

Annex XV report

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

Substance Name: Benz[*a*]anthracene

EC Number: 200-280-6

CAS Number: 56-55-3

Submitted by: Germany

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FOREWORD

Benz[*a*]anthracene (BaA) belongs to the substance group of Polycyclic Aromatic Hydrocarbons (PAHs), of which many are well-known to be hazardous for human health and the environment. Eight PAHs, including BaA, have a harmonised classification as carcinogenic, mutagenic, and/or 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, Coal Tar Pitch High Temperature (CTPHT).

BaA is constituent, *inter alia*, in CTPHT. In the Support Document of Pitch, coal tar, high temp. (CTPHT) it has been concluded by the Member State Committee (MSC) that benz[*a*]anthracene fulfils the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, BaA and further PAHs whose properties have already been agreed on by the MSC in the CTPHT SVHC identification process have not yet been proposed for formal SVHC identification and inclusion in the Candidate List.

The information which was available and led to the conclusion that BaA is a SVHC is summarized in the support document for CTPHT (ECHA, 2009). This information is still valid and allows compact review of the substance properties with a focus on PBT/vPvB. Therefore, the SVHC identification of BaA in this current dossier is based on the information provided in that support document.

In the following, the abbreviation BaA is used for the substance benz[*a*]anthracene.

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

Substance Name: Benz[a]anthracene

EC Number: 200-280-6

CAS number: 56-55-3

- The substance is proposed to be 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 1B¹.
- It is proposed to identify the substance as persistent, bioaccumulative and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).
- It is proposed to identify the substance 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

Art 57 (a):

Benz[a]anthracene is covered by index number 601-033-00-9 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 class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

Art 57 (d) and (e):

An assessment of the PBT/vPvB properties of benz[a]anthracene (BaA) was done by the MSC in the scope of the identification of CTPHT as SVHC (ECHA, 2009). The assessment of PBT/vPvB properties of BaA in this dossier is based on the information provided and analysed in the Support Document for the Identification of CTPHT as SVHC (ECHA, 2009).

Persistence

Based on the available information from experimental and estimated data, BaA degrades very slowly in soil with half-lives of > 180 d. Thus, the P and the vP criteria of REACH Annex XIII are fulfilled.

Bioaccumulation

The bioaccumulation of BaA in Crustacea were measured and BCFs > 5000 obtained.

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

Thus, the B and the vB criteria of REACH Annex XIII are fulfilled.

Toxicity (only relevant for PBT substances)

Based on available data, the lowest chronic aquatic toxicity was observed for the algae *Pseudokirchneriella subcapitata* with an EC10 of 1.2 µg/l for growth inhibition. Therefore, BaA 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 section 1.1.3 b) is fulfilled based on the classification of the substance as Carcinogenic category 1B (hazard statement H350: "May cause cancer").

Overall conclusion

In conclusion, benz[a]anthracene meets the criteria for a PBT and vPvB substance according to Article 57 (d) and (e) REACH based on a weight-of-evidence determination and the criteria for carcinogenicity according to Article 57 (a).

Registration dossiers submitted for the substance? No

PART I

Justification

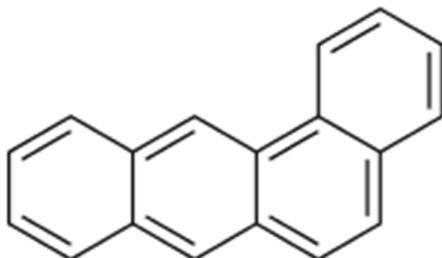
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	200-280-6
EC name:	Benz[<i>a</i>]anthracene
CAS number (in the EC inventory):	56-55-3
CAS number: Deleted CAS numbers:	
CAS name:	Benz[<i>a</i>]anthracene
IUPAC name:	Benzo[<i>a</i>]anthracene
Index number in Annex VI of the CLP Regulation	601-033-00-9
Molecular formula:	C ₁₈ H ₁₂
Molecular weight range:	228.29 g/mole
Synonyms:	Benzo[<i>a</i>]anthracene (BaA) tetraphene Benz[<i>a</i>]anthracene Tetraphene 1,2-Benz[<i>a</i>]anthracene Benzanthracene 1,2-Benzanthrene 1,2-Benzanthracene Benzanthrene Benzoanthracene 1,2-Benzoanthracene Benzo[<i>b</i>]phenanthrene 2,3-Benzophenanthrene <i>Benz(a)anthracen</i>

Structural formula:



1.2 Composition of the substance

Name: Benz[*a*]anthracene

Description: Benz[*a*]anthracene (BaA) belongs to the group of Polycyclic Aromatic Hydrocarbons (PAHs). BaA is not produced intentionally but does occur as constituent in UVCB² -often with other PAHs - mainly derived from the coal and petroleum stream. The dossier addresses the substance BaA as a substance itself and not in the context of its original occurrence in UVCB.

