Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)

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

mandipropamid

EC number:

CAS number: 374726-62-2

CLH-O-0000003601-83-01/A2

Adopted

08 March 2013

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

[ECHA has compiled the comments received via the internet that refer to several hazard classes and has entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.]

Substance name: Mandipropamid
EC number: -
CAS number: 374726-62-2

General comments

Date	Country / Organisation /MSCA	Comment	Dossier submitter's response to comment	The RAC's response to comment
12/04/2012	Germany/ MSCA	The German CA supports the proposed classification.	Noted	Noted
13/04/2012	Spain / MSCA	We agree with the Austrian proposal that no classification for human health is warranted In fact, in order to assess the applications for national provisional authorisations of several plant protection products containing the active substance mandipropamid, we reviewed the monograph prepared by Austria in the context of inclusion of mandipropamid in Annex I of the Council Directive 91/414/EEC (draft-2006 and revision 1-July 2011) and reached the same conclusions concerning the classification and labelling with regard to toxicological data, i.e., no classification for human health is justified.	Noted	Noted
13/04/2012	Switzerland / Syngenta Crop Protection AG / Company-Manufacturer	Page 28: In 2009, a new chronic Daphina study was issued. It was provided to the Commission and the RMS for Mandipropamid for their evaluation in 2010. We note that this study is not included in the CLH Report so we would therefore like to bring it to the attention to ECHA.	Noted	Thank you. RAC checked the original report of this additional study and acknowledges the particular relevance of this study for adequate classification of chronic

Date	Country / Organisation /MSCA	Comment	Dossier submitter's response to comment	The RAC's response to comment
				aquatic toxicity. A robust study summary is included in the opinion.

Other hazards and endpoints

Date	Country/ Organisation /MSCA	Comment	MSCA Response to comment	RAC response to comment
12/04/2012	Belgium/ MSCA	Environment : Based on the results of the aquatic toxicity test on the most sensitive species (Eastern oyster, 96hEC50=0.97mg/l (mm); Daphnia magna, 21dNOEC= 0.28mg/l (mm)) the fact that the substance is considered as not rapidly degradable (not readily degradable and low ultimate degradation in biotic and abiotic degradation studies) it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic Acute 1, H400 and Aquatic chronic 2,H411. The substance shows low potential to bioaccumulate (BCF corrected for lipid content between 35-48) In view of the proposed classification and toxicity band for acute toxicity between 0.1 and 1 mg/l, an M-factor for acute toxicity of 1 could be assigned. Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, Mandipropamid should be classified as N, R50/53. In conclusion: we agree with the proposed environmental classification by the Austrian MSCA. Some editorial or/and minor comments: • We recommend a continuous page numbering, and not a re-numbering by chapter • 5.1.2.3 Simulation tests Water/sediment studies	Noted Will be considered in Rev. 3 of the CLH Report.	Noted. Based on the additional *Daphnia* reproduction test (NOEC 0.076 mg/L), the conclusion for classification of chronic aquatic toxicity is however amended to chronic 1, H410, with M = 1. Noted, not directly relevant for RAC opinion - see appended revised version of CLH report

Date	Country/ Organisation /MSCA	Comment	MSCA Response to comment	RAC response to comment
		p. 4 last sentence : "… the recovery of applied recovery …" should read as "the recovery of applied radioactivity …" • Summary and discussion : acute (short-term) aquatic toxicity P.36, conclusion Based on the results from the acute aquatic tests, there is only acute toxicity seen for Crassostrea and NOT for fish, invertebrates, algae en water plants.		for details.
13/04/2012	France / MSCA	We agree with the classification proposal. p 18 point 5.3.2: Typo : the sentence "Based on the logKow (3.2)" is not complete.	Noted Will be considered in Rev. 3 of the CLH Report.	Noted, not directly relevant for RAC opinion - see appended revised version of CLH report for details.
13/04/2012	Switzerland / Syngenta Crop Protection AG / Company-Manufacturer	Page 38 and following, aquatics:It has been proposed by ECHA that mandipropamid should be labeled R50 based on the Eastern Oyster (Crassostrea virginica) EC50 at 0.97 mg/L. Syngenta respectfully disagrees with this classification and labelling. Please see attached statement for details. *ECHA comment: The document: Classification and labelling aq mandipropamid_final.docx was submitted as a separate attachment.* *The relevant text of the document is copied below.* According to the CLP guideline on Aquatic toxicity point 4.1.3.2.3.1 "*Fish, crustacea and algae or other aquatic plants are tested as surrogate species representing a range of trophic levels and taxa, and the test methods are highly standardised (see Annex I for further details). Valid data for short- and/or long term tests on other organisms shall also be considered, provided they represent equivalent species and test endpoints...".*	We do not agree with the proposal, to use the acute fish (*Oncorhynchusmykiss*) endpoint of >2.9 mg/L for classification and labelling. We still prefer the Eastern Oyster endpoint (Crassostrea virginica) EC50 at 0.97 mg/L. This test was conducted under EPA Guideline OPPTS 850.1025 and is used to develop data on the **acute toxicity** (EC50 Shell deposition) to Eastern oysters. According to Regulation (EC) No 1272/2008 4.1.1.2.2 > freshwater and marine species toxicity data are considered: *"Preferably data shall be derived using the standardised test methods referred to in Article 8(3). In practice data from*	Noted. RAC agrees to DS arguments and additionally points to consistency of all toxicity data available, both within and across acute and chronic. Although in both classes only a minority of the values meet the criterion for CLP categories acute and chronic 1, those values are considered conclusive, reliable and representative for aquatic hazards, thus justifying a classification based on these most sensitive organisms tested, i.e. R50/53 under DSD criteria.

Date	Country/ Organisation /MSCA	Comment	MSCA Response to comment	RAC response to comment
		Syngenta does not consider 96 hour shell deposition in oyster to be an equivalent test endpoint to a crustacean 48 hour EC_{50}. This is because the 48 hour EC_{50} should be based on an acute endpoint and in aquatic ecotoxicology acute endpoints are based on mortality or immobilization. Shell deposition of the Eastern Oyster is a growth endpoint and not equivalent to the crustacean EC_{50}. In the OECD guidelines[1] acute endpoints do not contain any growth endpoint (e.g. OECD 202 and 203) and thus using growth endpoint does not seem to be in line with the OECD guidelines. Syngenta therefore believes that the classification should be based on the most sensitive appropriate endpoint, the acute fish (*Oncorhynchusmykiss*) endpoint of >2.9 mg/L which suggests that mandipropamid should be labelled R51. *End of attachment*	*other standardised test methods such as national methods shall also be used where they are considered as equivalent. Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006.* ***In general, both freshwater and marine species toxicity data are considered."*** According to Annex 9 Guidance on hazards to the aquatic environment UNO 2007 *"Acute toxicity is generally expressed in terms of a concentration which is lethal to 50% of the test organisms (LC50, causes a measurable adverse effect to 50% of the test organisms (e.g. immobilization of daphnids),* ***or leads to a 50% reduction in test (treated) organism responses from control (untreated) organism responses (e.g. growth rate in algae)."***	RAC agrees in principle to consider results of a standardised and validated US-EPA OPPTS Ecological Effects Test Guideline designed for measuring acute toxicity as relevant for classification purposes. RAC final conclusion in this specific case is based on additional considerations, see above and opinion text.

ATTACHMENTS RECEIVED: 1

Classification and labelling aq mandipropamid_final.docx submitted by Switzerland / Syngenta Crop Protection AG / Company-Manufacturer. Relevant text of comment is copied in the table.

[1] http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761