

Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

Medetomidine;
(*RS*)-4-[1-(2,3-dimethylphenyl)ethyl]
-1*H*-imidazole

EC number: -
CAS number: 86347-14-0

CLH-O-0000001412-86-85/F

Adopted
4 December 2015

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON (RS)-4-[1-(2,3-DIMETHYLPHENYL)ETHYL]-1H-IMIDAZOLE; MEDETOMIDINE

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: Medetomidine; (RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole
EC number: -
CAS number: 86347-14-0
Dossier submitter: United Kingdom

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
11.03.2015	France		MemberState	1
Comment received				
MS FR agrees for the classification proposal based on the data reported in the CLH report for human health hazards (Acute Tox - H300; Acute Tox 2 - H330; STOT SE - H336).				
MS FR agrees for the classification proposal based on the data reported in the CLH report for environmental hazards (Aquatic Acute 1 (M=10) - H400; Aquatic chronic 1 (M=100) - H410)				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.03.2015	Germany		MemberState	2
Comment received				
1. Because of the aspect that the substance Medetomidine is not included in the EC inventory the CAS number given in Part B, Section 1.1, Table 5 of the CLH report under "CAS number (EC inventory)" should be deleted. Please amend Table 5 accordingly.				
2. It might be useful to mention in the CLH report that there are two tautomeric forms of Medetomidine in order to avoid confusion concerning the CAS name (1H-Imidazole, 5-[1-(2,3-dimethylphenyl)ethyl]-) and the IUPAC name ((RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole) of the substance.				

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Dossier Submitter's Response
Thank you for your comments. These should be noted, although we cannot update the CLH report at this stage.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
20.03.2015	Germany		MemberState	3

Comment received
Section 5.1, p. 44: Please correct whole system Degradation DT50 from OECD 308 in Table 21 to read 50.2 days at 20°C.
Section 5.1.2.3, p. 45: Please amend in paragraph 5 that the sample flasks were incubated at 20°C ± 2°C.
Section 5.1.2.3, p. 46: Please correct following values in Table 23: For W1 the DT50 is 52.6 days, the corresponding X ² error 10.3%. For W2 the DT50 is 47.9 days, the corresponding X ² error 10.0%.
In the conclusion of water/sediment test (last paragraph), the geomean DT50 value for the whole system must read 50.2 days.
Section 5.1.2.3, p. 47: In the first 2 paragraphs on this page, please also quote revised values for the geomean degradation DT50 for the whole system from the final drafts CAR/AR (both February 2015), i.e. 50.2 days (range 47.9-52.6) instead of 51.3 days (range 48.8-54).

Dossier Submitter's Response
We thank DE for their comments. These slight changes to environmental fate endpoints align with those recently agreed in the finalised biocide endpoints. Unfortunately they cannot be amended at this stage in the CLH Report but they do not affect the 'not rapidly degradable' proposal for medetomidine or the resulting environmental classifications and M-factors.
RAC's response
Noted. That doesn't change the classification or M factors.

Date	Country	Organisation	Type of Organisation	Comment number
20.03.2015	Belgium		MemberState	4

Comment received
Based on the results of the aquatic toxicity test on the most sensitive species (Algae - <i>Desmodesmus subspicatus</i> with 72hEC ₅₀ = 0.65 mg/l ; Fish - <i>Cypridon variegatus</i> with 28phNOEC= 0.001mg/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 shows no potential to bioaccumulate.
In view of the proposed classification and toxicity band for acute toxicity between 0.1mg/l and 1 mg/l, an M-factor for acute toxicity of 1 could be assigned and an M-factor for chronic toxicity of 100 (not rapidly degradable substance and NOEC between 0.0001 mg/l

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and 0.001mg/l)

In conclusion : we agree with the proposed environmental classification by the UK CA.

Some editorial or/and minor comments :

There are no reliable aquatic chronic toxicity studies available for invertebrates so the surrogate approach should also be explored, although this does not result in a more stringent outcome as the one based on the lowest NOEC.

Dossier Submitter's Response

We thank BE for their comments and note their support for the environmental classification proposal. Use of the surrogate acute approach for chronic hazard classification was considered, however given the relative acute insensitivity of invertebrates compared with algae, this would not lead to a higher chronic classification or M-factor.

RAC's response

Noted. That doesn't change the classification or M factors.

Date	Country	Organisation	Type of Organisation	Comment number
18.03.2015	Sweden		MemberState	5

Comment received

The Swedish CA supports the proposed classification of Medetomidine; Aquatic Acute 1; H400: Very toxic to aquatic life with the M factor 1 and Aquatic Chronic 1; H 410: Very toxic to aquatic life with long lasting effects with the M factor 100. This proposal is based on data of Medetomidine showing acute and chronic toxicity against aquatic organism and the fact that the substance is not rapidly degradable and has a low bioaccumulation potential.

Dossier Submitter's Response

We thank SE for their comments and note their support for the proposed environmental classification.

RAC's response

Noted.

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
11.03.2015	France		MemberState	6

Comment received

Page 15: flash point has been reported for medetomidine. Nevertheless, active substance is a solid. Flash point is not suitable for solid. This information should be corrected.

Dossier Submitter's Response

Thank you for your comments. We agree and note that this was included in error, but we cannot update the CLH report at this stage.

RAC's response

Noted.