Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)ben zoyl]-4- (phenylthio)bicyclo [3.2.1]oct-3-en-2- one

EC Number: -

CAS Number: 156963-66-5

CLH-O-0000007414-76-01/F

Adopted

14 March 2024

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ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZOBICYCLON (ISO); 3-[2-CHLORO-4-(METHYLSULFONYL)BENZOYL]-4-(PHENYLTHIO)BICYCLO[3.2.1]OCT-3-EN-2-ONE

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: benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo[3.2.1]oct-3-en-2-one
EC number: -
CAS number: 156963-66-5
Dossier submitter: Malta

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany		MemberState	1
Comment received				
We agree that classification for human health hazards is not required.				
Dossier Submitter's Response				
Thank you. Point closed				
RAC's response				
Noted. In the opinion of RAC classification for human health hazards is not required.				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany		MemberState	2
Comment received				
Based on a weight-of-evidence approach, it is concluded, that the positive findings in one in vitro chromosomal aberration assay are false positive, as both in vivo micronucleus tests were found to be negative. No mutagenicity, neither in mammalian, nor in bacterial cells was reported. No classification required.				
Dossier Submitter's Response				
Agree. Point closed				
RAC's response				
Noted. In the opinion of RAC classification for mutagenicity is not required.				

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany		MemberState	3
Comment received				
No classification possible. No studies conducted, no guidelines available. Respiratory sensitisation unlikely due to the negative outcomes of the skin sensitisation studies and the lack of indications for it in the repeated dose studies.				
Dossier Submitter's Response				
Respiratory sensitisation unlikely				
RAC's response				
Noted. In the opinion of RAC classification for respiratory sensitisation is not required.				

OTHER HAZARDS AND ENDPOINTS – Aspiration Hazard

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany		MemberState	4
Comment received				
As benzobicyclone is a solid, this field is not applicable.				
Dossier Submitter's Response				
Agree. Point closed				
RAC's response				
Noted. In the opinion of RAC classification for aspiration hazard is not required.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany		MemberState	5
Comment received				
We agree that benzobicyclon should be considered as not rapidly degradable for the purpose of classification and labelling. However, it could be helpful, if in Table 59: Summary of relevant information on rapid degradability, as result of the Hydrolysis beside the DT50 the sole hydrolysis product, metabolite 1315P-070, were added. The hint on the stability of the 1315P-070 metabolite in the OECD No. 309 and the DT50 in whole system of 167.5 -324 days of 1315P-070 t in the OECD No. 308 were given in Table 59. Furthermore, in 2.9.1.4 a supplemental hint that the metabolite 1315P-070 is the hydrolysis product could be helpful. Further it could be added there that the DT50 in total system of the hydrolysis product is higher than the trigger of 16 days. This could confirm that Benzobicyclon is not rapidly degradable We notice that e.g. in Tables 74 and 75, multiple studies per taxonomic group are indicated as key studies. Generally, only studies yielding the lowest reliable toxicity endpoint per taxonomic group should be marked as key study. We recommend to change the tables accordingly. However, as in Tables 76 and 77 only the actual key studies are given and used for classification, our remark does not influence the overall conclusion. Please consider that in the additional documents provided from the active substance				

renewal procedure (Vol 3 B.9), the data situation on aquatic plants is considered not sufficient. Further studies in addition to the current study with Lemna gibba, e.g. with Myriophyllum spicatum, are required to finalise the assessment. Since aquatic macrophytes are the most sensitive taxon, further studies may yield an even lower EC50/NOEC, which could also affect classification. The current classification proposal should be considered provisional.
Dossier Submitter's Response
Noted. As suggested, the Table 59 and the chapter 2.9.1.4 will be amended by specifying that the metabolite 1315P-070 is the hydrolysis product and that its DT_{50} in total system is higher than the trigger of 16 days. Please note that, in Tables 74 and 75, the RMS already indicated as key studies only those with the lowest reliable toxicity endpoint per taxonomic group. However, this was done both for the active substance Benzobicyclon and for each of its metabolites. We agree that the current classification proposal may be considered as provisional, since further studies on an additional aquatic macrophyte species (i.e. Myriophyllum spicatum) should be submitted.
RAC's response
Thank you for your comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
07.07.2023	Belgium		MemberState	6
Comment received				
Based on the available results in the CLH report on the aquatic toxicity tests, it can be concluded that the aquatic plant Lemna gibba is the most sensitive species (with a 7d ErC50 = 0.00619 mg/L and 7d ErC10 = 0.000447 mg/L). Together with the fact that the substance is not rapidly degradable, it is justified to classify Benzobicylcon, following the classification criteria of regulation 1272/2008, as Aquatic acute 1, H400 and Aquatic Chronic1, H410. Furthermore, the substance shows low potential to bioaccumulate. In view of the proposed classification and toxicity band for acute toxicity between 0.001 mg/L and 0.001 mg/L, an M-factor for acute toxicity of 100 could be assigned and an M-factor for chronic toxicity of 100 (not rapidly degradable substance and ErC10 between 0.0001 and 0.001 mg/L) In conclusion, the proposed environmental classification is supported.				
Dossier Submitter's Response				
Thank you. Please note that the relevant endpoint on *Lemna gibba* for the chronic classification of Benzobicyclon should be the 7d NOE_rC of 0.000167 mg/L, instead of the E_rC_{10} of 0.000477 mg/L. The CLH report will be amended, accordingly. However, the outcome of the environmental classification does not change.				
RAC's response				
Thank you for your comment. Support for the aquatic acute and chronic classification of the substance is noted by RAC. RAC is of the opinion that the 7-d E_rC_{10} of 0.000447 mg/L for aquatic plant *Lemna gibba* should be use as the key value for the chronic classification of the substance. This is in line with the CLP guidance (version 5.0, July 2017) which indicated that preference is given to EC_{10} over NOEC. However, the outcome of the chronic classification of the substance does not change.				

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Date	Country	Organisation	Type of Organisation	Comment number
06.07.2023	France		MemberState	7
Comment received				
FR agrees with the classification proposal for environmental hazard and with the acute and chronic M factors.				
Dossier Submitter's Response				
Noted. Thank you.				
RAC's response				
Thank you for your comment. Support for the aquatic acute and chronic classification of the substance is noted by RAC.				