Substance Name: Benzo[def]chrysene (Benzo[a]pyrene)

EC Number: 200-028-5

CAS Number: 50-32-8

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF

BENZO[DEF]CHRYSENE (BENZO[A]PYRENE)

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CARCINOGENIC (ARTICLE 57 A), MUTAGENIC (ARTICLE 57 B), TOXIC FOR REPRODUCTION (ARTICLE 57 C), PERSISTENT, BIOACCUMULATIVE, AND TOXIC (PBT) (ARTICLE 57 D) AND VERY PERSISTENT AND VERY BIOACCUMULATIVE (ARTICLE 57 E) PROPERTIES

Adopted on 27 May 2016

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FOREWORD

Benzo[def]chrysene (CAS name: Benzo[a]pyrene, B[a]P) belongs to the substance group of Polycyclic Aromatic Hydrocarbons (PAHs). Some PAHs are well-known to be hazardous for human health and the environment. Eight PAHs, including benzo[def]chrysene, have a harmonised classification as carcinogenic, mutagenic, and reprotoxic in the categories 1A, 1B, or 2 according to the CLP Regulation (EC 1272/2008).

Until now, several Annex XV dossiers for the identification of substances of very high concern (SVHC) were explicitly based on the properties of PAHs as constituents of concern in the identified substances, such as Anthracene, Anthracene Oils, Pitch, Coal Tar, High Temperature.

In the Support Document of Pitch, coal tar, high temp. (CTPHT) it has been concluded by the Member State Committee (MSC) that benzo[def]chrysene fulfils the criteria of article 57 (a) – (e) of the REACH Regulation (ECHA, 2009). Thus, the MSC has already concluded that benzo[def]chrysene meets the PBT and vPvB criteria and thereby has confirmed its SVHC properties in 2009 during the evaluation of CTPHT.

However, benzo[def]chrysene and further PAHs whose SVHC properties have already been agreed on by the MSC have not yet been proposed for formal SVHC identification and inclusion in the Candidate List. In this dossier, benzo[def]chrysene will be identified as SVHC according to the criteria of Article 57 (a) – (e).

In the following, either the CAS name benzo[a]pyrene or the abbreviation B[a]P is used for the substance benzo[def]chrysene.

IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Benzo[def]chrysene (Benzo[a]pyrene)

EC Number: 200-028-5

CAS number: 50-32-8

- The substance is identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1A or 1B[1].

- The substance is identified as a substance meeting the criteria of Article 57 (b) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class germ cell mutagenicity category 1A or 1B[1].

- The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class reproductive toxicity category 1A or 1B[1].

- The substance is identified as persistent, bioaccumulative, and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).

- The substance is identified as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Article 57 (a) – (c):

Benzo[def]chrysene (Benzo[a]pyrene, B[a]P) 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 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

Article 57 (d) –(e):

[1] Classification in accordance with section 3 of Annex I to Regulation (EC) No 1272/2008.

An assessment of the PBT/vPvB properties of B[a]P has already been carried out by the MSC in the context of the identification of CTPHT as SVHC as documented in the MSC Support Document on CTPHT (ECHA, 2009). In addition, for the purpose of this SVHC proposal for B[a]P, 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 B[a]P already drawn in the MSC Support Document on CTPHT.

Based on the available information from degradation experiments, B[a]P 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 B[a]P 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 B[a]P is *Crassostrea gigas*. The calculated EC_{10} was 0.22 µg/L whereas under UV-lacking fluorescent laboratory lighting conditions, the resulting EC_{10} was 1.1 µg/L.

Therefore, B[a]P 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 classifications:

- 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 B[a]P 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.

This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC as documented in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

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.

Registration dossiers submitted for the substance: No

Justification

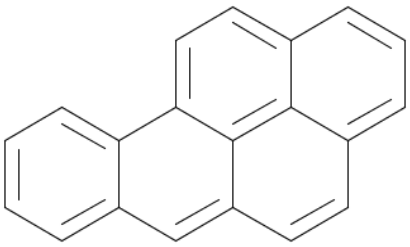
1. Identity of the substance and physical and chemical properties

1.1. Name and other identifiers of the substance

Table 1: Substance identity

EC number:	200-028-5
EC name:	Benzo[def]chrysene
CAS number (in the EC inventory):	50-32-8
CAS number: **Deleted CAS numbers:**	50-32-8
CAS name:	Benzo[a]pyrene
IUPAC name:	Benzo[def]chrysene
Index number in Annex VI of the CLP Regulation	601-032-00-3
Molecular formula:	$C_{20}H_{12}$
Molecular weight range:	252.31 g/mol
Synonyms:	Benzo-alpha-pyrene 3,4-Benzopyrene 4,5-Benzochrysene

Structural formula:



