Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

isoxaflutole

EC number: -

CAS number: 14111-29-0

CLH-O-0000002522-82-03/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 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: isoxaflutole
CAS number: 14111-29-0
EC number: -
Dossier submitter: Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
21/06/2012	Germany	Bayer CropScience AG	Company-Manufacturer	1
Comment received				
Page 17 (Table 11) and page 21 (point 5.2.2, volatilization). Henry constant should read 1.87 x 10-5 Pa m3/mol instead of 1.87 x 105 Pa m3/mol.				
Dossier Submitter's Response				
We agree with the comment. The value should be adapted.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	Spain		MSCA	2
Comment received				
p. 18 Summary and discussion on human health hazard assessment Isoxaflutole is a substance classified in Annex VI of Regulation 1272/2008 as Repr. 2, H361d***: Suspected of damaging the unborn child according to the CLP Regulation and as Xn; Repr. Cat. 3 R63 (Possible risk of harm to the unborn child) according to Directive 67/548/EC. After a detailed review of all available data (Draft Assessment Report and subsequent Addenda, Netherlands as RMS) the Spanish CA agrees with the Netherlands decision not to modify the current classification of the active substance isoxaflutole.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted – human health data and information not checked by the RAC.				

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	France		Company-Manufacturer	3
Comment received				
p.5 and following: although the translation of R63 to H361d*** is correct, we do not feel that the classification of isoxaflutole for developmental toxicity is correct based on the information provided in the submitted paper. ECHA comment: *The document: Isoxaflutole, Lack of justification for the H361d*** (isoxaflutole, lack of justification for H361d.pdf) was submitted as a separate confidential attachment.*				
Dossier Submitter's Response				
See the reaction to comment 4				
RAC's response				
Noted – human health data and information not checked by RAC.				

CARCINOGENICITY – no comments received
MUTAGENICITY – no comments received

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	France		Company-Manufacturer	4

Comment received

p.5 and following: although the translation of R63 to H361d*** is correct, we do not feel that the classification of isoxaflutole for developmental toxicity is correct based on the information provided in the submitted paper.

ECHA comment: *The document: Isoxaflutole, Lack of justification for the H361d*** (isoxaflutole, lack of justification for H361d.pdf) was submitted as a separate confidential attachment.*

Dossier Submitter's Response

This dossier was only intended to change the environmental classification of isoxaflutole. The information provided by the company-manufacturer on the developmental classification is outside the scope of our proposal. No information on reproductive toxicity was included in our proposal. Therefore, there was no possibility for others to react in the public consultation to the change in classification for developmental toxicity as proposed by the Company-manufacturer during the public consultation. We suggest the company-manufacturer to submit the new information to the competent authority in one of the member states where the substance is placed on the marked (CLP article 37.6). This competent authority can than decide whether to propose a change of the existing classification.

RAC's response

Noted – human health data and information not checked by RAC.

RESPIRATORY SENSITISATION – no comments received

OTHER HAZARDS AND ENDPOINTS

Aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
25/06/2012	Belgium		MSCA	5

Comment received

Based on the results of the aquatic toxicity test (most sensitive species : Lemna gibba), the fact that the substance is not rapidly biodegradable and that the substance shows low potential to bioaccumulate, it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic acute 1, H400 and Aquatic chronic 1, H410.

In view of the proposed classification and the L(E)C50 for acute toxicity (6dErC50 Lemna gibba = 0.0219mg/l), an M-factor for acute toxicity of 10 could be assigned, and an M-factor for chronic toxicity of 100(not rapidly degradable substance and toxicity band between 0.0001 and 0.001 mg/l).

Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, Isoxaflutole should be classified as N, R50/53.

In conclusion : we agree with the proposed adaptation of the environmental classification to the 2nd ATP by the NL MSCA.

Some editorial or/and minor comments:
The Henry law constant should be 1.87x10-5 instead of 1.87x 10 5

Dossier Submitter's Response

Thank you for your support and for pointing out the typing error, the Henry's law constant should indeed be 1.87x10-5 instead of 1.87x 10 5.

RAC's response				
Noted and agree				
Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
28/06/2012	France		MSCA	6
Comment received				
p 25: Concerning the re-calculation of the Lemna gibba endpoint in study 1, is the design of the EPA guideline for 14-day study relevant for this calculation at 6 days? With the initial value at 14 days indicated in the DAR, the acute M factor would not be the same (100 instead of 10).				
Dossier Submitter's Response				
In the EPA 14-day study, measurements were taken at day 3, 6, 9, 12 and 14. The EC10 and EC50 values used are based on a 6-day exposure period. A 6-day period was used since the control cultures did grow exponentially over this period whereas non-exponential growth was observed at days 9, 12 and 14. The OECD 221 guideline states that exponential growth of control cultures is a principle of this test. Therefore, a 6-day EC10 and EC50 were recalculated. The exposure period of 6 days is in good agreement with the exposure period of 7 days that OECD guideline 221 recommends. In conclusion, it is our view that the 14-day EPA study can be used for the calculation of the 6-day EC10, EC50 and M-factors since periodic measurements of growth were made over the study duration and the growth of the control cultures was exponential during the 6 day period.				
RAC's response				
Noted and agree with specific arguments of DS regarding exponential growth as prerequisite for valid growth inhibition data. RAC did not check original study report, raw data or recalculation of ECs.				

REFERENCES: None

ATTACHMENT RECEIVED: 1

*Isoxaflutole, Lack of justification for the H361d*** (isoxaflutole, lack of justification for H361d.pdf)* , submitted by France is a confidential document. Comment no. 3 and 4.