Substance type: mono-constituent

1.3 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20°C and 101.3 kPa		<i>solid</i>	<i>GSBL database, accessed at Mar-20-2017</i>
Melting/freezing point		160.5 °C	Mackay, 2006
Boiling point		438 °C	Mackay, 2006
Vapour pressure	reported vapour pressure values are within the range between of the two indicated values (3 rd column)	6.67 x 10 ⁻⁷ Pa at 20°C (effusion method) 1.47 x10 ⁻⁵ Pa at 25°C (effusion method)	Mackay, 2006
Density		1.2544 g/m ³ at 20°C	Mackay, 2006
Water solubility	reported water solubility values are within the range of the two indicated values (3 rd column)	0.00837 mg/L at 25°C 0,0168 mg/L at 25°C	Mackay, 2006
Partition coefficient n-octanol/water (log value)		log Kow 5.91 at 25°C	ECHA, 2009

² Substances of Unknown or Variable composition, Complex reaction products or Biological materials

2. Harmonised classification and labelling

Benz[a]anthracene is covered by Index number 601-033-00-9 in part 3 of Annex VI to the CLP Regulation as follows:

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	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
601-033-00-9	Benz(a)-anthracene	200-280-6	56-55-3	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	GHS08 GHS09 Dgr	H350 H410		M=100	

3. Environmental fate properties

3.1 Degradation

The data provided on degradation of BaA 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*). Additional information available in the EU risk assessment report on CTPHT (EC, 2008) and the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) but not discussed in the support document was included.

3.1.1 Abiotic degradation

3.1.1.2 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 BaA is hydrolytically stable.

3.1.1.3 Oxidation

The oxidation of PAHs 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).

BaA has 4 aromatic rings and a reported vapour pressure below 10^{-4} Pa. Therefore it is assumed that BaA is mainly particle associated and is degraded by photolysis instead of oxidization.

3.1.1.3 Phototransformation/photolysis

3.1.1.3.1 Phototransformation in air

Photolysis of PAHs at the atmosphere was assessed in the EU risk assessment report (EC, 2008) as following:

Photolysis in the troposphere results in the formation of reactive hydroxyl and nitrate (NO_3) radicals and ozone (O_3), which reacts as oxidizing agent with organic compounds, like PAHs. These radical and ozone reactions comprise mainly degradation of gas-phase PAHs (Calvert et al., 2002). Particle-associated PAHs are expected to degrade in air predominantly via direct photolysis by light with a wavelength < 290 nm (Kamens et al., 1988), although reaction with ozone will also occur (Peters and Seifert, 1980; Grosjean et al., 1983; Pitts et al., 1986; Coutant et al., 1988).

As stated earlier, BaA is mainly particle associated. The degradation rate of PAHs, and therefore of BaA, depends on the type of particle to which they are bound (Behymer & Hites, 1988, cited in The Netherlands, 2008). While half-lives for direct photolysis of PAHs are in the range of hours (Vu Duc & Huynh, 1991, cited in The Netherlands, 2008), it was demonstrated by Behymer & Hites (1988) (cited in The Netherlands (2008)), that particle surface-adsorbed BaA does have representative lifetimes between 15 min and 7.8 days under natural conditions. According to the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008), the photolysis of PAHs is as follows:

A two layer model has been proposed for the behaviour of naturally occurring PAH on airborne particulate matter, in which photo oxidation takes place in the outer layer, and much slower, 'dark' oxidation takes place in the inner layer (Valerio et al., 1987). This model is in line with the results of Kamens et al. (1991), who reported that PAH on highly loaded particles degrade more slowly than those on particles with low loads. As PAH occur mainly on particulate matter with a high carbon content, their degradation in the atmosphere is slower than that of PAH in the vapour phase under laboratory conditions or adsorbed on synthetic material.

3.1.1.3.2 Phototransformation in water

As assessed before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *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.*

3.1.1.3.3 Phototransformation in soil

As assessed before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *exposure to light is even more limited in soils, photodegradation is as well not considered a relevant degradation process in terrestrial environments.*

3.1.1.4 Summary on abiotic degradation

It is concluded that in the atmosphere, free BaA degrades within periods of 15 min to 7.8 days by direct photolysis. The substance is however mostly particle-associated and when adsorbed onto fine particles, BaA may be more stable in the atmosphere. In water, BaA 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 persistence of BaA 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. BaA 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 and sediments

The biodegradation in water was already assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) and will not be assessed again within this dossier.

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).

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

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 (Kow) (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.