1.2. Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Value	Reference/source of information
Physical state at 20°C and 101.3 kPa	*Solid, needle or plates*	*Merck Index, 10th edition, Windholz, M. (ed.), Rahway N.J. USA, 1983*
Melting/freezing point	*176.5 - 179.3°C*	*Merck Index, 10th edition, Windholz, M. (ed.), Rahway N.J. USA, 1983*
Boiling point	*310 – 312°C* *at 10 mmHg* *495°C* *at 101.325 kPa*	*Merck Index, 10th edition, Windholz, M. (ed.), Rahway N.J. USA, 1983;* *Handbook of Chemistry and Physics (CRC), 72th edition, Lide D. (ed.), CRC Press, Inc., 1992* *Auer-Technikum, 12th edition (1988)*
Vapour pressure	*5.49*10^{-9} mm Hg = 7.32*10^{-9} hPa* *at 25°C* *1.87*10^{-9} Torr* *at 25°C*	*Murray JJ et al., Can J Chem 52: 557-563 (1974)* *cited in HSDB Database* *calculated using Advanced Chemistry development (ACD/Labs) Software V11.02*
Water solubility	*0.00162 mg/L* *at 25°C*	*May WE et al., J Chem Ref Data 28: 197-200 (1983)* *cited in HSDB Database*
Partition coefficient n-octanol/water (log value)	*6.13*	*Demaagd PGJ et al., Environ Toxicol Chem 17: 251-257 (1998) cited in HSDB Database*

2. Harmonised classification and labelling

B[a]P is covered by Index number 601-032-00-3 in section 3 of Annex VI to the CLP Regulation as presented in Table 3.

Table 3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling		Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	
601-032-00-3	Benzo[a]pyrene	200-028-5	50-32-8	Carc. 1B Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350 H340 H360FD H317 H410	Carc. 1B; H350: C ≥ 0.01 %

3. Environmental fate properties

3.1. Degradation

The data provided on degradation of B[a]P in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are not assessed or discussed again in this dossier but included for convenience (flagged by *italic print*). In addition, a review of literature not addressed in the Support Document was carried out and some further data is presented in this dossier.

The reviewed additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and supports the conclusions on the degradation properties of B[a]P already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.1. Abiotic degradation

3.1.1.1. Hydrolysis

As assessed before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *PAHs are hydrolytically stable in aqueous systems*. The Support Document furthermore states as a result that *hydrolysis does not contribute to the degradation of PAHs under environmental conditions.*

Thus, it is concluded that B[a]P is hydrolytically stable.

3.1.1.2. Phototransformation/photolysis

The issue was summarized and discussed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) as follows:

"In the atmosphere, the PAHs are either gas phase or particle-associated. It has been shown that the 2-4 ring PAHs with vapour pressure higher than or equal to 10^{-4} Pa are mostly gas phase-related and PAHs of 4 rings or more with vapour pressure below 10^{-4} Pa are particle-associated. In the gas phase PAHs are oxidized by atmospheric hydroxyl (OH) and nitrate radicals and ozone, whereas the particle-associated PAHs are expected to be degraded by direct photolysis and by reaction with ozone (The Netherlands, 2008). […] Under environmental conditions, PAHs of higher molecular mass are almost completely adsorbed onto fine particles. Studies indicate that the degradation rate depends on the particle material, with PAHs being more stable when adsorbed to particles of higher carbon content.
[…]
PAHs are photo-degraded by two processes, direct photolysis by light with a wavelength < 290 nm and indirect photolysis (photo-oxidation) by at least one oxidizing agent (Volkering and Breure (2003) cited in The Netherlands, 2008). Singlet oxygen is the main oxidant, but also reactions with nitrite and to a lesser extent with nitrate may take place (Suzuki et al., (1987) cited in The Netherlands, 2008). The degradation rate depends on the content of dissolved oxygen, and may be increased in the presence of humic acid, while it increases exponentially with the temperature (Moore and Ramamoorthy, 1984 cited in The Netherlands, 2008). When PAHs are adsorbed to suspended particles, the accessibility for photochemical reactions will depend on the nature of the particles. Photodegradation in natural waters takes normally place only in the upper few centimetres of the water-column and is therefore not considered to have significant impact on the overall persistency of PAHs in the aquatic environment. As exposure to light is even more limited in soils, photodegradation is as well not considered a relevant degradation process in terrestrial environments."

Furthermore, the EU Risk Assessment Report on CTPHT (European Commission, 2008) has already assessed the following information.

Behymer and Hites (1988) described that particle-bound PAHs degrade very slowly. As underlying mechanism, the authors suggest that radiation energy is absorbed by the organic matter of particles and that PAHs therefore do not achieve the excited state in which they can be degraded (Behymer & Hites, 1988).

Atmospheric lifetimes of B[a]P were measured under simulated conditions representative of a clouded sky over southern UK and results range from 15 min to 2.5 days (Behymer & Hites 1988).

B[a]P consists of five aromatic rings and has a vapour pressure of 7.32×10^{-9} hPa at 25°C. Thus, B[a]P is expected to be mainly particle-bound in the atmosphere.

