazole is relevant for classification in the absence of data on chronic toxicity of methyl-1*H*-benzotriazole for the most sensitive species (*Daphnia galeata*).

There is no toxicity data available for 4-methyl-1*H*-benzotriazole in the CLH Report but Pillard et al 2001 concluded that all test organisms tested (*Ceriodaphnia dubia, Pimephales promelas*) were more sensitive to 5-methyl-1*H*-benzotriazole than to 4-methyl-1*H*-benzotriazole both in acute and chronic tests.

Acute

RAC agrees with the DS in concluding that acute aquatic classification is not warranted for methyl-1*H*-benzotriazole. All reliable LC/EC_{50} values both for methyl-1*H*-benzotriazole and 5-methyl-1*H*-benzotriazole (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 8.58 mg/L for *Daphnia galeata*.

Chronic

For methyl-1*H*-benzotriazole there were reliable chronic toxicity data available for *Daphnia magna* and *Skeletonema costatum*. For 5-methyl-1*H*-benzotriazole there were data on *Daphnia magna*, *Daphnia galeata, Desmodesmus subspicatus* and *Lemna minor*. The surrogate approach for fish for which there were no chronic fish data on methyl-1*H*-benzotriazole available based on the 96-hour LC_{50} of 55 mg/L methyl-1H-benzotriazole would warrant an Aquatic Chronic 3 classification (Table 4.1.0 (b) (iii) of the CLP Regulation).

RAC is of the view that the use of the Fish Sexual Development Test (OECD TG 234) result of 1.07 mg/L for 1*H*-benzotriazole (CAS: 95-14-7) in the place of the missing information on fish chronic toxicity is not appropriate in this specific case, where there is available reliable acute data on the substance itself to be used as a surrogate approach. Moreover, the acute data leads to a chronic classification whereas the use of data on 1*H*-benzotriazole does not and such approaches are typically not supported by the RAC for removing a classification.

The lowest value available was a 21-day EC_{10} of 0.40 mg/L 5-methyl-1*H*-benzotriazole with *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, Table 4.1.0 (b)(i)).

RAC agrees with the Dossier Submitter's proposal to classify the substance as **Aquatic Chronic 2.**

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13 ANNEXES

Annex I

Confidential Annex