3.1.2.1.1 Estimated data

As 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 BaA in water and sediments are in the range of 42 to 125 days and longer than 1250 days respectively.*

3.1.2.2 Biodegradation in soil

Biodegradation in soil was assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) as follows:

Biodegradation rates of PAHs in soil depend on several factors related to the soil type, including pH, moisture content, nutrients, oxygen, and the diversity of the 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 demonstrated enhanced PAH-degradation rates when the soil had been enriched with isolated PAH-degrading microorganisms ([...] The Netherlands, 2008). On the basis of a comparison between two studies (Wild et al. 1991 and Wild and Jones, 1993) it was illustrated that the half-lives observed under laboratory conditions can be much shorter than those obtained from long-term field studies. This was attributed by the authors to the more optimal conditions (temperature, moisture content, nutrient and oxygen supply) applied in the laboratory tests.

Wild and Jones (1993) and Wild et al. (1991) studied the biodegradation of PAHs in soil amended with sewage sludge under laboratory and field conditions, respectively. They determined dissipation half-lives for BaA in the range of 106 to 313 days in laboratory

soil microcosms and under field condition a half-life of 8.1 years.

In addition Mackay *et al.* (1992) as summarized by The Netherlands (2008) predicted half-lives for BaA in the range of 420 to 1250 days in soil. These predictions are in line with half-lives observed under laboratory conditions or under environmental conditions (field data).

Further the Support Document for identification of CTPHT as SVHC (ECHA, 2009) discusses “aging” for PAHs as following:

“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.”

3.1.2.4 Summary and discussion on biodegradation

The half-life predicted by Mackay *et al.* (1992) indicate that BaA persists in sediment with half-lives higher than 1250 days. For water degradation, Mackay *et al.* (1992) predicted long elimination half-lives between 42 and 125 days. However, considering the chemical structure of BaA that consists of four aromatic rings, standard tests for biodegradation in water demonstrated that BaA is biodegradable under aerobic conditions. Biodegradation studies in laboratory soil microcosms show dissipation half-lives between 106 and 313 days (Wild and Jones, 1993). Biodegradation studies on soil done by Wild *et al.* (1991) revealed a half-life of BaA of more than 8.1 years under field conditions.

Hence, BaA biodegrades very slowly in sediments and soils.

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

3.1.3 Summary and discussion of degradation

BaA 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 BaA, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Selected studies report dissipation half-lives in soil in the range from 106 to 313 days (Wild and Jones, 1993). Additionally, the study by Wild *et al.* (1991) reports a half-life for BaA of 8.1 years in soil, obtained in a long term field experiment.

Therefore, it is concluded that BaA is a very persistent substance.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009) the

adsorption properties of PAHs are described as follows:

“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} values 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 (The Netherlands, 2008).”

BaA has a Log K_{ow} value of 5.91. It is therefore concluded that BaA has a high potential to adsorb to particles in the environment.

3.2.2 Volatilisation

BaA has reported vapour pressure values between 6.67×10^{-7} Pa at 20°C and 1.47×10^{-5} Pa at 25°C (Mackay et al., 2006). It is therefore concluded that BaA is expected to volatilise very slowly. Further The Netherlands (2008) concluded that *“volatilisation of PAHs is insignificant”*.

3.2.3 Distribution modelling

Mackay Level III fugacity modelling was done using EPI Suite (version 4.11) with default values of environmental emission rates (it is assumed that BaA is released at equal rates to air, water, soil and sediment) and default values of physico-chemical properties (done in February 2017). Calculation revealed a distribution of BaA to soil and sediment phase (table 4).

Table 4: Fugacity Model calculation (EPI Suite, version 4.11) of BaA

Distribution to:	Mass amount (percent)
Air	0.0728
Water	4.52
Soil	46
Sediment	49.4

3.2.4 Summary and discussion of environmental distribution

BaA has a high potential to adsorb to particles and volatilisation of BaA is insignificant. Further modelling the fugacity reveals that BaA is mainly distributed in soil and sediment.

3.3 Data indicating potential for long-range transport

No data indicating potential for long-range transport are reviewed in the scope of this dossier.

3.4 Bioaccumulation

3.4.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

The data provided on bioaccumulation of BaA 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*). Additional information is taken from the European Union Risk Assessment Report on CTPHT (EC, 2008) and text cited from this report is flagged by Courier New print.

Bioaccumulation has been tested in different aquatic organisms.

The bioaccumulation of 5 PAHs in fathead minnows (*Pimephales promelas*) was studied in a static experimental set-up according to the so-called 'adjusted Banerjee method' (De Maagd, 1996; chapter 4). This study was designed to quantify the role of biotransformation in the bioaccumulation process. PAHs were added to tap water by a generator column. [...] The concentrations of the parent compounds in both water and fish in the static systems were analyzed using HPLC during 48 hours on 7 to 11 points in time. Fish were fed daily until two days prior to the experiment. [...] The bioaccumulation with and without biotransformation was determined by running parallel tests with and without the addition of piperonyl butoxide (PBO), a known biotransformation inhibitor for substrates binding to the site of cytochrome P450-isoenzymes. To distinguish between loss due to abiotic processes and biotransformation controls without fish were used as well. [...] For benz(a)anthracene this adjustment of the recovery did not result in a good fit of the data and therefore the uptake was also estimated on the concentration in the fish only. [...] The calculated BCF values in the absence of PBO were [...] 200 L/kg for benz(a)anthracene. For benz(a)anthracene, biotransformation, which was not completely inhibited by PBO, significantly influenced the bioaccumulation process. The validity (Klimisch score) of this study is 2 (ECHA, 2009).