3.1.1.3. Summary on abiotic degradation

It is concluded that in the atmosphere, free B[a]P degrades within periods of 15 min to 2.5 days by direct photolysis. The substance is however mostly particle-associated and when adsorbed onto fine particles, B[a]P may be more stable in the atmosphere. In water, B[a]P is not hydrolysed but can be photo-degraded. However, this only appears at the upper few centimetres of a water-column and is therefore not considered having a significant impact on the overall persistency of B[a]P in the aquatic environment. In soil, exposure to light is even more limited.

Thus, photodegradation is not considered as relevant degradation process in water and terrestrial environments. B[a]P is hydrolytically stable under environmental conditions.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.2. Biodegradation

3.1.2.1. Biodegradation in water

3.1.2.1.1. Estimated data

As already assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *Mackay et al. (1992) estimated half-lives in the different environmental compartments based on model calculations and literature research. The calculated half-lives of B[a]P in water and sediments are in the range of 42 to 125 days and > 1250 days respectively*.

3.1.2.1.2. Simulation tests (water and sediments)

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009) the following is stated:

"Standard tests for biodegradation in water have demonstrated that PAHs with up to four aromatic rings are biodegradable under aerobic conditions, but that biodegradation rates of PAHs with more aromatic rings are very low (The Netherlands, 2008). In general, the biodegradation rates decrease with increasing number of aromatic rings. This correlation has been attributed to factors like the bacterial uptake rate and the bioavailability. The bacterial uptake rate has been shown to be lower for the higher molecular weight PAHs as compared to the PAHs of lower molecular weight. This may be due to the size of high molecular weight members, which limits their ability to cross cellular membranes. In addition, bioavailability is lower for higher molecular PAHs due to adsorption to organic matter in water and sediment. It has further been shown that half-lives of PAHs in estuarine sediment are proportionally related

to the octanol-water partition coefficient (K_{ow}) (Durant et al,(1995) cited in The Netherlands, 2008).
[…]
In general, PAHs are considered to be persistent under anaerobic conditions (Neff (1979); Volkering and Breure (2003) cited in The Netherlands, 2008). Aquatic sediments are often anaerobic with the exception of a few millimetre thick surface layer at the sediment-water interface, which may be dominated by aerobic conditions. The degradation of PAHs in aquatic sediments is therefore expected to be very slow."

Due to the chemical nature and low water solubility of B[a]P, it is concluded that the substance which consists of five aromatic rings is resistant to biodegradation in water and sediment.

3.1.2.2. Biodegradation in soil

The following studies were already assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

Model calculations by Mackay et al. (1992) indicate that B[a]P persists in soil with half-lives in the range from 420 to 1250 days.

Wild et al. (1991) observed elimination half-lives (in form of dissipation times) of 8.2 years for B[a]P. In this field experiment, soils were enriched with PAH-contaminated sludge (Wild et al., 1991).

In another study, Wild and Jones derived different half-lives in a microcosm study with four soil types (Wild and Jones, 1993). The elimination half-lives for B[a]P ($DisDT_{50}$ = 120-258 days) are much lower than in the field study. Various studies on PAH-contaminated soils have revealed that the number of PAH-degrading microorganisms and the degrading capacity are much higher in PAH-contaminated soils than in pristine soils, indicating that adaptation may occur (European Commission, 2008).

Table 4: Elimination half-lives for B[a]P in soil (key studies are printed bold). Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Result	R[a)]	Reference
$DisDT_{50}$ = 8.2 years (field study)	***2***	***(Wild et al., 1991)***
$DisDT_{50}$ = 120 – 270 days (microcosm study)	***2***	***(Wild and Jones, 1993)***

a) Reliability score: 1-reliable without restrictions, 2-reliable with restrictions, 3-unreliable, 4-not assignable

Furthermore, the Support Document for identification of CTPHT as SVHC (ECHA, 2009) states the following:

"Biodegradation rates of PAH in soil depend on several factors such as soil type, pH, moisture content, oxygen and nutrient content, and soil microbial population. Various species (bacteria, fungi, yeasts and algae) are known to degrade PAHs in soil (The Netherlands, 2008). It has been shown that the number of PAH-degrading microorganisms and the degradation, capacity is higher in PAH-contaminated soils than in pristine soils, something explained by the development of an adapted soil microbial community. Several studies have also been demonstrated enhanced PAH-degradation rates when the soil had been enriched with isolated PAH-degrading microorganisms (Davis et al. (1993); Grosser et al. (1995); Schneider et al. (1996) cited in The Netherlands, 2008)."

