

Committee for Risk Assessment
RAC

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

2-phenylhexanenitrile

EC Number: 423-460-8
CAS Number: 3508-98-3

CLH-O-0000001412-86-181/F

Adopted
5 December 2017

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 2-PHENYLHEXANENITRILE

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: 2-phenylhexanenitrile

EC number: 423-460-8

CAS number: 3508-98-3

Dossier submitter: Spain

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
12.01.2017	Germany		MemberState	1
Comment received				
The German CA generally agrees to the proposed classification of 2-phenylhexanenitrile.				
Additionally the German CA strongly recommends the setting of harmonized ATEs whenever a substance is classified as acute toxic to facilitate the consistent classification of mixtures.				
Dossier Submitter's Response				
No LD50 value can be derived from the available fixed dose method procedure study. Therefore, the acute toxicity estimate (ATE) cannot set on its basis.				
Then ATE has to be derived from CLP Annex I, Table 3.1.2. In this regard, we note that since the study was conducted in 1996 according to the old guideline, the level of doses does not correspond to the ones used in the current updated method. Thus, the experimentally obtained acute toxicity range values ranged from 500 to 2000 mg/kg bw, that leads to category 4 according to CLP criteria. Therefore, using a conservative approach, we could adopt the converted acute toxicity point estimate value in the Table 3.1.2 corresponding to the acute toxicity range from 300 to 2000 mg/kg bw, although the dose of 300 mg/kg bw was not tested. This would lead to an ATE of 500 mg/kg bw.				
RAC's response				
We agree with the justification and ATE proposal provided by the Dossier Submitter. We note the support for the proposed environmental classification.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2017	France		MemberState	2
Comment received				
France agrees with the conclusions on classification for acute oral toxicity.				

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Dossier Submitter's Response
Thank you for your comment.
RAC's response
Thank you for the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
12.01.2017	Germany		MemberState	3
Comment received				
The German CA generally agrees to the proposed classification of 2-phenylhexanenitrile.				
Additionally the German CA strongly recommends the setting of harmonized ATEs whenever a substance is classified as acute toxic to facilitate the consistent classification of mixtures.				
Dossier Submitter's Response				
Please see the answer to comment number 1.				
RAC's response				
Please see the answer to comment number 1.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2017	France		MemberState	4
Comment received				
France supports the proposal to remove classification of 2-phenylhexanenitrile from the current entry Aquatic Acute 1 and Aquatic Chronic 1. Furthermore, based on long term test (algae test) and acute test information, France supports the proposal classification Aquatic Chronic 2.				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
We note the support for the proposed environmental classification.				

Date	Country	Organisation	Type of Organisation	Comment number
31.01.2017	Belgium		MemberState	5
Comment received				
Based on growth rate reduction in the algae growth inhibition study (OECD201), BE CA supports the environmental classification with Aquatic chronic 2, H411 on the condition that growth in the control was exponential (greater than factor 16).				
Dossier Submitter's Response				
Thank you for your comment. As indicated in the CLH report of the substance, in the algae growth inhibition study (OECD 201), the biomass of the control group increased exponentially by a factor of at least 16 within the 72-hour test period and the mean growth rate of the control group was in the range of 1.29-1.58 day ⁻¹ during the test.				
RAC's response				
We note the support for the proposed environmental classification, and the clarification provided by the Dossier Submitter.				