

**Committee for Risk Assessment**  
**RAC**

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

**benzo[*rst*]pentaphene**

**EC Number: 205-877-5**

**CAS Number: 189-55-9**

CLH-O-0000001412-86-159/F

**Adopted**  
**9 June 2017**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZO[*rst*]PENTAPHENE

### 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.

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

**Substance name: benzo[*rst*]pentaphene**

**EC number: 205-877-5**

**CAS number: 189-55-9**

**Dossier submitter: Germany**

#### GENERAL COMMENTS

| Date  | Country | Organisation | Type of Organisation | Comment number |
|---|---------|--------------|----------------------|----------------|
| 08.09.2016  | France  |              | MemberState          | 1              |
| Comment received  |         |              |                      |                |
| We support the classification proposal for both mutagenicity and carcinogenicity. |         |              |                      |                |
| Dossier Submitter's Response  |         |              |                      |                |
| Thank you for the support.  |         |              |                      |                |
| RAC's response  |         |              |                      |                |
| Noted.  |         |              |                      |                |

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 08.09.2016   | Belgium |              | MemberState          | 2              |
| Comment received   |         |              |                      |                |
| As a general comment, the adequacy and quality of the studies is not always easily identified without the Klimisch scores and results have to be carefully interpreted as sometimes no information on cytotoxicity is available. |         |              |                      |                |
| In conclusion, BE CA supports the proposal for harmonised classification submitted by BAuA and, based on the available data, agrees to classify Benzo( <i>rst</i> )pentaphene as follow:<br>- Muta. 2, H341<br>- Carc. 1B, H350  |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |
| RAC's response   |         |              |                      |                |
| Noted.   |         |              |                      |                |

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZO[*rst*]PENTAPHENE**

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 07.09.2016   | Sweden  |              | MemberState          | 3              |
| Comment received   |         |              |                      |                |
| The Swedish CA supports classification of benzo[ <i>rst</i> ]pentaphene (CAS No. 189-55-9) for germ cell mutagenicity and carcinogenicity as specified in the proposal. SE agrees with the rationale for classification into the proposed hazard classes and differentiations. |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |
| RAC's response   |         |              |                      |                |
| Noted.   |         |              |                      |                |

**CARCINOGENICITY**

| Date  | Country | Organisation | Type of Organisation | Comment number |
|---|---------|--------------|----------------------|----------------|
| 08.09.2016  | France  |              | MemberState          | 4              |
| Comment received  |         |              |                      |                |
| Table 13, page 30 and table 14 page 33<br>BauA could better justify the choice of relevant carcinogenicity studies listed in table 13 and in particular why the study from Sellakumar and Shubik (1974) which seems to be very similar to Stenback and Sellakumar (1974) is not included.   |         |              |                      |                |
| Dossier Submitter's Response  |         |              |                      |                |
| Our aim in preparation of the CLH-dossier of benzo( <i>r,s,t</i> )pentaphene was to evaluate and discuss all relevant available information on its carcinogenicity potential in order to drive the classification as carcinogen. In preparing the CLH-report we have kept very closely to the content of the CLH-template of ECHA. The listed carcinogenicity studies in Table 13 describe a selection of relevant carcinogenicity studies. In accordance with the table header of Table 13 <b>a summary</b> of relevant carcinogenicity studies selected on the basis of the relevant exposure routes is presented. The following presented and evaluated studies are also assessed as relevant information on the carcinogenicity potential of benzo( <i>r,s,t</i> )pentaphene including the study from Stenback and Sellakumar (1974). |         |              |                      |                |
| RAC's response  |         |              |                      |                |
| Noted.  |         |              |                      |                |

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 08.09.2016   | Belgium |              | MemberState          | 5              |
| Comment received   |         |              |                      |                |
| We support the proposed classification as Carc. 1B considering the available evidence on the carcinogenic potential of Benzo( <i>rst</i> )pentaphene. Indeed, development of cancer was observed in different species and strains, in various sites, following an exposure by different routes and in both sexes.<br>No epidemiological data is available on Benzo( <i>rst</i> )pentaphene, however, some occupational data suggests lung and bladder cancers due to workers exposure to PAH (though not to individual compounds), which is in line with the in vitro results presented in the CLH dossier.<br>Furthermore, this is supported by the previous evaluation by IARC (category 2B, confirmed after reevaluation with additional data in 2006). |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZO[*rst*]PENTAPHENE**

|                |
|----------------|
| RAC's response |
| Noted.         |

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 07.09.2016   | Sweden  |              | MemberState          | 6              |
| Comment received   |         |              |                      |                |
| Classification in Carc. 1B is warranted since benzo[ <i>rst</i> ]pentaphene caused tumours in two rodent species, at multiple tissue sites, and by different routes of administration. |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |
| RAC's response   |         |              |                      |                |
| Noted.   |         |              |                      |                |

**MUTAGENICITY**

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 08.09.2016   | Belgium |              | MemberState          | 7              |
| Comment received   |         |              |                      |                |
| BECA agrees to classify Benzo( <i>rst</i> )pentaphene as proposed by BAuA considering its mutagenic properties after metabolic activation to a reactive electrophilic compound. This proposal of classification is supported by the use of read-across: chrysene (Muta. 2) and benzo(a)pyrene (Muta.1B). |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |
| RAC's response   |         |              |                      |                |
| Noted.   |         |              |                      |                |

| Date   | Country | Organisation | Type of Organisation | Comment number |
|--|---------|--------------|----------------------|----------------|
| 07.09.2016   | Sweden  |              | MemberState          | 8              |
| Comment received   |         |              |                      |                |
| Classification in Muta. 2 is warranted since benzo[ <i>rst</i> ]pentaphene is mutagenic in vitro and shows chemical structure activity relationship to the known germ cell mutagens B[a]P and CHR. We agree with the arguments presented for justifying read-across from these substances. |         |              |                      |                |
| Dossier Submitter's Response   |         |              |                      |                |
| Thank you for the support.   |         |              |                      |                |
| RAC's response   |         |              |                      |                |
| Noted.   |         |              |                      |                |