In a second study by de Maagd et al. (1998) with fathead minnows benz(a)anthracene was tested in a flow-through study. In this study fish were exposed to a constant concentration of about $8.7 \pm 3.4 \mu\text{g/L}$. [...] The BCF study determined in this flow-through study is comparable to the value that was determined in the static test according to the "adjusted Banerjee method". (Validity = 2)

Freitag et al. (1985) determined concentration factors in activated sludge, algae and fish. Experimental protocols are described in detail in other publications (Freitag et al., 1982; Korte et al., 1978). Golden ide (*Leuciscus idus melanotus*; 1.5g) were exposed to ^{14}C labelled PAHs for 3 days, with a constant concentration of 0.05 mg/L. [...]

According to the EU risk assessment report on CTPHT (EC, 2008):

[...] The test is not performed in the dark (so breakdown may have occurred), no controls are mentioned. Fish were not fed during the test. Water concentrations are measured daily for total ^{14}C activity using LSC. Transformation products were determined with undefined chromatography techniques, but it is unclear if and how these results were used. Bioconcentration is calculated using the average aquatic exposure to the chemicals. Because the ^{14}C method in this case does not distinguish between the parent compound and its metabolites, the accumulation factor is a measure of both (ergo, the BCF for the parent compound is overestimated). [...] (Validity = 4)

Remarkably highest BCF values were measured for phenanthrene, anthracene, pyrene, B(a)A and B(a)P in the amphipod *Pontoporeia hoyi*, which has a 20-50% lipid content by wet weight and no capacity for biotransformation (Landrum, 1988). It is however also obvious that for all PAHs a large variation within the different taxonomic groups was observed, fish

included. In view of the high BCF values of molluscs, it is considered relevant not only to assess the risk for fish eating birds and mammals but for mollusc eating birds and mammals as well. Thus, molluscs may be an important species in determining bioaccumulation potential of PAHs. Because they do not metabolise PAHs, their BCF values may be higher than BCF values for fish. Consequently, mollusc-eating birds may therefore be at higher risk than fish-eating birds. However, for BaA no study analysing the BCF in mussels is available yet.

According to the Support Document for the identification of CTPHT as SVHC (ECHA, 2009),

Potential for biotransformation of substances in exposed species is also an important factor in assessing bioaccumulation. BCF values may be higher in early life stages of an organism than in the adult stage. Whereas fish, and to some extent also molluscs, have the ability to metabolise PAHs, no evidence of metabolism of PAHs has been observed in algae, or oligochaeta.

[...]

Bioaccumulation in Daphnia magna has been studied by McCarthy et al (1985) and Newsted & Giesy (1987). In the study by McCarthy the BCF value for benz[a]anthracene was reported as 2,920, determined as the ratio between uptake rate and depuration rate. In the study by 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 being [...] above 2,000 for [...] benz[a]anthracene, [...].

In a study by Southworth (1978) the potential for bioaccumulation in Daphnia pulex was studied for PAHs in a static system. The bioconcentration factor was determined at steady state conditions and as the ratio between the rates of uptake and elimination at non steady state conditions. The study indicated that the PAH content of Daphnia lipid was in equilibrium with the aqueous PAH concentration. The reported BCF was above 2,000 for pyrene and benz[a]anthracene [...]

Table 5: Experimentally obtained BCF values of BaA

Species	BCF	Temp.	Test type ^{a)}	Calculation ^{b)}	R ^{c)}	References
Fish:						
<i>P. promelas</i>	200-265		S, F	k1/k2 (parent)	2	De Maagd et al. (1996, 1998)
<i>L. melanotus</i>	350	20 -25 °C	S	NS (unclear)	4	Freitag et al. (1985)
Crustacea						
<i>Pontoporeia hoyi</i>	63,000	4°C	S	k1/k2		Landrum, 1988
<i>D. magna</i>	2,920 10,226	Not reported not reported	S S	k1/k2 Equi		McCarty et al., 1985 Newsted & Giesy, 1987
<i>D. pulex</i>	10,109	25°C	S	Equi		Southworth et al. (1978)

bold: The study by Newsted & Giesy (1987) was chosen in the Support Document for Identification of CTPHT as SVHC as the study having the highest weight for benz[a]anthracene, chrysene, benzo(k)fluoranthene, benzo(ghi)perylene and dibenzo(a,h)anthracene as the most reliable equilibrium study with BCF >2000.

a) F: flow-through system, S: static exposure system, SR: static renewal, FD: organisms collected from the field;

b) k1/k2: 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

3.4.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

The European Union Risk Assessment Report on CTPHT (EC, 2008) reports a calculated BCF value for BaA in *Eisenia andrei* of 9800 and this value is considered to represent a reasonable worst case.

