

Committee for Risk Assessment
RAC

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

1-vinylimidazole

EC Number: 214-012-0
CAS Number: 1072-63-5

CLH-O-0000001412-86-130/F

Adopted
9 December 2016

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-VINYLMIDAZOLE

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: 1-vinylimidazole

EC number: 214-012-0

CAS number: 1072-63-5

Dossier submitter:

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2016	France		MemberState	1
Comment received				
We agree with the classification proposal Repr. 1B, H360D.				
Dossier Submitter's Response				
No response needed as comment is in line with the submitted CLH proposal.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2016	Germany		MemberState	2
Comment received				
Overall, we support the proposal for harmonised classification of 1-vinylimidazole as Repr. 1B (H360D). There is clear evidence of developmental toxicity in rats as an intrinsic and hazardous property of 1-vinylimidazole. Some minor changes are suggested in the specific comments section.				
Dossier Submitter's Response				
Thank you for the suggested minor changes to which we agree.				
RAC's response				
Thank you for the suggestions				

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TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2016	France		MemberState	3
Comment received				
<p>Reproduction and delivery data, page 25: in the screening study, dose-related increase in the days for mating and gestation days have been observed. Although the changes were not statistically significant, historical control data may be helpful to conclude on the biological relevance of these findings.</p>				
Dossier Submitter's Response				
<p>The historical control data for the same rat strain and the same lab are as follows:</p> <p>1) Mating days: 1.6 – 6 days (31 studies conducted between 01.01.2007 – 01.11.2012)</p> <p>2) Duration of gestation: 21.6 – 22.4 days (31 studies conducted between 01.01.2007 – 01.11.2012)</p>				
RAC's response				
The HCD are included in the opinion				

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2016	Germany		MemberState	4
Comment received				
<p>Minor comments</p> <p>Section 4.11.2, p. 26 From the text and table 15 it is not clear how many pups were affected by macroscopic and microscopic findings of dilated vessels altogether. Please clarify how many of the pups showed as well "dilated aortic arch" as "dilated aorta" together and how many of the pups showed only one of these effects. Please add that altogether 1 male and 3 female pups of the middle dose group and 4 male and 4 female pups of the high dose group were affected by aneurysms in the vessels macroscopically described as dilated (aorta, arteries or ductus arteriosus) (as stated in the IUCLID-Dossier).</p> <p>Section 4.11.5, p. 30 (about line 39) The DE-CA recommends to change the phrase "There were no indications of reproduction toxicity up to the highest dose level..." as follows: "There were no indications of impaired fertility up to the highest dose level..."</p> <p>Section 4.11.5, p. 30 (about line 46) The DE-CA recommends to amend the phrase "Therefore, the substance does not meet the criteria for reproductive toxicity category 1 or 2..." as follows: "Therefore, the substance does not meet the criteria for reproductive toxicity (related to fertility) category 1 or 2".</p>				
Dossier Submitter's Response				
<p>Section 4.11.2, p. 26 We would like to provide the following additional information as requested by the MS.</p>				

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- 1) At the mid dose one female pup (out of 4 pups) showed a dilated arteria as well as a dilated aortic arch. The other three affected pups showed only one of these effects.
- 2) At the high dose, two female pups (out of 8 pups) showed a dilated arteria as well as a dilated aortic arch. The other six affected pups showed only one of these effects.
- 3) We agree to the proposal. Altogether 1 male and 3 female pups of the middle dose group and 4 male and 4 female pups of the high dose group were affected by aneurysms in the vessels macroscopically described as dilated (aorta, arteries or ductus arteriosus).

Section 4.11.5, p. 30 (about line 39)

We agree to the proposal.

Section 4.11.5, p. 30 (about line 46)

We agree to the proposal.

RAC's response

1. The available information on the affected pups is included. Please note that histopathological examination was not possible for all pups.
2. We have included wording on the reproduction toxicity/fertility. We have also included a remark regarding the limited information available for this endpoint.