3.1.2.3. Summary and discussion on biodegradation

The Support Document for identification of CTPHT as SVHC (ECHA, 2009) presents in this context the following information:

"'Aging' is a phenomenon associated with increased residence time of PAHs in soil, which can further decrease the bioavailability of PAHs in the terrestrial environment. Freshly spiked PAHs are more readily desorbed and thus more bioavailable than PAHs that have been in soil or sediment for a longer period of time (The Netherlands, 2008). This means that studies involving artificially added PAHs (e.g. 14C-labelled) often result in biodegradation rates much higher than rates observed for the same substances present in soil as part of a contamination by coal tar."

Considering the chemical structure of B[a]P that consists of five aromatic rings, degradation in water is deemed to be low. *Mackay et al. (2000) calculated half-lives of 42 to 125 days in water.*

The model calculations by Mackay et al. (1992) indicate that B[a]P persists in sediment and soil with half-lives of > 1250 and 420 to 1250 days, respectively. Biodegradation studies in soils show dissipation half-lives between 120 and 270 days (Wild and Jones, 1993). Additionally, a dissipation half-life of more than 8.2 years was measured in a field study (Wild et al., 1991).

Hence, B[a]P biodegrades very slowly in water, sediment, and soil.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.3. Field data

Assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.4. Summary and discussion of degradation

B[a]P has a low water solubility and shows a high tendency to adsorb to particles and organic matter in the environment. The resulting low bioavailability is one of the limiting factors of its biodegradation.

For assessing the persistence of B[a]P, half-lives obtained under realistic conditions, such as field conditions, are given priority. *Selected key studies report dissipation half-lives in soil in the range from 120 to 270 days (Wild and Jones, 1993). Additionally, a dissipation half-life of more than 8.2 years was measured in a field study (Wild et al., 1991).*

Mackay et al. (1992) estimated half-lives in the different environmental compartments based on model calculations and literature research. The estimated half-lives of B[a]P in sediments and soil range from 420 to 1250 days.

Hence, it is concluded that B[a]P is a persistent substance.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). The reviewed additional information supports this conclusion on the degradation properties of B[a]P.

3.2. Environmental distribution

3.2.1. Adsorption/desorption

As described before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

"*A linear relationship between K_{ow} and the organic carbon-water partitioning coefficient K_{oc} has been demonstrated for PAHs in sediments and soil. The Log K_{ow} value from 4.6 to 6.6 can be translated as a high potential for partitioning to soils and sediments. Partitioning processes like adsorption to airborne particulate matter, as well as accumulation in sludge during wastewater treatment, have been demonstrated especially for high molecular weight PAHs.*"

B[a]P has an octanol-water coefficient of 6.13. Thus, it is concluded that B[a]P has a high potential to adsorb to particles in the environment.

3.2.2. Volatilisation

B[a]P has a low vapour pressure of 7.32 x 10^{-9} hPa at 25°C and is therefore expected to volatilise very slowly.

3.2.3. Summary and discussion of environmental distribution

B[a]P shows a high potential to adsorb to particles and organic matter and is expected to volatilise very slowly.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

3.3. Bioaccumulation

The data provided on bioaccumulation of B[a]P in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are not assessed or discussed again in this document but included for convenience (flagged by *italic print*). In addition, a review of literature not addressed in the Support Document was carried out and some further data is presented in this dossier.

The reviewed additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and supports the conclusions on the degradation properties of B[a]P already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

Note that the most sensitive organisms towards PAHs are those lacking cytochrome P450 enzyme systems. As reported in the following, it can be convincingly demonstrated that very high bioaccumulation of B[a]P and other PAHs occurs in those organisms because they cannot degrade PAHs. Therefore, it is considered not relevant to report in this assessment further, and potentially more recent, data on organisms in which no bioaccumulation of B[a]P takes place because due to the presence of P450 enzyme systems they are able to metabolise PAHs.

3.3.1. Bioaccumulation in aquatic organisms (pelagic and sediment organisms)

Bioaccumulation of B[a]P has been investigated in various species. The measured BCFs strongly depend on the taxonomic group of the respective aquatic organisms. In fish, B[a]P is

rapidly metabolised due to the presence of Cytochrome P450 enzymes.

In this context, the Support Document for identification of CTPHT as SVHC (ECHA, 2009) summarizes the assessed studies as follows:

"Bruner et al. (1994) exposed the zebra mussel (Dreissena polymorpha) in a static system to 3H-labelled benzo(a)pyrene and pyrene. BCFs were calculated using kinetic rate constants and ranged from […] 41,000 to 84,000 for benzo(a)pyrene.

Gossiaux et al. (1996) exposed the zebra mussel (Dreissena polymorpha) in a static system to radiolabelled benzo(a)pyrene […]. In total a number of 23 experiments with benzo(a)pyrene […] were conducted under either ambient field temperatures or laboratory temperatures. BCFs were calculated using kinetic rate constants and ranged from […] 133,000 to 142,000 for benzo(a)pyrene.[2]

Experimental BCF values for crustaceans […] has been studied […] Newsted & Giesy (1987). […] the BCF was determined at steady state in a static system. Bioconcentration was determined for a range of PAHs, with the resulting BCFs […] above 2,000 for […] benzo(a)pyrene […]."

