Committee for Risk Assessment

RAC

Annex 3

Records

of the targeted public consultation following the submission of additional experimental information on aquatic species

(RS)-1-{1-ethyl-4-[4-mesyl-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5-yloxy}ethyl methyl carbonate; tolpyralate

EC Number: -
CAS Number: 1101132-67-5

CLH-O-0000001412-86-268/F

Adopted
15 March 2019

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Following the initial public consultation which ran from 3 May to 2 July 2018, an additional targeted consultation was carried out from 17 to 21 January 2019 following the submission of additional experimental information on aquatic species made available during the parallel ongoing renewal of approval process under Regulation EU 844/2012 for this pesticide-active substance.

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.

Last data extracted on 24.01.2019

Substance name: (RS)-1-{1-ethyl-4-[4-mesyl-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5-yloxy}ethyl methyl carbonate; tolpyralate
EC number: -
CAS number: 1101132-67-5
Dossier submitter: United Kingdom

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2019	Germany		MemberState	1
Comment received				
The DE-CA agrees with the proposal of classification for environmental hazards as Aquatic acute 1 (H400), Aquatic chronic 1 (H410) and the acute M-factor of 10, chronic M-factor of 100.				
RAC's response				
Noted				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2019	United Kingdom		MemberState	2
Comment received				
We welcome the opportunity to consider the new aquatic studies submitted via the pesticide review for tolpyralate in terms of their potential impact on the 2018 harmonised hazard classification proposal. The previous aquatic hazard classification proposal was based on data on both the parent substance and its main degradant (MT-2153) since the substance rapidly degrades in simulation tests. This is primary degradation rather than ultimate degradation and so tolpyralate is considered 'not rapidly degradable' - however, since it is rapidly formed at a high percentage, the toxicity and classification of the main degradant has also be considered. The most recent studies include a new study on the toxicity of tolpyralate to mysid shrimp. This study appears reliable and its 28-day NOEC of 0.022 mg tolpyralate/L still indicates				

that invertebrates are not as chronically sensitive as aquatic plants and so it doesn't alter the original classification proposal

The other study is on the aquatic plant Myriophyllum with the active substance tolpyralate. Although it includes the complicating factor of sediment and analytics at low concentrations and different pH were variable, this new study can probably be considered reliable and of some relevance to classification since Myriophyllum appears to be more sensitive than Lemna. There is little dissipation to sediment and the endpoint was also generated as a mean measured concentration in the water phase. The lowest 14-day NOErC (for all parameters) for Myriophyllum in this new study was 0.000603 mg tolpyralate/L. The lowest 14-day ErC10 for dry weight was however lower at 0.000129 mg tolpyralate/L (mean measured). EC10 values are generally preferred over NOECs for classification purposes if available. So - the lowest new chronic endpoint is still in the range > 0.0001 to ≤ 0.001 mg/l and, since tolpyralate is not 'rapidly degradable', it should still be classified as Chronic 1 with a chronic M-factor of 100 based this time on more reliable data for tolpyralate with Myriophyllum. Ideally a new reliable Myriophyllum endpoint should also be generated on the MT-2153 degradant, however the new data presented do not alter the original classification proposal based on either the parent substance or its major degradant.

RAC's response

Noted. RAC is of opinion that identified uncertainties (related to the pH and lower test concentrations) do not have critical impact on the 14-day study with the aquatic plant *Myriophyllum aquaticum* validity and does not eliminate the reliability of the results on long-term toxicity.

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2019	Germany		MemberState	3

Comment received

The new available study reports for tolpyralate containing additional experimental information for long-term aquatic toxicity are valid and relevant for the assessment of the environmental hazard.
The study with the aquatic plant Myriophyllum aquaticum according to OECD 239 with duration of 14 days fulfils the requirements for a reliable endpoint for classification purposes.

The results from the study are NOErC (14 days) = 0.0006 mg a.s./L (mean measured) and ErC10 (14 days) = 0.000129 mg a.s./L derived for the most sensitive growth rate parameter (dry weight).

The study with the saltwater mysid Americamysis bahia according to EPA OPPTS 850.1350 with duration of 28 days fulfils the requirement for a long term study with the most sensitive aquatic invertebrate species.

The result from the study is NOEC (28 days) = 0.022 mg a.s./L (mean measured) for survival of the adults and EC10 (28 days) = 0.024 mg a.s./L (mean measured) for number of young produced per female. This is clearly below the result of the long-term study with Daphnia magna NOEC (21 days) > 8.94 mg/L.

The new study results confirm the proposed classification of Aquatic Chronic 1, H410, M=100.

RAC's response

Noted.