

**AGREEMENT OF THE MEMBER STATE COMMITTEE  
ON THE IDENTIFICATION OF  
Benzo[def]chrysene (Benzo[a]pyrene)  
AS A SUBSTANCE OF VERY HIGH CONCERN  
According to Articles 57 and 59 of  
Regulation (EC) 1907/2006<sup>1</sup>**

**Adopted on 27 May 2016**

**This agreement concerns**

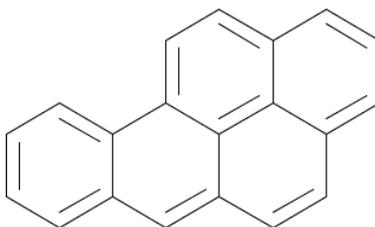
**Substance name: Benzo[def]chrysene (Benzo[a]pyrene)**

**EC number: 200-028-5**

**CAS number: 50-32-8**

**Molecular formula: C<sub>20</sub>H<sub>12</sub>**

**Structural formula:**



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<sup>1</sup>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (23, February 2016, submission number SPS-011979-16-1) on identification of *Benzo[def]chrysene* (*Benzo[a]pyrene*) as a substance of very high concern due to its carcinogenic, mutagenic, toxic for reproduction (CMR), persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties.

The Annex XV dossier was circulated to Member States on 29 February 2016 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 17 May 2016 and agreed in the written procedure of the Member State Committee with closing date of 27 May 2016.

### **Agreement of the Member State Committee in accordance with Article 59(8):**

***Benzo[def]chrysene* (*Benzo[a]pyrene*) is identified as a substance meeting the criteria of Article 57 (a) to (e) of Regulation (EC) 1907/2006 (REACH):**

- **as this substance meets the criteria for classification as carcinogenic category 1B, mutagenic category 1B, toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008<sup>2</sup>, and**
- **it is persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH Regulation.**

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<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

## **UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN**

### **Carcinogenicity, mutagenicity, toxicity for reproduction:**

Benzo[def]chrysene (Benzo[a]pyrene) is covered by index number 601-032-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard classes:

- Carcinogenicity category 1B (hazard statement H350: "May cause cancer")
- Germ cell mutagenicity category 1B (hazard statement H340: "May cause genetic defects")
- Reproductive toxicity category 1B (hazard statement H360FD: "May damage fertility. May damage the unborn child")

Therefore, Benzo[def]chrysene (Benzo[a]pyrene) meets the criteria of Article 57(a)-(c) of Regulation (EC) 1907/2006 for SVHC identification in the following hazard classes:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH
- Germ cell mutagenicity category 1B in accordance with Article 57 (b) of REACH
- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

### **Persistency, bioaccumulation and toxicity (PBT/vPvB)**

An assessment of the PBT/vPvB properties of Benzo[def]chrysene (Benzo[a]pyrene) has already been carried out by the MSC in the context of the SVHC identification of Pitch, coal tar, high temp. (CTPHT) as documented in the MSC Support Document on CTPHT (ECHA, 2009). In addition, for the purpose of this SVHC proposal for Benzo[def]chrysene (Benzo[a]pyrene), further literature not addressed in the Support Document has been reviewed. The reviewed additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and supports the conclusion on the PBT and vPvB properties of Benzo[def]chrysene (Benzo[a]pyrene) already drawn in the MSC Support Document on CTPHT.

Based on the available information from degradation experiments, Benzo[def]chrysene (Benzo[a]pyrene) degrades very slowly in soil with half-lives of > 180 d. Thus, the P and vP criteria of REACH Annex XIII are fulfilled.

The bioaccumulation of Benzo[def]chrysene (Benzo[a]pyrene) in aquatic species was measured and BCFs > 5000 obtained. Thus, the B and vB criteria of REACH Annex XIII are fulfilled.

Based on the available information, the most sensitive organism to Benzo[def]chrysene (Benzo[a]pyrene) is *Crassostrea gigas*. The calculated EC<sub>10</sub> was 0.22 µg/L whereas under UV-lacking fluorescent laboratory lighting conditions, the resulting EC<sub>10</sub> was 1.1 µg/L.

Therefore, Benzo[def]chrysene (Benzo[a]pyrene) is a very toxic substance and fulfils the T criteria in accordance with the criteria and provisions set out in Annex

XIII section 1.1.3 a) of REACH.

Additionally, the criteria for toxicity of Annex XIII sections 1.1.3 b) and c) are fulfilled based on the classification as:

- Carcinogenicity category 1B (hazard statement H350: "May cause cancer")
- Germ cell mutagenicity category 1B (hazard statement H340: "May cause genetic defects")
- Reproductive toxicity category 1B (hazard statement H360FD: "May damage fertility. May damage the unborn child")

Therefore, the available data shows that Benzo[def]chrysene (Benzo[a]pyrene) meets all criteria listed in Annex XIII of the REACH Regulation for PBT and vPvB substances according to Article 57 (d) and (e) of REACH.

**In conclusion**, the substance *Benzo[def]chrysene (Benzo[a]pyrene)* meets the criteria for a CMR, PBT and vPvB substance according to Article 57(a)-(e) of REACH.

**Reference:**

Support Document on *Benzo[def]chrysene (Benzo[a]pyrene)* (Member State Committee, 27 May 2016)