

Committee for Risk Assessment
RAC

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

Dibenzo[*b,def*]chrysene; Dibenzo[*a,h*]pyrene

EC Number: 205-878-0

CAS Number: 189-64-0

CLH-O-0000001412-86-160/F

Adopted
9 June 2017

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON DIBENZO[B,DEF]CHRYSENE;
DIBENZO[A,H]PYRENE**

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: Dibenzo[b,def]chrysene; Dibenzo[a,h]pyrene

EC number: 205-878-0

CAS number: 189-64-0

Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
08.09.2016	France		MemberState	1
Comment received				
We agree with 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
07.09.2016	Sweden		MemberState	2
Comment received				
The Swedish CA supports classification of dibenzo[b,def]chrysene (CAS No. 189-64-0) 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.				

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CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2016	Sweden		MemberState	3
Comment received				
Classification in Carc. 1B is warranted since dibenzo[b,def]chrysene 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
07.09.2016	Sweden		MemberState	4
Comment received				
Classification in Muta. 2 is warranted since dibenzo[b,def]chrysene 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.				