

**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
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

**Adopted**  
**15 September 2022**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1H-BENZOTRIAZOLE

### COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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**Substance name: 1H-benzotriazole**

**EC number: 202-394-1**

**CAS number: 95-14-7**

**Dossier submitter: Germany**

### OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2022	France		MemberState	1
Comment received				
FR supports the proposal to classify the substance 1H-benzotriazole (n° CAS: 95-14-7) Aquatic chronic 2, H411.				
We agree that based on the studies performed according to OECD TG 301D and TG 301B and regarding the results of hydrolysis (according to OECD TG 111), 1H-benzotriazole is considered to be not readily biodegradable. Besides, based on the Kow, the substance is predicted to have a low bioaccumulation potential.				
Concerning the results of acute and chronic toxicity studies, if you have the information, could you please specify if they are nominal or measured values?				
Dossier Submitter's Response				
Thank you for your support. The results of the acute and chronic toxicity studies are nearly all nominal values (as for the studies conducted by Seeland et al., 2012 the measured concentrations deviated less than 20 % from the nominal concentrations). The result of the FSDT is a measured value.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2022	Finland		MemberState	2
Comment received				
The FI CA agrees with the DS that the Substance is not rapidly biodegradable based on two valid OECD TG 301 ready biodegradation studies. The conclusion is further supported with results from OECD TG				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1H-BENZOTRIAZOLE**

	<p>302B inherent biodegradability test. The Substance is also hydrolytically stable at various pH-values (4,7 and 9).</p> <p>The DS reports some evidence that phototransformation may affect the toxicity and degradability of the substance. However, this does not affect the classification, as there is compelling evidence that the Substance is not rapidly biodegradable.</p> <p>No experimental information on bioaccumulation is available. However, FI CA agrees that the bioaccumulation potential of the Substance is low due to low log Kow value of 1.34, derived from valid OECD TG 117 study.</p> <p>Valid acute and chronic aquatic toxicity data is available on all three thropic levels. The most sensitive species for acute and chronic endpoints is invertebrate <i>Daphnia galeata</i> with 48h-EC<sub>50</sub> and 21d-EC<sub>10</sub> value of 15.8 mg/L and 0.91 mg/l, respectively. As the EC<sub>50</sub> value is &gt; 1 mg/L, the Substance does not fulfil the criteria for acute aquatic toxicity. The FI CA agrees with the DS that 1<i>H</i>-Benzotriazole should be classified as Aquatic Chronic 2, based on the results and criteria given in Table 4.1.0(b)(i) of the CLP Regulation.</p>
	Dossier Submitter's Response
	Thank you for your support.
	RAC's response
	Noted.

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2022	Belgium		MemberState	3
Comment received				
<p>BE CA supports the proposed environmental classification of Aquatic Chronic 2, H411 for 1<i>H</i>-benzotriazole.</p> <p>We agree that based on results of the OECD TG 301D and OECD TG 301B studies, 1<i>H</i>-benzotriazole is considered to be not rapidly degradable.</p> <p>BE CA agrees that the classification should be based on the 21d-EC<sub>10</sub> value for aquatic invertebrates of 0.97 mg/L, which leads to the environmental classification of Aquatic Chronic 2, H411 for 1<i>H</i>-benzotriazole.</p>				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2022	United Kingdom	Health and Safety Executive	National Authority	4
Comment received				
<p>1<i>H</i>-benzotriazole (EC: 202-394-1; CAS: 95-14-7)</p> <p>The key study for aquatic chronic 2 classification is a non GLP, academic publication</p>				

(Seeland et al, 2012) using the non-validated invertebrate species *Daphnia galeata* in an OECD TG 211 test design. The study appears to have been well conducted although some relevant information is not presented to consider study reliability/relevance for hazard classification. Therefore, please can the DS clarify if the following information is available /consider contacting the study authors to request details.

We note that 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). If other daphnid are used they should be clearly identified and their use justified.' Therefore, please can the DS confirm if the following validity criteria were met: the mortality of the parent animals (female *Daphnia*) does not exceed 20% at the end of the test. Regarding the second validity criteria of 'the mean number of living offspring produced per parent animal surviving at the end of the test is > 60', we note this was not met. However, the *Daphnia galeata* brood size may be smaller than that of *Daphnia magna* given the smaller physical size of the organism, and therefore, we are unclear whether this cut off is appropriate to assess the reductive output of this species. The percentage or number of dead offspring are not also reported. Is this information available from the study authors as it would be useful to calculate the CoV of living offspring as an indicator of experimental reliability? The study 21-day EC<sub>10</sub> 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. We are therefore unclear if the NOEC would be a preferable key endpoint for *D. galeata* for hazard classification – this would not impact the classification band in this instance.

The Seeland et al 2012 paper includes data for algae (*Desmodesmus subspicatus*) and an aquatic plant (*Lemna minor*) as cited in the CLH dossier. It would be useful for the DS to confirm whether endpoints are based on growth rate – the text indicates they are but Table 2 in the paper is unclear. Also, while it would not impact the classification given the presented EC<sub>10</sub> endpoints, it would be useful to confirm if ErC<sub>50</sub> endpoints are available.

We presume that the chronic Fish Sexual Development Test (OECD 234) is currently undergoing review as part of the ongoing REACH Substance Evaluation. There is limited information presented in the CLH report and the study appears to have some deficiencies, in particular the lack of statistics for the later part of the study. Please can you confirm if the study has been reviewed under Substance Evaluation as the agreed endpoint should be used to inform the hazard classification.

#### Dossier Submitter's Response

Thank you for your comments.

Concerning *Daphnia galeata*: As you describe, this species is smaller than *Daphnia magna*. Seeland et al., 2012 also describes that the difference in brood size was coherent with different body length for *D. magna* and *D. galeata*. Another publication (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>) compared the both species, e.g. in their life span, first brood, total number of offspring.

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1H-BENZOTRIAZOLE**

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*,

	<i>Daphnia galeata</i> <sup>24</sup>	<i>Daphnia magna</i> <sup>25a)</sup>
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

<sup>24</sup> Data from this study

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

We have also contacted the authors to solve the questions. The answer is still pending.

Concerning the use of NOEC or EC<sub>10</sub> from the Daphnia-test: Yes, the use of the NOEC would be a possibility but for us it seems not to be necessary to do so even as the confidence interval spans the CLH classification band.

Concerning the FSDT: The study has been/ is currently reviewed under Substance Evaluation. As the post-hatch survival of the control group at 35 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 NOEC for this endpoint at 35 dpf. All the post-hatch survival rates in this test were above the validity criterion of 75 % of OECD TG 234.

ECHA note – An attachment was submitted with the response from the dossier submitter. Refer to attachment CuiR\_etal\_2016\_JKoreanSEnvironEnDgaleata\_Dmagna.pdf

**RAC's response**

RAC agrees with the Dossier Submitter answer's regarding the use of *Daphnia galeata* studies for classification. RAC also prefers to use EC<sub>10</sub> instead of NOEC and does not need necessary to deviate from this practice in this case.

**PUBLIC ATTACHMENTS (Dossier Submitter's response)**

1. CuiR\_etal\_2016\_JKoreanSEnvironEnDgaleata\_Dmagna.pdf [Please refer to response to comment No. 3]