

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: Benzo[ghi]perylene
EC Number: 205-883-8
CAS Number: 191-24-2

Submitted by: Denmark
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FOREWORD

Benzo[*ghi*]perylene (BgP) belongs to the group of Polycyclic Aromatic Hydrocarbons (PAHs), which includes several substances that are known to be hazardous to human health and the environment. BgP has, however, not received a harmonised classification according to the CLP Regulation (EC 1272/2008).

BgP is a constituent of coal-tar pitch, high temperature (CTPHT). During the process of identifying CTPHT as a substance of very high concern (SVHC) it has been concluded by the Member State Committee (MSC), that BgP fulfills the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, BgP has not yet been proposed for formal SVHC identification and inclusion in the Candidate List.

BgP was assessed with respect to PBT/vPvB properties in the context of the identification of CTPHT as SVHC as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). For the purpose of the present SVHC proposal for BgP, a supplementary literature search was made. The search identified only very few studies not included in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008). Thus, the assessment of the PBT/vPvB properties in the present dossier and the conclusion that BgP fulfils the criteria in Article 57 (d) and (e) was based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009) and supplemented with information from newer studies.

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

Substance Name: Benzo[*ghi*]perylene

EC Number: 205-883-8

CAS number: 191-24-2

- 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 (d) and (e):

There are only few studies available on the persistency, bioaccumulation and toxicity of BgP in the aquatic and soil environment. The limited information is, however, supported by studies of other PAH compounds with a four or five ring structure with respect to the degradation, bioaccumulation and toxicity to aquatic organisms.

Persistence

The observed half-lives of BgP in soil microcosms are in the range of 365-535 days. Moreover, a long-term field experiment reported a half-life in soil of 9.1 years. As these half-lives in soil exceed the P- and vP-criteria (half-life of 120, respectively 180 days in soil), it is concluded that the P- and vP-criteria are fulfilled by BgP.

Bioaccumulation

A BCF value of 28288 has been reported in a static test with *Daphnia Magna*. This BCF value exceeds the B- and vB criteria (measured BCF values in aquatic species > 2000, respectively > 5000) and it is concluded that the B- and vB-criteria are fulfilled by BgP.

Toxicity

The EC₁₀ (reproduction) of BgP has been determined at 0.082 µg/L in a long-term study (7d) with the aquatic invertebrate *Ceriodaphnia dubia*. As the EC₁₀ is lower than the T criteria (the long-term no-observed effect concentration (NOEC) or EC₁₀ for marine or freshwater organisms is less than 0.01 mg/l) it is concluded that the T-criteria is fulfilled by BgP.

Overall conclusion

In conclusion, BgP is identified as a PBT and vPvB substance according to Art. 57(d) and (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Registration dossiers submitted for the substance?

Benzo[*ghi*]perylene has not been registered under REACH.

PART I

Justification

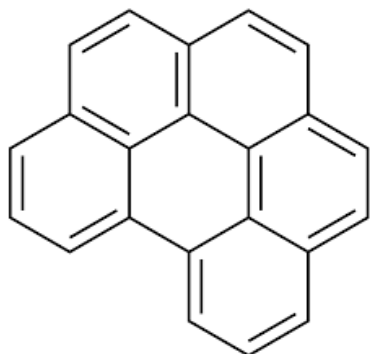
1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	205-883-8
EC name:	Benzo[<i>ghi</i>]perylene
CAS number (in the EC inventory):	191-24-2
CAS number: Deleted CAS numbers:	- -
CAS name:	Benzo[<i>ghi</i>]perylene
IUPAC name:	Benzo[<i>ghi</i>]perylene
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C ₂₂ H ₁₂
Molecular weight range:	276.3 g/mol
Synonyms:	hexacyclo[12.8.0.0 ^{2,11} .0 ^{3,8} .0 ^{4,21} .0 ^{17,22}]dodecose-1(22),2,4(21),5,7,9,11,13,15,17,19-undecaene

Structural formula:



1.2 Composition of the substance

Name: Benzo[*ghi*]peryleneDescription: Benzo[*ghi*]perylene (BgP) belongs to the group of Polycyclic Aromatic

Hydrocarbons (PAHs). BgP is not produced intentionally but occur as a constituent together with other PAHs in a number of UVCB¹ substances derived from coal and petroleum streams. The dossier addresses the substance BgP as a substance on its own and not in the context of its original occurrence in UVCB's.