Furthermore, the European Union Risk Assessment Report on CTPHT (European Commission, 2008) assessed the below summarized studies in detail.

In the study by Jimenez et al. (1987), radiolabelled B[a]P was administered to bluegill sunfish in a flow-through system. B[a]P was shown to be rapidly metabolised within the first hours of exposure, leading to moderate BCFs of 367 to 608. As a side effect of metabolisation, 40-50 % of the radioactivity remained as non-extractable residues in the fish tissue.

Accumulation in the larger mussel species *Perna viridis* (green lipped mussel) was investigated by Richardson et al. (2005). In this study, Specimens with a shell length of about 10 cm were exposed to B[a]P for 20 d followed by a depuration period of 10 d. All analyses were performed by HPLC-based determination of the parent compound. The kinetic BCF was calculated as 8470 after lipid normalisation to 5 %.

Comparably high BCFs were observed for the oligochaete *Stylodrilus heringianus* (Frank et al., 1986). The uptake of ^{3}H-B[a]P was investigated during a 6-h exposure at 4°C, but depuration kinetics were monitored for a second group of animals previously exposed to the substance for 12-15 h. The depuration phase was extended to 8 d. The kinetic BCF was calculated as 7050 (no lipid normalisation) and thin layer chromatography of tissue extracts revealed a negligible transformation of less than 2 % of the parent substance.

Very high bioaccumulation of B[a]P was also found in two studies on *Pontopreia hoyi* (Landrum and Poore, 1988; Evans and Landrum, 1989). Although not lipid normalised, the BCFs were calculated as 73000 and 48600. In the same study by Evans, a BCF of 8500 was observed in *Mysis relicta* (Evans and Landrum, 1989). In another study by Landrum and Poore, the BCFs in the Mayfly species *Hexagenia limbata* were determined as 3680 to 5610 (Landrum and Poore, 1988).

The most relevant studies and results are summarised in Table 5.

Table 5: Overview of the bioaccumulation studies for B[a]P (key studies are printed bold). Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009) (*italic*) and EU Risk Assessment Report on CTPHT (European Commission, 2008)

Species	**BCF**	**Temp.**	**Test type[a)]**	**Calculation[b)]**	**R[c)]**	**References**

[2] *Lipid normalised BCFs (5 % lipid content) range from 20000 to 140000*.

Species	BCF	Temp.	Test type[a)]	Calculation[b)]	R[c)]	References
Fish:						
Lepomis macrochirus	**377[d)]** **608**	**13°C** **23°C**	**F**	**k_1/k_2** **(total)**	**2**	**(Jimenez et al., 1987)**
Invertebrates:						
Dreissena polymorpha[o)]	***84000[f)] -> 23500 (5 % lipids)*** ***41000[g)] -> 23000 (5 % lipids)*** ***77000[h)] -> 15500 (5 % lipids)***	***20°C***	***S***	***k_1/k_2 (total=parent)***	***2***	***(Bruner et al., 1994)***
Daphnia magna	***12761***		***S***	***k_1/k_2***	***2***	***(Newsted and Giesy, 1987)***
Dreissena polymorpha[o)]	***20000 -> 140700[i)] (5 % lipids)*** ***30650 -> 117860[i)] (5 % lipids)***	***4°C*** ***23°C***	***S***	***k_1/k_2 (total=parent)***	***2***	***(Gossiaux et al., 1996)***
Perna viridis[o)]	**8475[j)]**	**19°C**	**SR**	**k_1/k_2 substance specific**	**2**	**(Richardson et al., 2005)**
Stylodrilus heringianus[o)]	**7050[k)]**	**4°C**	**F**	**k_1/k_2 (total=parent)**	**2**	**(Frank et al., 1986)**
Pontoporeia hoyi[o)]	**73000[l)]**	**4°C**	**F**	**k_1/k_2 (total=parent)**	**1**	**(Landrum and Poore, 1988)**
Pontoporeia hoyi[o)]	**48600[m)]**	**4°C**	**F**	**k_1/k_2 (total=parent)**	**2**	**(Evans and Landrum, 1989)**
Mysis relicta[o)]	**8500[m)]**	**4°C**	**F**	**k_1/k_2 (total=parent)**	**2**	**(Evans and Landrum, 1989)**
Hexagenia limbata[o)]	**3680 -> 5610 (5 % lipids)[n)]**	**10 – 20°C**	**F**	**k_1/k_2 (total=parent)**	**2**	**(Landrum and Poore, 1988)**