3.4.3 Field data

Field data have not been assessed for the assessment of bioaccumulation of this dossier.

3.4.4 Summary and discussion of bioaccumulation

Bioaccumulation potential of BaA differs between the organisms due to the organism's ability to metabolise PAHs (biotransformation). BaA is transformed in fish, and to some extent also in molluscs, using enzymes belonging to the Cytochrome P450 enzymes (Cyt P450) and other mechanism. Biotransformation contributes to detoxification of fish and molluscs, but no evidence for transformation processes of PAHs in algae and oligochaeta exist. Bioaccumulation of BaA in those organism of low trophic level could contribute to a constant exposure of predators and therefore hamper the integrity of aquatic ecosystems.

For Daphnia and earthworm experimental and predicted data for BaA indicate BCF values above 5000. Thus, it is concluded that BaA is a bioaccumulative and very bioaccumulative substance.

This conclusion was already drawn 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 report (see harmonised classification and labelling in Section 2 :as Carc. 1B, H350).

PBT considerations regarding human health hazard assessment:

Benz[a]anthracene is classified in hazard carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH is fulfilled according to the provision of Annex XIII Section 1.1.3 b).

5. Environmental hazard assessment

5.1 Aquatic compartment (including sediment)

According to the Support Document for the identification of CTPHT as SVHC (ECHA, 2009):

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). Phototoxic effects can be observed after a short period of exposure, which explains why for PAHs like anthracene, fluoranthene and pyrene, where phototoxicity is most evident, the acute toxicity values under simulated solar radiation may be lower than the chronic toxicity values determined under less harsh radiation.

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. Photo-induced chronic effects have been reported for anthracene at UV intensities occurring at depths of 10-12 m in Lake Michigan (Holst & Giesy, 1989). 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.

5.1.1 Fish

5.1.1.1 Short-term toxicity to fish

No standard data on short-term toxicity to fish are available (search done March 2017).

The Netherlands (2008) summarizes acute toxicity on fish tests as following:

*For fish, no standard acute toxicity data are available. In a study with larvae of *Pimephales promelas* the median lethal time was determined (Oris & Giesy, 1987). 7-d old larvae were exposed to a measured concentrations of 1.8 µg/L benz[a]anthracene for an incubation period of 24 hour in the absence of UV-radiation and thereafter exposed to UV-light with an intensity of 20 µW/cm² UV-B (290-336 nm), 95 µW/cm² UV-A (336-400 nm). After the incubation time of 24 hours, the medium was renewed every 12 hours. The median lethal time after UV-radiation started was 65 hours. Thus, after 89 hours, of which the last 65 hours were with UV radiation, 50% mortality of the fish larvae occurred at 1.8 µg/L.*

5.1.1.2 Long-term toxicity to fish

No data on long-term toxicity to fish are available (search done March 17).

5.1.2 Aquatic invertebrates

5.1.2.1 Short-term toxicity to aquatic invertebrates

The Netherlands (2008) summarizes acute toxicity on invertebrates as following:

Data on acute toxicity of benz[a]anthracene are available for algae, crustaceans and amphibians.

The 96-h LC50 of Daphnia pulex exposed under a 12:12 h photoperiod to mixed fluorescent and natural light was 10 µg/L (Trucco et al., 1983). The 48-h LC50 of Daphnia magna from a test in the dark was higher than 9.1 µg/L (Bisson et al., 2000). Also under artificial light with a photoperiod of 16:8 h light:dark 50% mortality was not reached in the highest concentration when Daphnia magna was exposed for 24 hour. The same test followed by irradiation with UV (295-365 nm; peak 340 nm) with an intensity of 370 ± 20 µW/cm² for 2 hours and 1 hour of recovery in the test medium lead to an LC50 of 3.4 µg/L. UV-radiation thus increases the toxicity of benz[a]anthracene.

Of the mentioned studies, only in the study with Daphnia magna from Bisson et al. (2000) concentrations were determined.

5.1.2.2 Long-term toxicity to aquatic invertebrates

The Netherlands (2008) summarizes chronic toxicity on invertebrates as following:

Chronic toxicity data are available for algae, cyanophyta, aquatic plants and crustaceans.

[...]

For Ceriodaphnia dubia no effects were observed in a 7-d study at concentrations up to 8.7 µg/L (Bisson et al., 2000).

5.1.3 Algae and aquatic plants

The Netherlands (2008) summarizes toxicity on algae and aquatic plants as following:

The growth of Pseudokirchneriella subcapitata, exposed to concentrations far above the aqueous solubility, was not inhibited by 50% when illuminated with a 16:8 h light:dark photoperiod with cool white fluorescent light (Cody et al., 1984).

