Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

clethodim (ISO); (5RS)-2-{(1EZ)-1-[(2E)-3-chloroallyloxyimino] propyl}-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one

EC Number: -
CAS Number: 99129-21-2

CLH-O-0000001412-86-91/F

Adopted

4 December 2015

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON CLETHODIM (ISO); (5RS)-2-{(1EZ)-1-[(2E)-3-CHLOROALLYLOXYIMINO]PROPYL}-5-[(2RS)-2-(ETHYLTHIO)PROPYL]-3-HYDROXYCYCLOHEX-2-EN-1-ONE

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: Clethodim (ISO); (5RS)-2-{(1EZ)-1-[(2E)-3-chloroallyloxyimino]propyl}-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one
CAS number: 99129-21-2
EC number:
Dossier submitter: Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
26.05.2015	Germany		MemberState	1
Comment received				
The proposed classification of Aquatic Chronic 3 H412, Acute Tox. 4 H302 and Skin Sens. 1 H317 is supported by the German CA. In addition we propose to classify as Skin Irritant, Cat 2 H315 (see specific comment below). General comment on substance identity: * In section 1.2 of the IUCLID file only the purity of the substance and impurities are given. The field "Constituents" is left empty. Please fill in the missing information. *In section 13 of the IUCLID file the assessment report is attached. In the document "NL_AVI CLH reportACC_clethodim _Jan2015.doc" the following aspects have been noticed: - In Part B, section 1.1, table 4, column 2 the fields "EC number", "EC name" and "CAS number (EC inventory)" are left empty. In order to avoid misunderstandings it should be clearly stated, that there is no entry for Clethodim in the EC inventory e.g. by adding "n. a." in the corresponding field. - In Part B, section 1.1, table 4, column 2 the following name is given as CAS name: "2-Cyclohexen-1-one, 2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydrox-". The last character of the CAS name is missing; therefore, the stated information should be replaced using "2-Cyclohexen-1-one, 2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-" instead. - In Part B, section 1.3, table 8 the unit for the given vapour pressure values is missing. Please add the corresponding information. - In Part B, section 1.3, table 8 for the property "Stability in organic solvents and identity of relevant degradation products" the solubility of Clethodim in different solvents is given.				

Therefore, the physical-chemical property should be renamed using "Solubility in organic solvents" instead.
Dossier Submitter's Response
We agree that missing information on constituents should be added in the IUCLID. We agree that "n. a." should be added in the corresponding field. We agree that the CAS name should be changed as suggested. The unit "Pa" for vapour pressure should be added. We agree that "Stability in organic solvents and identity of relevant degradation products" should be changed into "Solubility in organic solvents". However, these changes cannot be made as no changes are allowed to the CLH proposal during the public consultation. Over the suggestion of classifying as Skin Irritant, Cat 2 H315, please see answers in the corresponding section. We do not agree with the suggestion.
RAC's response
As indicated by the Dossier Submitter, the CLH report cannot be amended but your comments are noted.

Date	Country	Organisation	Type of Organisation	Comment number
26.05.2015	Norway		MemberState	2
Comment received				
Norway would like to thank the Netherlands for the proposal for harmonised classification and labeling of clethodim. Norway supports the classification as proposed: Acute Tox. 4, H302 Skin Sens. 1 H317 Aquatic Chronic 3 H412 We also supports that clethodim should be labelled with EUH066.				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
RAC shares the view that EUH066 is appropriate to cover the potential for skin effects.				

Date	Country	Organisation	Type of Organisation	Comment number
22.05.2015	France		MemberState	3
Comment received				
Part B. 1.1 Table 4. CAS name: Please RMS, correct the CA name, a "y" is missing at the end of the name (highlighted in grey): "2-cyclohexen-1-one, 2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-". Part B. 1.3 Surface tension: Please RMS, confirm that surface tension values in the study Butler, 2009 have been obtained on the technical active substance and indicate the purity of the technical material used in this study. If this is the case, please indicate the method used to determine the surface tension and clarify the term of "neat product".				

Part B. 1.3 Water solubility:
Please RMS, clarify why the water solubility increases until pH 9, then decreases at pH 10.

Part B. 1.3 Viscosity:
Please, RMS confirms that viscosity values in the study Lezberg 2003, have been obtained on the technical active substance and indicate the purity of the technical material used in this study.

Dossier Submitter's Response

We agree that the CAS name should be corrected according to the suggestion. However, no changes can be made to the proposal after the public consultation.