a) F: flow-through system, S: static exposure system, SR: static renewal, FD: organisms collected from the field
b) k_1/k_2: kinetic: uptake rate/depuration rate, total: total compound concentration (including transformation products), parent: parent compound concentration
c) Reliability score: 1-reliable without restrictions, 2-reliable with restrictions, 3-unreliable, 4-not assignable
d) exposure duration 48 h, elimination 144 h
e) exposure duration 4 h, elimination 120 h
f) exposure duration 6 h, elimination duration 168 h, mussels with high lipid content, 21 mm shell length
g) exposure duration 6 h, elimination duration 168 h, mussels with low lipid content, 21 mm shell length
h) exposure duration 48 h, elimination duration 168 h, mussels with high lipid content, 15 mm shell length
i) exposure duration 6 h, elimination duration 15 d
j) exposure duration 20 d, elimination duration 10 d
k) exposure duration 6 h, elimination was monitored over 8 days in a second group of animals, previously exposed for 12-15 h
l) exposure duration 6 h, elimination duration 14 d
m) exposure duration 6 h, elimination duration 10-26 d

n) exposure duration 6 h, elimination duration 14 d
o) field collected organisms

3.3.2. Summary and discussion of bioaccumulation

The bioaccumulation potential of B[a]P strongly varies with the organism´s ability to metabolise PAHs. In general, fish and other vertebrates are able to efficiently metabolise B[a]P due to the presence of Cytochrome P450-like enzymes, leading to a low to moderate BCF. In contrast, many invertebrates (in particular mussels and crustaceans) are lacking those enzymes suitable for metabolising B[a]P and, therefore, very high BCFs were observed in the range from 3680 to 140700.

Thus, it is concluded that B[a]P is a bioaccumulative substance.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

The reviewed additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and supports the conclusion on the biodegradation properties of B[a]P that has already been reached in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

4. Human health hazard assessment

Information on hazard to human health relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c) of the REACH Regulation is provided in section 2 of this dossier (classification information).

5. Environmental hazard assessment

The data provided on environmental toxicity of B[a]P in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009) are not assessed or discussed again in this dossier but included for convenience (flagged by *italic print*).

5.1. Aquatic compartment (including sediment)

5.1.1. Fish

5.1.1.1. Long-term toxicity to fish

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009), the issue has already been summarized and discussed appropriately as follows:

"In a 28-d early life stage (ELS) study with Brachydanio rerio no effects were observed up to the highest test concentration of 4.0 µg/l, which is already above the water solubility of benzo(a)pyrene (Hooftman & Evers-de Ruiter, 1992). In another ELS study with Oncorhynchus mykiss a NOEC of 1.5 µg/l was obtained for developmental abnormalities as endpoint (Hannah et al., 1982). Evaluation of the data presented by Hannah et al. with a log-logistic relationship resulted in the derivation of an EC_{10} of 2.9 µg/l (The Netherlands 2008), which again is above the water solubility of benzo(a)pyrene."

As different fish species may vary in their sensitivity, the described effect value for *O.mykiss* is not contradicting the no observed effect in *D.rerio* (reported as *Brachydanio rerio*).

Table 6: Overview of studies concerning the long-term toxicity of B[a]P to fish (nominal concentrations are given if not stated otherwise; all listed studies are considered reliable with restrictions). Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Species	Duration	Endpoint	Effect level	Conc.	Comment	References
Oncorhynchus mykiss (reported as Salmo gairdneri R.)	*36 d*	*Abnormalities*	*NOEC* *EC_{10}*	*1.5 µg/L (m)* *(2.9 µg/L calculated, above WS)*	*ELS* *(EC_{10}: determined from presented data with log-logistic dose-response relationship (The Netherlands 2008))*	*(Hannah et al., 1982)*
D.rerio (reported as Brachydanio rerio)	*28 d*	*Abnormalities*	*No effect*	*4 µg/L (above WS)*	*ELS*	*(Hooftman and Evers-de Ruiter, 1992)*

5.1.2. Aquatic invertebrates

5.1.2.1. Short-term toxicity to aquatic invertebrates

As the Support Document for identification of CTPHT as SVHC (ECHA, 2009) discussed before:

"PAHs can be toxic via different modes of action, such as non-polar narcosis and phototoxicity. Phototoxicity is caused by the ability of PAHs to absorb UVA radiation, UVB radiation, and in some instances, visible light. It may occur as the result of the production of singlet oxygen, which is highly damaging to biological material, or as result of the formation of new, more toxic compounds from the photomodification (usually oxidation) of PAHs (Lampi et al., 2006).
[…]
The phototoxicity of PAHs is relevant where the PAHs are exposed to light and UV radiation, and considered to be most important for upper layers of aquatic and terrestrial environments. Although UV penetration depths may vary among PAH-contaminated sites, it is not unlikely that significant portions of the aquatic community may be exposed to UV levels sufficient to induce phototoxicity, as UV levels occurring under normal sun light conditions have been shown to elicit these effects.
There is growing evidence which suggests that phototoxic PAHs may be degrading aquatic habitats, particularly those in highly contaminated areas with shallow or clear water.
[…]
Phototoxicity of PAHs may also be initiated in aquatic organisms which have accumulated PAHs from the sediment and subsequently are exposed to sun light closer to the surface (The Netherlands, 2008). Phototoxic effects of PAHs are therefore considered relevant in this hazard, respectively T-assessment.
[…]
Only acute toxicity studies with exposure to UV-light result in effects at concentrations near the water solubility of 1.2 - 1.8 µg/l (Mackay et al. 2000, cited in The Netherlands 2008). Results from studies on the aquatic toxicity of benzo(a)pyrene are shown in Table 5.9. The lowest acute toxicity of benzo(a)pyrene was observed in a test with Daphnia magna under exposure to UV radiation."