The 72-h EC10 for inhibition of growth of Pseudokirchneriella subcapitata from a study with measured concentrations is 1.2 µg/L (Bisson et al., 2000). For the same algae species Cody et al. (1984) presented a dose-effect relationship. From the data in the figure, a 96-h EC10 of 18 µg/L can be estimated with a log-logistic relationship. However, the uncertainty in this estimate is substantial due to the flatness of the dose-response curve, probably as a result of solubility limitations: the aqueous solubility of benz[a]anthracene is around 10 µg/L (Mackay et al., 2000). Further, this value is based on nominal concentrations. Probably most important, from the presented spectra it is estimated that the total light intensity is less than 50 µW/cm², although the light intensities are given at single wavelengths (Cody et al., 1984). The light intensity may play an important role in the lower EC10 from the study by Bisson et al. (2000). Therefore, the aforementioned values of 1.2 µg/L is considered to be more realistic than this value of 18 µg/L, due to the low light intensity. For the cyanophyte Anabaena flos-aquae the NOEC for after two weeks of exposure was 8.3 µg/L although at 5 µg/L

also significant effects were observed (Bastian & Toetz, 1982). Therefore, no clear dose-response relationship was observed. The light regime was continuous light at 951-1903 $\mu\text{W}/\text{cm}^2$ (200-400 foot candles). The concentration of benz(a)anthracene declined by 85% in 14 days. The real effect concentration is therefore overestimated. Not the growth rate was determined in this study, but the biomass after 14 days.

[...]

In the study with the duckweed *Lemna gibba* only concentrations far above the aqueous solubility are reported (Huang et al., 1997ab).

According to the Support Document for identification of CTPHT as SVHC (ECHA, 2009), the lowest chronic toxicity has been observed for the alga *Pseudokirchneriella subcapitata* with an EC10 of 1.2 $\mu\text{g}/\text{l}$ for growth inhibition. This study was therefore chosen as study having the highest weight for the T assessment of BaA.

5.1.4 Sediment organisms

No data on toxicity to sediment organisms are available (search done March 2017).

5.1.5 Other aquatic organisms

Acute toxicity studies with the marine bacterium *Vibrio fischeri* reported concentrations above the aqueous solubility (El-Alawi et al., 2002; Johnson & Long, 1998 cited in the Netherlands (2008)).

5.2 Summary and discussion of the environmental hazard assessment

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

The experimental data indicate a high chronic and acute toxicity of the PAH constituents of CTPHT for aquatic organisms.

Table 6: Ecotoxicological experimental data on aquatic organism. Key study is marked in bold. Please note the aqueous solubility of BaA at 10 $\mu\text{g}/\text{L}$ (Mackay, 2000)

Species	Duration	Endpoint	Effect level	Conc.	Comment	References
<i>Pimephales promelas</i>	89 h (65 h with UV radiation)	Mortality	LC ₅₀	1.8 $\mu\text{g}/\text{L}$	with simulated natural sunlight 24 h preincubation without simulated natural sunlight	Oris & Giesy, 1987
<i>Daphnia pulex</i>	96 h	Mortality	LC ₅₀	10 $\mu\text{g}/\text{L}$	12:12 h photo-period	Trucco et al., 1983
<i>Daphnia magna</i>	48 h	Mortality	LC ₅₀	> 9.1 $\mu\text{g}/\text{L}$	dark	Bisson et al., 2000
<i>Daphnia magna</i>	24 h + 3 h	Mortality	24h-LC ₅₀	> Highest test concentration	16:8 h light:dark	Bisson et al., 2000

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			27h-LC ₅₀	3.4 µg/L	+ 2 h UV-radiation exposure + 1 h recovery	
<i>Ceriodaphnia dubia</i>	7 days	Reproduction	EC ₁₀	No effect up to 8.7 µg/L	16:8 h light:dark	Bisson <i>et al.</i> , 2000
<i>Pseudokirchneriella subcapitata</i>	-	Growth	EC ₅₀	> aqueous solubility	16:8 h light:dark Cool white fluorescent light	Cody <i>et al.</i> , 1984
	96 h	Growth	E _r C ₁₀	18 µg/L	Estimated from dose-effect relationship	
<i>Pseudokirchneriella subcapitata</i>	72 h	Growth	E_rC₁₀	1.2 µg/L	Radiation 6000 – 8000 lux	Bisson <i>et al.</i>, 2000
<i>Anabaena flos-aquae</i>	2 wk	Biomass rate	NOE _{bC}	8.3 µg/L significant effects at 5 µg/L observed	-	Bastian & Toetz, 1982
<i>Lemna gibba</i>	8 days	Growth	Effects	>> aqueous solubility (2 mg/L)	Simulated solar radiation	Huang <i>et al.</i> , 1997a+b
<i>Vibrio fischeri</i>	8 h pre-incubation + 18 h growth	Luminescence, Growth	EC ₅₀	> aqueous solubility	Both dark and simulated solar radiation	El-Alawi <i>et al.</i> , 2002 Johnson & Long, 1998

