



**Committee for Risk Assessment
RAC**

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

3,7-DIMETHYLOCTA-2,6-DIENENITRILE

EC number: 225-918-0
CAS number: 5146-66-7

CLH-O-0000001412-86-26/F

Adopted
04 December 2014

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 3,7-DIMETHYLOCTA-2,6-DIENENITRILE

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 attachments including confidential documents received during the public consultation have been provided in full to the dossier submitter, to RAC members and to the Commission (after adoption of the RAC opinion). 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.

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Substance name: 3,7-dimethylocta-2,6-dienitrile

CAS number: 5146-66-7

EC number: 225-918-0

Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
10.01.2014	Sweden		MemberState	1
Comment received				
The SE CA supports classification of 3,7-dimethylocta-2,6-dienitrile (Cas No 5146-66-7) as specified in the proposal. SE agrees with the rationale for the classification into the proposed hazard class and differentiation.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
10.01.2014	France		MemberState	2
Comment received				
FR supports the proposed classification for human health of 3,7-dimethylocta-2,6-dienitrile as Muta Cat.1B since the substance has clearly been shown to be clastogenic in vitro and in vivo. And since 3,7-dimethylocta-2,6-dienitrile is genotoxic in vivo for somatic cells (bone marrow) but also for spermatogonial cells this proposal is fully warranted.				
Additionally, we would like to point the fact that in the notifications several but not all registrants propose a classification for environment: Aquatic Chronic 2 or Aquatic Chronic 3. Indeed it seems that according to some MSDS LC50 (96h) for <i>Leuciscus idus</i> (fish) is 22-44 mg/L and EC50 (48h) for <i>Daphnia magna</i> is 7.66 mg/L, and may warrant a classification for aquatic toxicity. Harmonisation of the classification of 3,7-dimethylocta-2,6-dienitrile for environment may also be considered.				
Dossier Submitter's Response				
Thank you for your support of the classification proposal. We also appreciate your comment				

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on aquatic toxicity. However, this endpoint does not necessarily require harmonized classification and was therefore not included. Furthermore, when the Annex VI dossier was prepared the differences between the notifications were not in evidence. The C&L inventory did not exist. After public consultation no new harmonised classification and labelling can be submitted, otherwise the dossier has to be withdrawn. In addition, it is the role of the registrants to achieve a consistent self-classification. If no agreement will be achieved a proposal for environmental classification should be submitted.
RAC's response
Noted

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
10.01.2014	Sweden		MemberState	3
Comment received				
We note that the proposed classification, i.e. Muta. 1B, is not correctly designated throughout the CLH Report. p.14. The bacterial test referred to in Table 9 and in Section 4.9.1.1 is termed as a bacterial genotoxicity test, which is strictly correct. However, since the actual test detects gene mutations, i.e. permanent transmissible changes in the DNA, we would have preferred the term bacterial reverse mutation test, which is commonly used for this test. p.19-20. The Swedish CA agrees that there is sufficient evidence from studies in animals for concluding that 3,7-dimethylocta-2,6-dienitrile (Cas No 5146-66-7) can cause chromosomal aberrations in somatic cells in vivo and in spermatogonial cells in vivo and, accordingly, the substance should be considered as a germ cell mutagen. Therefore, classification in Muta. 1B; H340 is warranted. Since evidence from human epidemiological studies is not available, classification in Muta.1A is not warranted.				
Dossier Submitter's Response				
Thank you for your support. The German CA agrees with your statement on the bacterial reverse mutation test but at this point an amendment of the CLH report is not foreseen in the process.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
19.12.2013	Netherlands		MemberState	4
Comment received				
The Netherlands agrees with the proposed Muta. Cat. 1B (H340, may cause genetic defects) classification for 3,7-dimethylocta-2,6-dienitrile. Several in vivo studies in mice have demonstrated the induction of chromosomal aberrations in somatic and male germ cells. In addition, toxicokinetic studies have shown that 3,7-dimethylocta-2,6-dienitrile is rapidly absorbed and detected in the ovaries and testis of mice.				
Dossier Submitter's Response				
Thank you for your support.				

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RAC's response
Noted