Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

metosulam

EC number: -
CAS number: 139528-85-1

CLH-O-0000002525-76-03/A2

Adopted

7 June 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: Metosulam
EC number: -
CAS number: 139528-85-1
Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
27/06/2012	Germany		MSCA	1
Comment received				
The German CA supports the proposed classification of Metusolam as Carc. 2 - H351				
Dossier Submitter's Response				
-				
RAC's response				
RAC supports the classification proposal of the DS.				

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	Denmark		MSCA	2
Comment received				
The Danish Competent Authority agrees with the French Proposal for the classification of metosulam as Carc3; R40 Xn; R48/22 N; R50/53 with SCLs C > 0.025% N;R50/53 0.0025% < C < 0.025% N;R51/53 0.00025% < C < 0.0025% N;R52/53 according to DSD and Carc2 H351 STOT-RE 2 H373 Acute cat 1 H400; M-factor 1000 Chronic category 1 H410; M-factor 10 according to CLP.				
Dossier Submitter's Response				
-				
RAC's response				
RAC supports the classification proposal of the DS.				

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	France	Bayer CropScience / Germany	Company-Manufacturer	3
Comment received				
page 16 paragraph 2.2 : The product is also intended for outdoor use under home garden conditions on natural surfaces, not intended to bear vegetation and permeable surfaces overlying soil such as gravel terraces, walkways, paths and drives and other garden places such as under and around trees, fruit trees, hedges, shrubs and woody ornamentals and along fences, walls and on waste ground.				
Dossier Submitter's Response				

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RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS

Specific target organ toxicity – repeated exposure

Date	Country	Organisation	Type of Organisation	Comment number
27/06/2012	Germany		MSCA	4
Comment received				
pp. 27-59 We propose to report the NOAELs in the conclusions on the studies.				
Dossier Submitter's Response				
The LOAELs derived from the effects considered relevant for classification are given in the conclusion of each study. This is deemed sufficient to establish the classification.				
RAC's response				
RAC supports the DS as LOAELS are required for comparison to the classification cut off limits while NOAELS are of limited relevance to classification.				

Aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
07/06/2012	Netherlands	RIVM Bureau REACH	MSCA	5
Comment received				
To further substantiate the argumentation that the degradation products are not classifiable we would like to invite the dossier submitter to provide evidence that these compounds are not more toxic for daphnia and fish than the parent compound.				
Dossier Submitter's Response				
No toxicity data are available for daphnia and fish in the DAR of metosulam for the degradation products. However, a low toxicity is observed for fish (LC50 > 29.3 mg/L) and for daphnia (EC50 > 100 mg/L) for the parent and the degradation products are at least 1080 and 10 000 times less toxic than the parent for algae and aquatic plant, respectively. Therefore, since a significant decrease of toxicity is observed for the most sensitive species for the metabolites, it is considered that the data on fish and daphnia are not required to conclude on the non classification for the degradation products. Indeed, toxicity values < 1 mg/L are not expected for the degradation products.				
RAC's response				
RAC does not see the connection between the toxicity of the parent compound and the metabolites. Therefore RAC agrees with the MS. However, there are also other data gaps on metabolites that lead to the conclusion 'not rapidly degradable'.				
Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
25/06/2012	Belgium		MSCA	6
Comment received				
We agree partially with the proposed environmental classification by the FR MSCA: We are of the opinion that the substance should be considered as NOT rapidly degradable as it is not demonstrated that the substance ultimately degrades. In the aqueous simulation test a DT50 <16 days was determined with forming of 3 major metabolites which are not classified for the environment. However it is stated that mineralisation only accounted for a maximum of 3.6% of AR at day120. Also in the soil study no ultimate degradation is demonstrated. DAR : The Baloch R; Grant R (1192) aerobic degradation study in four soils concludes that				

mineralisation occurs at a generally low extent, reaching 10% AR 122DAT in the soil with the highest microbial activity.
For field soils a DT50 of 31.9 days is determined but no info is given on mineralisation.