The following table gives an overview on the relevant studies.

Table 7: Overview of studies concerning the short-term toxicity of B[a]P to aquatic invertebrates (nominal concentrations are given if not stated otherwise; all listed studies are considered reliable with restrictions). Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Species	Duration	Endpoint	Effect level	Conc.	Comment	References
Daphnia magna	*27 h*	*Immobility*	*EC_{50}*	*1.2 µg/L (n)*	*based on: mobility (in the presence of UV (2 h UV-A/B radiation and 1 h recovery))*	*(Wernersson, 2003)*
Daphnia magna	*48 h*	*Immobility*	*EC_{50}*	*3.89 nM (0.89 µg/L), (n)*	*Stimulated solar radiation (visible light + UV A + UV B)*	*(Lampi et al., 2006)*
Daphnia magna	*48 h*	*Immobility*	*EC_{50}*	*6.44 nM (1.67 µg/L), (n)*	*Visible light + UV A*	*(Lampi et al., 2006)*

5.1.2.2. Long-term toxicity to aquatic invertebrates

The Support Document for identification of CTPHT as SVHC (ECHA, 2009) reasoned before:

"Chronic toxicity of benzo(a)pyrene was reported for the alga Pseudokirchneriella subcapitata with an EC_{10} of 0.78 µg/l, and for reproduction of Ceriodaphnia dubia with an EC_{10} of 0.5 µg/l in a 7-d study when exposed to laboratory light without UV (Bisson et al., 2000).
[…]
Furthermore, it has been shown that UV radiation increases the long term toxicity of benzo(a)pyrene. For shell development of Crassostrea gigas, when exposed to UV radiation, the calculated EC_{10} was 0.22 µg/l whereas under UV-lacking fluorescent laboratory lighting conditions the resulting EC_{10} was 1.1 µg/l (Lyons et al. 2002). As the study on shell development of the marine mollusc Crassostrea gigas resulted in the lowest reliable chronic EC_{10} value (0.22 µg/l) it was chosen as key study for T-assessment."

The following table gives an overview on the relevant studies.

Table 8: Overview of studies concerning the long-term toxicity of B[a]P to freshwater and marine invertebrates (nominal concentrations are given if not stated otherwise; the key study for the toxicity assessment is printed bold; all listed studies are considered reliable with restrictions). Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Species	Duration	Endpoint	Effect level	Conc.	Comment	References
<u>*Freshwater organisms:*</u>						
Ceriodaphnia dubia	*7 d*	*Reproduction*	*EC_{10}*	*0.5 µg/L (m)*	*Laboratory light photoperiod 16:8 h light:dark at less than 500 lux*	*(Bisson et al., 2000)*
<u>*Marine organisms:*</u>						
Crassostrea gigas	***48 h***	***Shell development***	***NOEC*** ***EC_{10}***	***0.5 µg/L (n)*** ***0.22 µg/L (n)***	***Embryos 12:12 h light:dark UV-A/B radiation***	***(Lyons et al., 2002)***
Crassostrea gigas	*48 h*	*Shell development*	*NOEC*	*1 µg/L (n)*	*Embryos 12:12 h light:dark*	*(Lyons et al., 2002)*

Species	Duration	Endpoint	Effect level	Conc.	Comment	References
			EC_{10}	*1.1 µg/L (n)*	*fluorescent light without UV radiation*	

5.1.3. Algae and aquatic plants

As described before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

"Chronic toxicity of benzo(a)pyrene was reported for the alga Pseudokirchneriella subcapitata with an EC_{10} of 0.78 µg/l […] when exposed to laboratory light without UV (Bisson et al., 2000)."

5.2. Summary and discussion of toxic effects

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009), the issue has already been summarised and discussed appropriately as follows:

"Only acute toxicity studies with exposure to UV-light result in effects at concentrations near the water solubility of 1.2 -1.8 µg/l (Mackay et al. 2000, cited in The Netherlands 2008). […] The lowest acute toxicity of benzo(a)pyrene was observed in a test with Daphnia magna under exposure to UV radiation.