The lowest chronic effect concentration of BaA was estimated on growth for *Pseudokirchneriella subcapitata* with an EC₁₀ value of 1.2 µg/L after 72h (Bisson *et al.*, 2000). The study was chosen as the study having the highest weight (ECHA, 2009). It should be noted that at a concentration of BaA of 1.8 µg/L the fish *Pimephales promelas* showed a mortality of 50% after 89h. Therefore fish might be the most sensitive species within the test data. However, the test is not done under standardized condition and no long-term toxicity to fish is available for BaA.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Benz[a]anthracene is covered by index number 601-033-00-9 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 class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

6.2 PBT and vPvB assessment

6.2.1 Assessment of PBT/vPvB properties

The PBT/vPvB assessment is based on information provided in the support document for the identification of CTPHT as SVHC (ECHA, 2009). As additional information earlier assessments documented in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (NL, 2008) have been considered. The information summarised in these documents is still valid and allows a compact assessment of the substance properties with a focus on PBT/vPvB.

6.2.1.1 Persistence

BaA 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.

A dissipation half-life of more than 8.1 years was measured in a field study (Wild *et al.*, 1991). Wild *et al.* (1991) was selected as the study having the highest weight for the P assessment. Additionally, the study by Wild and Jones (1993) reports a half-life value of BaA in soil between 106 to 313 days and is therefore above the P and vP criteria set in REACH Annex XIII. Furthermore, model calculations done by Mackay *et al.* (1992) do confirm that BaA is very persistent in the compartment soil and predicted that P and vP criteria are fulfilled for the compartments water and sediment.

Therefore, it is concluded that BaA fulfils the P and vP criteria according to REACH Annex XIII. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

6.2.1.2 Bioaccumulation

Experimentally obtained BCF values above 5000 are reported for BaA in Crustacea. In accordance to REACH Annex XIII, BaA fulfils the B and vB criteria. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

6.2.1.3 Toxicity

The lowest aquatic chronic toxicity has been observed for the alga Pseudokirchneriella subcapitata with an EC10 of 1.2 µg/l for growth inhibition. Therefore, BaA fulfils the T

criterion according to REACH Annex XIII Section 1.1.3 a). This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

In addition, benz[a]anthracene is classified in hazard carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH is also fulfilled according to Annex XIII Section 1.1.3 b).

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

An assessment of the PBT/vPvB properties of benz[a]anthracene (BaA) was done by the MSC in the scope of the identification of CTPHT as SVHC (ECHA, 2009). The assessment of PBT/vPvB properties of BaA in this dossier is based on the information provided and analysed in the Support Document for the Identification of CTPHT as SVHC (ECHA, 2009).

Persistence

Based on the available information from experimental and estimated data, BaA degrades very slowly in soil with half-lives of > 180 d. Thus, the P and the vP criteria of REACH Annex XIII are fulfilled.

Bioaccumulation

The bioaccumulation of BaA in Crustacea were measured and BCFs > 5000 obtained. Thus, the B and the vB criteria of REACH Annex XIII are fulfilled.

Toxicity (only relevant for PBT substances)

Based on available data, the lowest chronic aquatic toxicity was observed for the algae *Pseudokirchneriella subcapitata* with an EC10 of 1.2 µg/l for growth inhibition. Therefore, BaA 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 section 1.1.3 b) is fulfilled based on the classification of the substance as Carcinogenic category 1B (hazard statement H350: "May cause cancer").

Conclusion

In conclusion, benz[a]anthracene meets the criteria for a PBT and vPvB substance according to Article 57 (d) and (e) REACH based on a weight-of-evidence determination.

Part II

7. Registration and C&L notification status

7.1 Registration status

BaA is not produced intentionally and is not registered within the scope of the Regulation REACH.

7.2 CLP notification status

Table 7: CLP notifications

	CLP Notifications ³
Number of aggregated notifications	9
Total number of notifiers	480

8. Total tonnage of the substance

BaA is not produced intentionally and is not registered within the scope of the Regulation REACH. In general, PAHs occur as constituents in substances from the coal and petroleum stream. Such substances are mostly Multi-Constituent Substances (MCSs) or Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances). UVCB substances and MCSs, containing BaA are used in a broad range of uses, e.g. production of other chemicals and rubber, uses in road construction and as lubricants.

Please refer to Annex III for an overview of tonnages of UVCBs which do contain BaA as a constituent.

