Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

(RS)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl]acetamide; mandestrobin

EC Number: -
CAS Number: 173662-97-0

CLH-O-0000001412-86-151/F

Adopted
15 March 2017

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON (RS)-2-METHOXY-N-METHYL-2-[A-(2,5-XYLYLOXY)-O-TOLYL]ACETAMIDE; MANDESTROBIN

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

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.

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Substance name: (RS)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl]acetamide; mandestrobin
CAS number: 173662-97-0
EC number:
Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
14.07.2016	Belgium		MemberState	1
Comment received				
We want to thank the Austrian CA for the very well elaborated CLH report.				
Dossier Submitter's Response				
Thank you!				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
12.07.2016	France		MemberState	2
Comment received				
We agree with the proposal to have no classification for Human Health and the classification proposal for environmental hazards. Test material purity: Part A, 1.1 (p6): It is mentioned that the technical material does not contain relevant impurities. However, according to Efsa Conclusions (EFSA Journal 2015;13(5):4100), Xylenes (ortho, meta, para), ethyl benzene (max. 5 g/kg (TK)) has been identified as relevant impurities. Part B, 1.2 (p12): there is no typical purity as stated in table 5. The minimum purity is 940g/kg (dry weight basis).				
Dossier Submitter's Response				
No comment on the proposal for classification.				

Part A, 1.1 (p6): During the revision of the CLH report after ECHA accordance check the addition of the impurities in this table was forgotten. It is however present in Part B, 1.2 table 6.

Part B, 1.2 (p12): the CLH-report format requires "typical purity" in table 5. We agree that the mentioned purity is a minimum purity, this is explained in the next column (concentration range).
The value of 934 g/kg is taken from the (eco)tox-batches. This was required by ECHA during the Accordance check (March 2016).

RAC's response

No comment on the proposal for classification.
RAC agrees with the presentation of impurities.

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2016	Germany		MemberState	3

Comment received

The German CA supports the proposed non classification for human health and the proposed environmental classification as Aquatic Acute 1 and Aquatic Chronic 1 as well as the corresponding M-factors of 1 and 10 respectively.

In Part A, Table 1 it is stated, that there are no relevant impurities. In Part B, 1.2 Table 6 xylenes (ortho, meta, para) and ethyl benzene are stated as relevant impurities. From the German CAs point of view both impurities should be mentioned in Part A with their respective maximum concentration (i.e. 5 g/kg).

Dossier Submitter's Response

No comment on the proposal for classification.

Part A, Table 1: During the revision of the CLH report after ECHA accordance check the addition of the impurities in this table was forgotten. We agree that the impurities should be mentionend here.

RAC's response

No comment on the proposal for classification.
RAC agrees that the impurities should be mentioned.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
14.07.2016	Belgium		MemberState	4

Comment received

Based on the results of the aquatic toxicity test on the most sensitive species (Invertebrate : mysid shrimp Americamysis bahia with 96hEC50 = 0.43mg/l, 36dNOEC = 0.0056mg/l), the fact that the substance is not rapidly degradable it is justified to classify, following the classification criteria of the regulation 1272/2008, as Aquatic acute 1, H400 and Aquatic Chronic 1, H410. Furthermore, the substance does not meet the criteria for bioaccumulation (BCF = 8 <500).

In view of the proposed classification and toxicity band for acute toxicity between 0.1 mg/l and 1 mg/l, an M-factor for acute toxicity of 1 could be assigned and an M-factor for

chronic toxicity of 10 (not rapidly degradable substance and NOEC between 0.001 mg/l and 0.01 mg/l)

In conclusion : we support the proposed environmental classification.

Some editorial comments :
An inconsistency in the author mentioned for the "Full life cycle toxicity test with water flee Daphnia magna under Flow through conditions – ROW-0020" : on p. 298 it is Sayers Lee, 2010 while in Table 112 the study with the same results is reported under ROW-0012 with Putt A.E., 2006b as author.

In Table 112, the Claude et al, 2012 study with Americamysis bahia mentions a 36dNOEC, while on p 305-306 a 34d NOEC is mentioned.

Dossier Submitter's Response

No comment on the proposal for classification.

The study author of the full life cycle test with Daphnia magna is Sayers, Lee E. (2010). Table 112 was amended accordingly.
The duration of the study by Claude et al (2012) was 36 days. The study report on page 305-306 was corrected accordingly.

RAC's response

No comment on the proposal for classification.
RAC agrees with the amendements.

Date	Country	Organisation	Type of Organisation	Comment number
12.07.2016	France		MemberState	5

Comment received

p. 264: NOECgrowth for Hyalella azteca does not seem to be "10 mg a.s./kg" but "5 mg a.s./kg". Could you check, please ?

Dossier Submitter's Response

Agreed. The $NOEC_{Growth}$ is 5 mg a.s./kg based on mean measured concentrations. Table 112 was corrected accordingly.

RAC's response

RAC agrees with the correction. The $NOEC_{Growth}$ should be 5 mg a.s./kg based on mean measured concentrations.

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2016	Germany		MemberState	6

Comment received

Page 264, Table 112: summary of relevant information on aquatic toxicity

The endpoints of the flow-through study with Hyalella azteca over 42 days (Thomas et al, 2013c) should be amended as mean measured values NOEC = 5.0 mg a.i./kg sediment and EC50 > 14.0 mg a.i./kg sediment instead of NOEC = 10.0 mg a.i./kg sediment and EC50 > 30.0 mg a.i./kg sediment, because these are nominal values.

The NOEC for growth rate of the 7-day static renewal test with Lemna gibba (Jacobs et al,

2012a) should be 0.32 mg a.i./L (mean measured) instead of 2.3 mg a.i./L. These minor corrections have no influence on the classification and labeling of Mandestrobin
Dossier Submitter's Response
Agreed. The $NOEC_{Growth}$ is 5 mg a.s./kg based on mean measured concentrations. The $EC_{50\ Growth}$ is greater than 14 mg a.s./kg. Table 112 was corrected accordingly. The NOEC for growth rate is 0.32 mg a.s./L, table 112 was corrected accordingly.
RAC's response
RAC agrees with the use of measured means for the endpoints (NOEC and EC50) of the flow-through study with *Hyalella azteca* over 42 days (Thomas et al, 2013c). RAC also agrees with the NOEC for growth rate being 0.32 mg a.s./L.