Chronic toxicity of benzo(a)pyrene was reported for the algae Pseudokirchneriella subcapitata with an EC_{10} of 0.78 µg/l, and for reproduction of Ceriodaphnia dubia with an EC_{10} of 0.5 µg/l in a 7-d study when exposed to laboratory light without UV (Bisson et al., 2000). In a 28-d early life stage (ELS) study with Brachydanio rerio no effects were observed up to the highest test concentration of 4.0 µg/l, which is already above the water solubility of benzo(a)pyrene (Hooftman & Evers-de Ruiter, 1992). In another ELS study with Oncorhynchus mykiss a NOEC of 1.5 µg/l was obtained for developmental abnormalities as endpoint (Hannah et al., 1982). Evaluation of the data presented by Hannah et al. with a log-logistic relationship resulted in the derivation of an EC_{10} of 2.9 µg/l (The Netherlands 2008), which again is above the water solubility of benzo(a)pyrene.

Furthermore, it has been shown that UV radiation increases the long term toxicity of benzo(a)pyrene. For shell development of Crassostrea gigas, when exposed to UV radiation, the calculated EC_{10} was 0.22 µg/l whereas under UV-lacking fluorescent laboratory lighting conditions the resulting EC10 was 1.1 µg/l (Lyons et al. 2002).

As the study on shell development of the marine mollusc Crassostrea gigas resulted in the lowest reliable chronic EC_{10} value (0.22 µg/l) it was chosen as key study for T-assessment."

6. Conclusions on the SVHC Properties

6.1. CMR assessment

B[a]P is covered by index number 601-032-00-3 of Regulation (EC) No 1272/2008 (CLP) in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and 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 following criteria for identification as substance of very high concern 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.

6.2. PBT and vPvB assessment

6.2.1. Assessment of PBT/vPvB properties

6.2.1.1. Persistence

B[a]P has a low water solubility and shows a high tendency to adsorb to particles and organic matter in the environment. The resulting low bioavailability is one of the limiting factors of its biodegradation.

Mackay et al. (1992) estimated half-lives in the different environmental compartments based on model calculations and literature research. The estimated half-lives of B[a]P in sediments and soil are > 1250 and 420 to 1250 days, respectively.

Increased residence times of PAHs in soil can further decrease their bioavailability in the terrestrial environment. In studies involving artificially added PAHs, biodegradation rates are often higher than these observed for the same substances present in soil as part of a contamination. Therefore, half-lives obtained under realistic conditions, such as field conditions, are given priority for assessing the persistence of B[a]P. *Selected key studies report dissipation half-lives in soil in the range from 120 to 270 days (Wild and Jones, 1993). Additionally, a dissipation half-life of more than 8.2 years was measured in a field study (Wild et al., 1991).*

6.2.1.2. Bioaccumulation

The bioaccumulation potential of B[a]P strongly varies with the organism´s ability to metabolise PAHs. In general, fish and other vertebrates are able to efficiently metabolise B[a]P due to the presence of Cytochrome P450-like enzymes, leading to a low to moderate BCF. In contrast, many invertebrates (in particular mussels and crustaceans) are lacking those enzymes suitable for metabolising B[a]P. Very high BCFs were observed in the range from 3680 to 140700 (Frank et al., 1986; Landrum and Poore, 1988; Evans and Landrum, 1989; Bruner et al., 1994; Gossiaux et al., 1996; Richardson et al., 2005).

6.2.1.3. Toxicity

It has been shown that *UV radiation increases the long-term toxicity of B[a]P. For shell development of Crassostrea gigas, the calculated EC_{10} was 0.22 µg/L when exposed to UV radiation (Lyons et al. 2002).*

Chronic toxicity of B[a]P was reported for the alga Pseudokirchneriella subcapitata (EC_{10} of 0.78 µg/L) and for reproduction of Ceriodaphnia dubia (EC_{10} of 0.5 µg/L) in a 7-d study when exposed to laboratory light without UV (Bisson et al., 2000).

In fish, no effects were observed up to the highest test concentration of 4.0 µg/L which is already above the water solubility of B[a]P (Hooftman and Evers-de Ruiter, 1992). In another fish study, a NOEC of 1.5 µg/L was obtained.

6.2.2. Summary and overall conclusions on the PBT and vPvB properties

An assessment of the PBT/vPvB properties of B[a]P has already been carried out by the MSC in the context of the identification of CTPHT as SVHC as documented in the MSC Support Document on CTPHT (ECHA, 2009). In addition, for the purpose of this SVHC proposal for B[a]P, 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 conclusions on the PBT and vPvB properties of B[a]P already drawn in the MSC Support Document on CTPHT.

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

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

Based on the available information, the most sensitive organism to B[a]P is *Crassostrea gigas*. *The calculated EC_{10} was 0.22 µg/L whereas under UV-lacking fluorescent laboratory lighting conditions, the resulting EC_{10} was 1.1 µg/L (Lyons et al. 2002).*

Therefore, B[a]P 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 following classification as:

- Carcinogenic 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 B[a]P 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.

This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC as documented in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

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.

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