Substance type: mono-constituent

1.3 Physicochemical properties

Table 2: Overview of physicochemical properties (ECHA, 2009)

Property	Value [Unit]
Physical state at 20°C and 101.3 kPa	<i>solid</i>
Melting/freezing point	<i>277 °C</i>
Boiling point	<i>545 °C</i>
Vapour pressure	<i>1.4 x 10⁻⁸ Pa at 25 °C</i>
Density	<i>1.329 kg/L</i>
Water solubility	<i>0.14 µg/L at 25 °C</i>
Partition coefficient n-octanol/water (log K _{ow} value)	<i>6.22 at 25 °C</i>

2. Harmonised classification and labelling

There is no harmonised classification of benzo[*ghi*]perylene.

¹ Substances of Unknown or Variable composition, Complex reaction products or Biological materials

3 Environmental fate properties

3.1 Degradation

3.1.1 Abiotic degradation

3.1.1.1 Hydrolysis

PAHs are chemically stable under environmental conditions, with no functional groups that result in hydrolysis. Therefore, hydrolysis is not expected to contribute to the degradation of PAHs (Howard *et al.* 1992, cited in The Netherlands, 2008).

3.1.1.2 Oxidation

BgP has been confirmed to be 100 % bound to particles in air (The Netherlands, 2008). This reduces the availability to reaction with OH-radicals and ozone, and the degradation rate is markedly lower compared to PAHs in gas phase. In the gas phase, PAHs are oxidised 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).

3.1.1.3 Phototransformation/photolysis

3.1.1.3.1 Phototransformation in air

BgP has a very low vapour pressure (1.4×10^{-8} Pa at 25 °C) and is estimated to be 100 % adsorbed to particulate matter in the atmosphere where it can be degraded by photolysis by light with a wavelength < 290 nm and indirect photolysis (photo-oxidation) (ECHA, 2009).

The estimated lifetimes of adsorbed PAHs depend on the nature of the particle it adsorbs to: the higher the carbon content, the more stable the PAH. As PAH compounds in the atmosphere occur mainly on particulate matter with a high carbon content, the degradation in the atmosphere is slower than in experiments where it is adsorbed to materials like alumina or silica gel. The reported representative lifetimes in air for BgP are from 1.9 hours to 7.5 days (The Netherlands, 2008).

3.1.1.3.2 Phototransformation in water and soil

The main abiotic transformation of BgP is by photochemical decomposition. In natural water this process takes place only in the upper few centimetres of the aqueous phase and is therefore not considered to have significant impact on the overall persistency of PAHs in the aquatic environment. In soil where the exposure to light is even more limited, photodegradation is also not considered a significant degradation process (The Netherlands, 2008).

3.1.1.4 Summary on abiotic degradation

When present in the atmosphere BgP is observed to be 100 % adsorbed to fine particulate matter where it can be photodegraded by exposure to sunlight. Representative lifetimes for BgP adsorbed to different types of particles are from 1.9 hours to 7.5 days. BgP is expected to adsorb mainly to particles with a high carbon content where the lifetime is in the high end of this range. Since photodegradation takes place only in the upper few centimetres of a water column and in the upper few

millimetres of soil, this degradation route is not considered to significantly influence the environmental fate of BgP.

BgP is, like other higher PAH compounds, chemically stable and will not hydrolyse under environmental conditions in water and soil.

These conclusions on the abiotic degradability of higher PAH compounds were derived in the transitional dossier on CTPHT (The Netherlands 2008) based on the content of individual PAH compounds, including BgP.

3.1.2 Biodegradation

3.1.2.1 Biodegradation in aqueous environments

Experimental information for biodegradation in water has demonstrated that PAH substances with up to four aromatic rings are biodegradable under aerobic conditions, but that biodegradation rates of PAHs with more than four aromatic rings, such as BgP, are very low (ECHA, 2009).

