Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

cis-Tricos-9-ene (Muscalure)

EC number: 248-505-7

CAS number: 27519-02-4

ECHA/RAC/CLH-O-0000001670-80-02/A2

Adopted

30 November 2012

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.

Substance name: cis-Tricos-9-ene (Muscalure)

EC number: 248-505-7
CAS number: 27519-02-4

GENERAL COMMENTS

Date	Country / Organisation/MSCA	Comment	Dossier submiter's response to comment	RAC's response to comment
02/03/2012	Belgium / MSCA	We agree with the proposed classification.	Thank you	Noted.
09/03/2012	France / MSCA	In order to help the dossier reading, could you please add as reference, close to the section reference of the Biocide dossier (ie. DocIIIA A.4.2), the name of the author studies?	We understand your request, but it was agreed within the biocides review program not to mention the names of study authors in the reference lists. There were concerns by ap plicants about public pressure against authors of controversial studies. Therefore we would like to keep the reference lists as they are.	Agreed.
12/03/2012	Germany / MSCA	The German CA supports the proposal from the Austrian CA.	Thank you	Noted.
12/03/2012	Sweden / MSCA	SE supports classification of cis-tricos-9-ene (Cas No 27519-02-4) as Skin. Sens. 1B as specified in the proposal. SE agrees with the rationale for classification into the proposed sub category.	Thank you	Noted.

Carcinogenicity: No comments received
Mutagenicity: No comments received
Toxicity to reproduction: No comments received
Respiratory sensitisation: No comments received

Other hazards and endpoints

Date	Country/ Organisation / MSCA	Comment	Dossier submiter's response to comment	RAC's response to comment
12/03/2012	Germany / MSCA	Skin Sensitisation: DE can support the classification of cis-Tricos-9-ene as Skin Sensitizer 1B, H317. We would like to note, however, that while the criteria for Cat. 1B are formally fulfilled (i.e., response ≥30% at intradermal induction dose of >1%), all positive readings were observed only at the second day after challenge (no response in the first 24 hours) with animals showing minimal irritation scores of 1 from maximal 4. In our experience, reaction to clear sensitizers is most prominent during the first 24 hours after challenge, with subsequently decreasing intensity. From the data provided, there is no plausible explanation for such unusual behaviour.	We will introduce your comment in the discussion of this endpoint.	We agree with your comment about the unusual behaviour of the substance. On the other hand in the OECD 406 both observations recorded at 24h and 48h after the challenge lead to classification.
09/03/2012	France / MSCA	IUPAC name (p12): The IUPAC name is (Z)-Tricos-9-ene and not (9Z)-Tricos-9-ene Toxicological hazards: 4.1.3 Summary and discussion on toxicokinetics (p.18) 4.7.4 Summary and discussion of repeated dose toxicity (p.26) 4.10.4 Summary and discussion of carcinogenicity (p.28) 4.11.4 Summary and discussion of reproductive toxicity (p.29) Please remove the arguments based on the low exposure. Indeed, they are not suitable for a classification proposal. Environmental fate hazards: 5.1.2.Biodegradability	Toxicological hazards: The arguments provided explain the reason for waiving the studies and do not address C&L. We prefer to maintain these arguments for clarity with regard to data requirements for biocides. Biodegradability: Argumentation about the	RAC supports the France's position.

Date	Country/ Organisation / MSCA	Comment	Dossier submiter's response to comment	RAC's response to comment
		Very few data were provided by the applicant to study Muscalure biodegradation. However, according to the weight of evidence provided by the applicant based on QSAR prediction, it is feasible to assume that Muscalure will be degraded in environmental compartments. Even if no exposure of the environmental compartments is expected, due to the intended indoor use, the classification of the active substance should reflect their intrinsic properties independently of uses. Therefore, we think that the argumentation about the intended indoor uses should be deleted. Ecotoxicology hazards: 5.4.Acute aquatic toxicity The endpoint value of the daphnia test, used for the classification, is EC50>0.25 mg/L. According to the study, the highest tested measured concentration causing no effect was 0.25 mg/L. Some effects were found at 0.83 mg/L (geometric mean measured concentration, equivalent to the nominal concentration 100 mg/L) but not directly linked to the substance exposure. So it was stated to use the endpoint EC50>0.25 mg/L. First, is it possible to complete in the referenced doc IIIA 7.4.1.2 with the mean measured value used as endpoint in this study? Could you please also add a weight of evidence in your classification dossier to explain why the aquatic toxicity of this substance should be considered higher than the threshold value of 1 mg/L with the result of the daphnia test expressed as EC50>0.25 mg/L? In our point of view, this argumentation is important because an acute aquatic endpoint below 1 mg/L could lead to an acute and chronic classification in the case of this substance, according to the CLP regulation.	intended indoor use has been deleted. Ecotoxicological hazards: Mean measured concentrations were added in Doc. III-A 7.4.1.2. An argumentation why the aquatic toxicity should be considered higher was added to the CLH-dossier.	Biodegradability: The dossier submitter has deleted argumentation about the intended indoor use in the biodegradation part of the revised-CLH. Ecotoxicological hazards: An argumentation why the aquatic toxicity of daphnia should be considered higher was added to the revised CLH-dossier by the dossier submitter: "…*At 0.83 mg/L the observed effects on mobility were attributed to physical burden. Therefore it is considered, that an EC50 based on toxicological effects would be*

Date	Country/ Organisation / MSCA	Comment	Dossier submiter's response to comment	RAC's response to comment
				higher and in any case exceed 1mg/L". However, according to the Guidance on the application of Regulation (EC) No 1272/2008, when the acute toxicity is recorded at levels in excess of the water solubility due to physical effects, the test should be considered invalid for classification purposes.

ATTACHMENTS RECEIVED: none