Committee for Risk Assessment

RAC

Annex 3

Records

of the targeted public consultation following the submission of additional information on the hazard to the aquatic environment

diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide

EC Number: -
CAS Number: 83164-33-4

CLH-O-0000001412-86-285/F

Adopted

13 June 2019

ANNEX 3 – RECORDS OF THE TARGETED PUBLIC CONSULTATION FOLLOWING THE SUBMISSION OF ADDITIONAL INFORMATION ON CLH PROPOSAL ON DIFLUFENICAN (ISO); N-(2,4-DIFLUOROPHENYL)-2-[3-(TRIFLUOROMETHYL)PHENOXY]-3-PYRIDINECARBOXAMIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

The proposal for the harmonised classification and labelling (CLH) of diflufenican (ISO); N-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide (EC 617-446-2; CAS 83164-33-4) was submitted by the United Kingdom and was subject to a public consultation, from 08/10/2018 to 07/12/2018. The comments received by that date are compiled in Annex 2 to the opinion.

After the above public consultation, one study report containing additional information on the hazard to the aquatic environment was submitted to both ECHA and EFSA. The information is relevant to the assessment of the environmental hazards for this substance. This study report is the subject of the present targeted public consultation. A target consultation was launched from 01/04/2019 to 15/04/2019 and the comments received are listed below.

Comments provided during public 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 public 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 public 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.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide
EC number: 617-446-2
CAS number: 83164-33-4
Dossier submitter: United Kingdom

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2019	Finland		MemberState	1
Comment received				
FI CA has evaluated the relevancy and the quality of growth inhibition test with alga Ankistrodesmus falcatus in targeted public consultation of diflufenican (ISO). Validity criteria have been fulfilled and this test has been conducted according to OECD test guideline 201. FI CA considers this study valid for the classification purposes. The most relevant chronic toxicity endpoint is 72 h EC10 value of 0.029 µg/L for growth rate inhibition of Ankistrodesmus falcatus based on nominal concentrations. For acute toxicity the most relevant endpoint is 72 h EC50 value of 0.071 µg/L based on nominal concentrations for growth rate inhibition. Measured concentrations are preferred for the classification. In this study test concentrations were at the start of the exposure between 91 and 110 %, and at the end of the exposure period (72 h) between 91 and 125% of the nominal value. Thus, it can be assumed that diflufenican did not substantially degrade during the test period, and the classification could be based on the nominal test concentrations in this case.				

Solely based on this study M-factor of 1000 for classification Aquatic Chronic 1 (not rapidly degradable substance) and M-factor of 10 000 for classification Aquatic Acute 1 could be warranted for diflufenican (ISO). This would result in different M-factors than currently proposed.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2019	Germany		MemberState	2
Comment received				
The new study for diflufenican with the green algae Ankistrodesmus falcatus is valid and reliable. The study results are relevant for classification and labelling for acute and long-term aquatic hazard.(Aquatic acute 1 and Aquatic chronic 1) The ErC50 (72 hours) of 0.000071 mg a.s./L is now the lowest available data for algae, fish and invertebrates. The acute M-Factor should be therefore 10000. The ErC10 (72 hours) of 0.000029 mg a.s./L is now the lowest available data for algae, fish and invertebrates. The chronic M-Factor should be therefore 1000.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2019	Germany	Bayer AG	Company-Manufacturer	3
Comment received				
Ankistrodesmus falcatus is not a standard species for testing of algae toxicity under laboratory conditions. This species is not described as test species in the current OECD TG 201 and no standardized and validated test conditions are available. Current information implies that the growth of A. falcatus in a standard growth inhibition test over 72 hours is rather slow compared to standard algae test species. In the invalid A. falcatus study as summarized and evaluated in the RAR for diflufenican, the biomass increase of A. falcatus has been 21. In the study open for consultation (20160072) the biomass increase is 38. Furthermore, although fulfilling the respective validity criteria, high variability is observed in the reported growth rates during the main test including both recovery periods. Moreover, in the study report (20160072) it is described that the range finder resulted in 0.5 %, 27% and 90% growth inhibition at the test levels of 0.01, 0.1 and 1.0 µg/L, respectively. Based on these results the ErC50 can be assumed to be around 0.2 µg/L. This would be in line with the green algae endpoint currently used in Tier 1 risk assessment for DFF (based on Pseudokirchneriella subcapitata). The 1st main test of the study open for consultation (20160072) had to be repeated and its data are not reported. It is only stated in the report that this test did not fulfil the validity criteria. The 2nd main				

test resulted in an ErC50 of 0.071 µg/L and in 70% growth inhibition at the test level of 0.1 µg/L. This is very inconsistent compared to the corresponding range finder results and sheds doubt on the scientific robustness of the study. Also considering the fact that two out of three main tests (the study as summarized and evaluated in the RAR for diflufenican and the 1st main test of the study open for consultation (20160072) were invalid) underlines that appropriate laboratory conditions for testing this non-standard species seem to be not yet available.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.04.2019	United Kingdom		MemberState	4
Comment received				
We consider the new algal data to be reliable and valid. The test species is non-standard but all study validity criteria were met, exposure concentrations were maintained and a clear dose-response was observed. On this basis we agree with the using the endpoints for hazard classification would result in Aquatic Acute 1 (M=10,000), Aquatic Chronic 1 (M=1,000).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.04.2019	Belgium		MemberState	5
Comment received				
Although Ankistrodesmus falcatus is not listed in annex 2 of OECD TG 201 (strain shown suitable for the test) other species may be used. The growth inhibition study with the green algae A. falcatus performed according to OECD TG 201 is considered relevant and reliable and should be taken into account for classification purposes of diflufenican. A 72hErC50 of 0.000071 mg/L and a 72hErC10 of 0.000029 mg/L were determined, meaning that A. falcatus is the most sensitive species tested with diflufenican. M-factors should be therefore 10 times more stringent than proposed by UK CA during public consultation. The above results warrant a classification with : Aquatic acute 1, H400 and Macute = 10 000 (0.00001 mg/L <LC50≤0.0001 mg/l) Aquatic Chronic 1, H410 and Mchronic = 1000 (NRD, 0.00001 mg/L<NOEC≤0.0001 mg/l)				
RAC's response				
Noted.				