9. Information on uses of the substance

There are numerous UVCB substances that contain BaA. These substances have wide dispersive uses for which BaA was reported as constituent or are known to contain BaA. Among the reported uses are: Uses in Coatings, uses in road and construction applications, in binders or agents and in cleaning agents. Those uses are suitable to contribute to a significant environmental exposure. The low quality of registration dossiers were issued during informal meetings between authorities and industry. Therefore it is likely that more than these substances do contain BaA and are used wide dispersively.

In addition to the above uses, two UVCBs containing BaA are registered according to Art. 18 (transported isolated intermediate) with industrial uses in the production of other chemicals and rubbers.

³ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 15. November 2016)

Information on tonnage per identified use for the substance are limited. The use pattern of "Pitch, coal tar, high-temp" (CAS: 65996-93-2) was analysed and discussed in detail in the Risk Assessment Report of CTHPH (EC, 2008). It is reported that CTPHT is mainly used as a binding agent for anodes and electrodes. Taking the use as binding agent for refractory materials into account, these applications covered 94 % of the sales in the EU in 2003.

10. Information on structure of the supply chain

The structure of the supply chain and downstream users is complex. Primary producers of the UVBCs are organized in industry consortia like: CONCAWE⁴, cefic⁵, LOA⁶ and other. This allows a regular exchange of information between regulatory authorities and industry associations, at least for primary coal and petroleum stream products. However, the knowledge of uses decreases with the increase in the level of downstream uses, indicating a poor flow of information from downstream user to producers.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

BaA is not produced intentionally but occurs together with other PAHs as constituent of coal and petroleum stream UVCB substances. Among the PAHs benzo[a]pyrene (B[a]P, EC number: 200-028-5) and anthracene (EC number: 204-371-1) are included in the Candidate List due to PBT and vPvB properties already.

Further UVCBs like CTPHT (EC number: 266-028-2) and five anthracene oil-derivatives (EC numbers: 292-604-8, 295-278-5, 295-275-9, 292-603-2, and 292-602-7) are listed in the Candidate List due to assessment of the intrinsic properties of their PAH constituents. BaA was one of these constituents which caused the inclusion of CTPH into the Candidate List based on its PBT and vPvB properties.

11.2 Alternatives

It is possible to considerably decrease the PAH content of UVCB substances derived from coal or mineral oil (see for example use of low aromatic oils in tires, (KEMI, 2003)). Furthermore, there seems to be no unique, essential technical function of PAHs in PAH-containing UVCB substances in most cases. Currently, only in some limited cases no alternatives to PAH-containing substances seem to be available, e.g. for binding material used in certain electrodes in the aluminium production. Hereby PAHs are essential constituents which are needed to form a graphite structure.

It is important to stress that the complete picture of uses of BaA-containing UVCB substances remains unclear as it is not possible to identify all of these substances themselves. Further regulatory actions on these substances might be warranted in the future.

⁴ ConcaWE is a division of the European Petroleum Refiners Association and supports members in implementation of the REACH regulation

⁵ European Chemical Industry Council

⁶ Lower Olefins and Aromatics Reach Consortium

11.3 Existing EU legislation

BaA is harmonized classified as carcinogenic 1B (regulation EU 1272/2008, Annex VI, Table 3.1). Entry 28 of Regulation REACH (907/2006) applies accordingly.

In addition to entry 28 BaA is further restricted by entry 50 Annex XVII of the REACH-Regulation. Therefore, use of extender oils in tyres is prohibited, if the sum in content of following PAHs is above 10 mg/kg: Benz(a)pyrene (50-32-8, Benzo(e)pyrene (192-97-2), Benzo(a)anthracene (56-55-3), Chrysene (218-01-9), Benzo(b)fluoranthene (205-99-2), Benzo(j) fluoranthene (205-82-3), Benz(k)fluoranthene (207-08-9) and Dibenzo(a,h)anthracene (53-70-3). Further articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come to direct and prolonged or short-term repetitive contact with human skin or oral cavity contains more than 1mg/kg BaA. For toys the same applies but the limit of BaA content is 0.5 mg/kg.

BaA is listed in Annex II of EU Regulation 1223/2009 as a substance which is prohibited in cosmetic products.

11.4 Previous assessments by other authorities

BaA belongs to the substance group of PAHs of which many are well-known to be hazardous for human health and the environment. Eight PAHs, including BaA which is carcinogenic, are already classified as CMR substances. Until now, several Annex XV dossiers for the identification of PAHs as substances of very high concern were explicitly based on their intrinsic properties (anthracene, B[a]P) or of their PAH constituents (Anthracene Oils, CTPHT).

In the Support Document of Pitch, coal tar, high temp. (CTPHT) it has been concluded by the Member State Committee (MSC) that benz[a]anthracene fulfils the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, BaA and further PAHs whose properties have already been agreed on by the MSC in the CTPHT SVHC identification process have not yet been proposed for formal SVHC identification and inclusion in the Candidate List.

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