Based on the results of the aquatic toxicity test (most sensitivie species Lemna minor : 7dErC50=0.789µg/l; 7dNOErC= 0.15µg/l), the fact that the substance, in our opinion, is NOT rapidly biodegradable and that the substance is considered to show 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, an M-factor for acute toxicity of 1000 (0.0001mg/l≤LC50<0.001 mg/l) could be assigned.

Based on the above, we believe that an M-factor for chronic toxicity of 100 is more appropriate (not rapidly degradable substance and toxicity band between 0.0001mg/l and 0.001 mg/l).

Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, Metosulam should be classified as N, R50/53 (LC50≤1mg/l + not rapidly degradable).

Some editorial or/and minor comments:
P 94. 5.3.1 Bioaccumulation
A BCF study was performed according to OECD guideline 305 (Hawkins et al., 1992). It is stated that there was no evidence of bioaccumulation. Please mention the result of this study and compare it with the criteria for DSD (BCF >100) and CLP (BCF>500).

Dossier Submitter's Response

Response for the rapidly degradation:
Considering your comments and the comments number 7, France agrees with the fact that the metosulam as a rapidly degradable substance is not fully demonstrated. Then France support the new M-factor for chronic toxicity of 100.

Response to the minor comments:
In the BCF study, there was no evidence of bioaccumulation of metosulam in fish tissues after exposure to the active substance for 96 hours at the actual concentrations of 0.08 and 0.8 mg/L. The BCF could not be calculated as the radioactivity levels in fish were all below the limit of quantification (0.032 mg/kg for the low level and 0.28 mg/kg for the high level). Then, it is assumed that the BCF is below 100.

RAC's response

RAC agrees with the MS comments on degradation and with the new M-factor. RAC welcomes the detailed data from the BCF test.

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	Sweden	KEMI	MSCA	7

Comment received

In general, we support the dossier submitter in its proposal to classify the substance for the aquatic hazard. We do however have some specific comments regarding assessment of degradation of the substance.
According to the dossier submitter the substance should be regarded as rapidly degradable according to CLP criteria (which explicitly allow taking into account degradation products while assessing degradation of parent compound) but not readily degradable based on the DSD criteria. Although we understand that the lack of similar wording in DSD (compared to CLP) lies behind the proposed not readily biodegradability of the substance according to DSD, we would like to point out that the CLP approach was already applied under DSD by the TCC&L mainly because the group used the GHS guidance for the assessment of biodegradation. Therefore in our opinion, the assessment of biodegradation is similar in both legislations, although the criteria are more clearly stated in CLP.
Taking into consideration degradation products in water/sediment study the dossier submitter concludes that the substance is rapidly biodegradable. In general we agree that the formed

metabolites are not classifiable (based on toxicity data) but we believe that more information is needed in order to conclude whether (i) the DT50 means degradation or dissipation and (ii) how much of the parent compound is transformed into degradation products. According the data in the dossier around 60% AR is measured 120 DAT in bound residues. This would imply that a considerable amount of the parent compound does not undergo the primary degradation but is bound into the residues. If so we do not believe that the criterion for fast primary degradation is met and the reason for substance to be considered as rapidly degradable is absent.

Dossier Submitter's Response

See response to the comment number 6.

RAC's response

RAC agrees with the MS comments on degradation of metosulam. RAC also agrees with the MS view that there is no difference in the concepts rapidly degradable (CLP) and readily degradable (DSD) in practice.

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	United Kingdom	HSE UKCA	MSCA	8

Comment received

We do not feel the current dossier includes sufficient evidence to justify the substance as rapidly degradable for classification. We think that more explanation of the aquatic fate of the parent and it's degradants is needed, for example, do metabolites M01, M02 and M04 undergo degradation to produce further metabolites? Details of aquatic ecotoxicity of degradants M01, M02 and M04 are not presented in the dossier. Whilst the parent is most toxic to algae/aquatic plants the dossier does not provide evidence that the same sensitivity occurs in the degradants.

Dossier Submitter's Response

For rapidly degradation, see response to the comment number 6.
For the aquatic toxicity of degradants, see response to the comment number 5.

RAC's response

RAC agrees with MS comments on degradation and aquatic toxicity.

REFERENCES: None

ATTACHMENTS RECEIVED: None