The purity of the test substance is 98.5%. The test method is EC A5 (ISO 304). Tests were performed on neat product without any dilution into water. The term neat product should be kept.
According to the DAR, there are two studies on water solubility tested at different pH values. The result from the first study was 58.9 g/L at pH 9 (in the DAR pH 10 is mentioned but in the study report is was noted that the pH after adding the a.s. was 9 in stead of 10). In the second study, only 30 g/L was tested, which is lower than the value of 58.9g/L. The DAR concluded that both studies are acceptable as there is no reason to reject one of them. Therefore, the stated water solubility at pH10 is lower than that at pH9.

Data on viscosity was performed by using "Select 240 EC" containing the active substance with a purity close to the nominal concentration of clethodim in Select 240 EC of 25.2%.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
26.05.2015	France	Arysta LifeScience	Company-Manufacturer	4

Comment received

I just would like to inform you about a mistake about Clethodim use , indeed Clethodim is a selective herbicide but not only for sugar beet.
Thanks a lot in advance to take into account this remark

Dossier Submitter's Response

Thanks for your kind information. However, no changes to the proposal can be included after the public consultation. In any case, we do not think that this information will affect the proposed clasification.

RAC's response

Noted.

Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
22.05.2015	France		MemberState	5

Comment received

We agree with the classification proposed for toxicological hazards.

Dossier Submitter's Response

Thank you for your kind support.

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2015	Spain		MemberState	6
Comment received				
The Spanish CA supports the proposed classification of clethodim for acute oral toxicity as Acute Tox 4 (H302: Harmful if swallowed) (limits 300 < ATE ≤ 2000 mg/kg bw) according to CLP classification criteria. This classification is based on the LD50 value in females (LD50 = 1133 mg a.i./kg bw) obtained in the acute oral toxicity study in rats (Cushman, 1986).				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
Noted.				

Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
26.05.2015	Germany		MemberState	7
Comment received				
According to the Guidance on the Application of the CLP Criteria, Clethodim should be classified as skin irritant, Cat 2: H315. Justification: Macroscopic post mortem examination of the animals at termination showed flaky skin, amongst others. Furthermore, the microscopic examination revealed trace to mild hyperkeratosis among the treated animals. [Annex I: 3.2.2.8.2: "Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a material shall be considered to be irritant."] In addition, a proposal for classification is in line with the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance clethodim (EFSA Journal 2010;8(9): 1771				
Dossier Submitter's Response				
In our view, clethodim does not fulfil the criteria for classification as a skin irritant (category 2, H315) of the CLP Regulation, because mean values for erythema and edema are <2.3 in three tested animals and all effects were reversible within 9 days. It is not clear to us where the information on macroscopic and microscopic effects is coming from. The classification proposed by EFSA was based on the DSD criteria which require classification if a score 2.0 (average 24-72 hours) is observed in 2 out of 3 animals. However, the CLP criteria require score 2.3 in 2 out of 3 animals.				
RAC's response				
Based on the details of the skin irritation study provided by the Dossier Submitter, it seems that labelling with EUH066 is justified. The low scores and reversibility of the effects point against classification as Skin Irritant Cat 2: H315.				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2015	Spain		MemberState	8
Comment received				
The Spanish CA agree with the fact that clethodim does not fulfil the criteria for classification as a skin irritant (category 2, H315) of the CLP Regulation, because mean values for erythema and edema are <2.3 in three tested animals and all effects were reversible within 9 days. Besides, we also support the need to labell clethodim as EUH066; because dryness of the skin from day 2 up to day 7 was observed in the irritation test and abraded, thickened, blackened/darkened, crusty and/or cracked skin was seen in the treated animals during the observation period of an acute dermal toxicity test.				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
Please see response to comment No. 7; agreed.				

Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
22.05.2015	France		MemberState	9
Comment received				
We agree with the classification proposed for toxicological hazards.				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2015	Spain		MemberState	10
Comment received				
The Spanish CA supports the proposed classification of clethodim as skin sensitiser (category 1, H317) because a positive response in a GPMT test higher than 30% was observed. Subcategory 1B is required when ≥30% responses at intradermal induction dose ≥1%. In this case, as category 1A cannot be excluded category 1 is adequate.				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
Noted.				

Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
22.05.2015	France		MemberState	11
Comment received				
We agree with the classification proposed for Environmental hazards.				
Dossier Submitter's Response				
Thank you for your kind support.				
RAC's response				
Noted.				