

**Committee for Risk Assessment**  
**RAC**

Annex 2

**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of

**mesosulfuron-methyl (ISO); methyl 2-[(4,6-  
dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]- $\alpha$ -  
(methanesulfonamido)-*p*-toluate**

**EC Number: -**

**CAS Number: 208465-21-8**

CLH-O-0000001412-86-131/F

**Adopted**  
**9 December 2016**

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON MESOSULFURON-METHYL (ISO); METHYL 2-[(4,6-DIMETHOXYPYRIMIDIN-2-YLCARBAMOYL)SULFAMOYL]-A-(METHANESULFONAMIDO)-P-TOLUATE**

**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: mesosulfuron-methyl (ISO); methyl 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-a-(methanesulfonamido)-p-toluate**  
**EC number: -**  
**CAS number: 208465-21-8**  
**Dossier submitter: France**

**GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
25.01.2016	Spain		MemberState	1
Comment received				
The Spanish CA supports not classification regarding human health				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
05.02.2016	Germany		MemberState	2
Comment received				
The German CA supports the proposed harmonised classification as Aquatic Acute 1 and Aquatic Chronic 1 as well as the corresponding M-factors of 100.				
However, in Part A of the CLH report under section 1.1 the first substance which is stated is mesosulfuron which is furthermore named as "parent compound" in table 1.1-1. In this table also the substance identity (i.e. Name and EC No, CAS No) for three substances are given. These are mesosulfuron-methyl, mesosulfuron and mesosulfuron-methyl-sodium.				
In Part B of the CLH report the identity data of these three substances are also given in section 1.1 without further information. The substance composition is only given for mesosulfuron-methyl which is also the test substance for the cited physicochemical, toxicological and ecotoxicological tests.				

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<p>It is not apparent to us why the other two substances are mentioned in this dossier as the IUCLID Dossier and the Cover page of the CLH report are indicating that the CLH dossier refers solely to the substance mesosulfuron-methyl. Further elaboration for the sake of clarity why these substances are mentioned would be helpful.</p> <p>In the case that all three substances should be classified we like to note that these are three different substances and that for each individual substance an own CLH dossier should be prepared.</p>
<b>Dossier Submitter's Response</b>
<p><u>Classification proposal:</u> Thank you for your support.</p> <p><u>Substance identity:</u> Mesosulfuron is the ISO common name. The active substance manufactured is the variant mesosulfuron-methyl. All data are related to this variant. The representative formulation contains the variant mesosulfuron-methyl-sodium, which is prepared from mesosulfuron-methyl (the manufactured active substance) in the first step of the formulation process. Therefore, for better clarity, only mesosulfuron-methyl shall be considered in the CLH report proposal.</p>
<b>RAC's response</b>
Noted.

**OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment**

Date	Country	Organisation	Type of Organisation	Comment number
05.02.2016	Sweden		MemberState	3
<b>Comment received</b>				
<p>The Swedish CA support the classification of Mesosulfuronmethyl in Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) as specified in the proposal. This conclusion is based on the effect of the most sensitive aquatic plant Lemna gibba and that the substance is not rapidly degradable and has a low bioaccumulation potential. The SE CA do agree with the rationale for the setting of M-factors of 100 for both acute and chronic toxicity for the aquatic organisms.</p> <p><u>Minor comments:</u> It would have been helpful in the assessment if key and supportive studies were identified and also if reliability of the studies were indicated.</p>				
<b>Dossier Submitter's Response</b>				
<p>Thank you for your support. All aquatic toxicity studies reported in the CLH report are reliable. In "algae and aquatic plants" part (5.4.3), the key study for classification was identified as follows: "This study is considered to be relevant and reliable and is carried forward for classification purposes with a 7-day ErC50 of 1.29 a.i./L and 7-day NOErC of 0.388 µg a.i./L" and a detailed summary of this study was reported in CLH report.</p>				
<b>RAC's response</b>				
Noted.				

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Date	Country	Organisation	Type of Organisation	Comment number
05.02.2016	Belgium		MemberState	4
Comment received				
<p>With the exception of the more detailed description for the study on <i>Lemna gibba</i>, little information is given for the other reported studies on aquatic toxicity (reliability, material and methods, possible deviations from the guideline and the impact on the results, ...) which makes it difficult to make an objective evaluation of the environmental hazards and to decide which study should be regarded as key study.</p> <p>Nevertheless, it is clear that <i>Lemna gibba</i> (aquatic plant) is the most sensitive species tested.</p> <p>Based on the results of the aquatic toxicity test on <i>Lemna gibba</i> (7dErC50&lt;1mg/l and a 7dNOEC=0.388µg/l) , the fact that the substance is not rapidly degradable it seems justified to classify mesosulferon-methyl as Aquatic acute 1, H400 and Aquatic chronic 1, H410 .</p> <p>In view of the proposed classification and the toxicity band for acute and chronic toxicity a M-factor for acute and chronic toxicity of 100 seems appropriate.</p>				
Dossier Submitter's Response				
<p>All aquatic toxicity studies reported in the CLH report are reliable. Detailed description of these studies are reported in the RAR volume 3 CA-B9. A detailed description of the key study for classification (study on the most sensitive species <i>Lemna gibba</i>) is reported in the CLH report.</p>				
RAC's response				
Noted.				