Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

Adopted

15 September 2022

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: methyl-1*H*-benzotriazole
EC number: 249-596-6
CAS number: 29385-43-1
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 methyl-1*H*-benzotriazole (n° CAS: 29385-43-1) Aquatic chronic 2, H411. We agree that based on the studies performed according to OECD TG 301F and ISO 7827 and regarding the results of hydrolysis (according to OECD TG 111), methyl-1*H*-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 all nominal values (as for the studies conducted by Seeland et al., 2012 the measured concentrations deviated less than 20 % from the nominal concentrations).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2022	Belgium		MemberState	2
Comment received				
BE CA supports the proposed environmental classification of Aquatic Chronic 2, H411 for methyl-1*H*-benzotriazole. We agree that based on results of the OECD TG 301F study, methyl-1*H*-benzotriazole is				

considered not rapidly degradable.

As chronic data are not available for fish, BE CA agrees that the classification should be based on the 21d-EC_{10} value for aquatic invertebrates of 0.4 mg/L. This representing the most stringent outcome, based on NOEC/EC_x available for invertebrates and algae, and LC_{50} for fish, which leads to the environmental classification of Aquatic Chronic 2, H411 for methyl-1*H*-benzotriazole.

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	3

Comment received

Methyl-1*H*-benzotriazole (EC: 249-596-6; CAS: 29385-43-1)
Is there further information regarding the solubility of the test item in test media and actual test concentrations in the acute ecotoxicity tests which are based on nominal WAF concentrations? This is relevant for acute hazard classification and chronic hazard classification given consideration of the surrogate approach.

The key study for aquatic chronic 2 classification is a non GLP, academic publication (Seeland et al, 2012) using the read-across substance 5-methyl-benzotriazole (CAS 136-85-6) and 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_{10} of 0.4 mg/L is below the 21-day NOEC of 1 mg/L (and the 0.5 mg/L treatment with no statistical effects) and has confidence intervals of 0.08 – 1.95 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. It would also be useful to see endpoint data to consider the dose-response curve.

The CLH report notes that there are no long term toxicity to fish data for the substance. We wonder if the chronic Fish Sexual Development Test (OECD 234) for 1*H*-benzotriazole (CAS:

95-14-7) is a relevant read-across endpoint noting the study is currently undergoing review as part of the ongoing REACH Substance Evaluation.

Dossier Submitter's Response

Thank you for your comments.

Concerning the solubility of the test item in test medium in the acute toxicity tests using WAF approach: The short-term fish toxicity test with *Cyprinodon variegatus* used this approach. No analytical measurements of the test substance concentration in the test samples were conducted. According to the water solubility test according to OECD 105, the water solubility of the substance is 4049.4 mg/L at pH 5.65 and 20°C. The concentration of the read-across substance 5-methyl-benzotriazole was analytically determined in the tests conducted by Seeland et al., 2012. Here, a good recovery rate was reported which allowed using nominal test concentrations as basis for the results.

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.

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 *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_{10} 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: It is correct that there is a chronic fish toxicity test (FSDT) available for 1H-benzotriazole, which is currently under review as part of the REACH SEV. This test could be used for the assessment of the chronic fish toxicity of methyl-1*H*-benzotriazole. The key result for the CLH process is a 35d-NOEC of 1.07 mg/L (mean measured concentration) for mortality (post-hatch survival).

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_{10} instead of NOEC and does not need necessary to deviate from this practive in this case. Moreover, 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.

PUBLIC ATTACHMENTS (Dossier Submitter's response)
1. CuiR_etal_2016_JKoreanSEnvironEnDgaleata_Dmagna.pdf [Please refer to response to comment No. 3]