

Committee for Risk Assessment
RAC

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

Methylhydrazine

EC number: 200-471-4

CAS number: 60-34-4

CLH-O-0000001412-86-75/F

Adopted
11 September 2015

ANNEX 2B - COMMENTS ON THE ADDITIONAL INFORMATION PROVIDED BY THE DOSSIER SUBMITTER AND RESPONSE TO COMMENTS

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.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: methylhydrazine
EC number: 200-471-4
CAS number: 60-34-4
Dossier submitter: Netherlands

GENERAL COMMENTS

| Date | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 31.07.2015 | Germany | | MemberState | 1 |
| Comment received | | | | |
| The German CA supported the original CLH proposal of methylhydrazine during the public consultation in December 2014. The additional information provided in the current public consultation supports the CLH proposal for classification of methylhydrazine as Carc.1B. | | | | |
| Dossier Submitter's Response | | | | |
| Thank you for your support. | | | | |
| RAC's response | | | | |
| RAC considers that the classification of methylhydrazine as Carc.1B, H350 is justified. This conclusion is also based on taking into consideration the additional information provided. Formation of DNA adducts by methylhydrazine cannot be excluded. | | | | |

CARCINOGENICITY

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---------|--------------|----------------------|----------------|
| 31.07.2015 | France | | MemberState | 2 |
| Comment received | | | | |
| The data on analogues support the need of a classification for carcinogenicity endpoint. Therefore, we maintain our support to the proposed classification: Carc. 1B. | | | | |
| Dossier Submitter's Response | | | | |
| Thank you for your support. | | | | |
| RAC's response | | | | |
| RAC considers that the classification of methylhydrazine as Carc.1B, H350 is justified. This suggestion is also based on taking into consideration the additional information provided. Formation of DNA adducts by methylhydrazine cannot be excluded. | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|------|---------|--------------|----------------------|----------------|
| | | | | |

ANNEX 2B - COMMENTS ON THE ADDITIONAL INFORMATION PROVIDED BY THE DOSSIER SUBMITTER AND RESPONSE TO COMMENTS

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|--|---------|--|-------------|---|
| 31.07.2015 | Germany | | MemberState | 3 |
| Comment received | | | | |
| <p>The DS has submitted read-across information based on the 'Read-across Assessment Framework (RAAF)' established by ECHA to support the carcinogenicity assessment of methylhydrazine.</p> <p>The presented information support the CLH proposal for classification of methylhydrazine as Carc.1B. All three source substances have a harmonized classification as Carc. 1B.</p> | | | | |
| Dossier Submitter's Response | | | | |
| Thank you for your support. | | | | |
| RAC's response | | | | |
| <p>RAC considers that the classification of methylhydrazine as Carc.1B, H350 is justified. This suggestion is also based on taking into consideration the additional information provided.</p> <p>Formation of DNA adducts by methylhydrazine cannot be excluded.</p> | | | | |