The biodegradation pathway of the different PAHs is very similar but their biodegradation rates differ considerably. In general, the biodegradation rate decreases with increasing number of aromatic rings. The bioavailability is determined by the degree of sorption to organic matter in the environment and is believed to be an important factor for the degradability. It has been shown that the degradation rates in sediments are reversely related to the adsorption to organic matter expressed as the partitioning coefficient between organic carbon and water (K_{oc}). Therefore, with a $\log K_{oc}$ of 6.01, BgP is expected to have a low bioavailability and corresponding low biodegradation rate compared to PAHs with lower number of aromatic rings and lower molecular weights. Although there is evidence for anaerobic transformation, PAHs are usually considered to be persistent under anaerobic conditions (The Netherlands, 2008).

Based on model calculations, Mackay (1992) (cited in The Netherlands, 2008) suggests a ranking of PAH compounds according to their biodegradability. BgP is placed in the group of high molecular weight PAH with a half-life in the aquatic environment water phase of 1000-3000 hours (42 – 125 days) and in sediments >30000 hours (>1250 days).

3.1.2.2 Biodegradation in soil

The half-lives for biodegradation obtained in soil microcosms are for BgP from 365 days to 535 days. A reported half-life in a long-term field experiment was 9.1 years (The Netherlands, 2008). Very low degradability rates have been observed also for other higher PAH compounds. Experimentally determined half-lives in soil were reported for the 5 ring PAH compounds benzo[*b*]fluoranthene, benzo[*k*]fluoranthene and benzo[*a*]pyrene at 120 – 359 days in soil microcosm studies, and 8.2 – 9.0 years in long-term field experiments (ECHA 2009). These half-lives are comparable or lower than for the 6 ring PAH BgP.

As in the aqueous environment, the biodegradation rate of PAH compounds in the soil compartment is correlated to the molecular weight and the bioavailability of the compounds. The rate of biodegradation also depends on other external factors, like temperature, the characteristics of the soil and its microbial population. This may explain that the half-lives observed under optimised laboratory conditions are much shorter than those obtained from long-term field-based experiments (The Netherlands, 2008).

3.1.2.3 Summary and discussion on biodegradation

The observed biodegradation of PAH compounds in water and soil indicates that the biodegradation rates are correlated to the molecular size and weight. Probably this is due to the variation in the aqueous solubility, bioavailability and structural stability of PAHs through the compound group. The CTPHT SVHC support document (ECHA 2009) concludes that the vP criterion is fulfilled for 10 PAH-constituents of CTPHT, including BgP.

The estimated half-lives of BgP in the aquatic compartment is from 42 days to 125 days, and in sediments >1250 days. Results from soil experiments show half-lives in the range 365-535 days and in long-term field experiment 9.1 years.

3.1.3 Summary and discussion of degradation

Abiotic degradation of BgP and other higher PAH compounds is not regarded as a significant route of degradation of the substances in the environment. In the atmosphere, BgP is adsorbed to particulates where the photolysis is relatively slow (1.9 hr to 7.5 days) compared to non-particular bound PAH compounds. The degradation rate of BgP, which is mainly adsorbed to carbon rich particles, is likely to be in the high end of this range. In the water and soil compartments, photolysis is only relevant in the upper few centimetres of the water column and the upper few millimetres of the soil.

In general, PAHs are chemically stable, with no functional groups that results in hydrolysis in the water and soil compartments.

The biodegradation of PAH compounds with more than four aromatic rings is slow and is correlated to the molecular weight and bioavailability of the compounds. BgP has six aromatic rings and has a very low water solubility and bioavailability. The estimated half-lives for BgP in the aqueous environment is 1000-3000 hours (42 – 125 days) and in sediments >30000 hours (>1250 days).

In soil, measured half-lives of BgP obtained in microcosms are from 365-535 days and the reported half-life in a long-term field experiment was 9.1 years.

The observed half-lives for biodegradation of BgP is supported by experimentally determined biodegradation rates for other PAH constituents of CTPHT.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

BgP has a log K_{ow} at 6.22. In general, substances with log K_{ow} value from 4 to 6 can be assumed to have a high potential for partitioning to the organic phase of soils and sediments (ECHA, 2009). Based on the log K_{ow} value, the coefficient of partitioning between organic carbon and water, log K_{oc} , has been estimated at 6.01 (The Netherlands, 2008).

3.2.2 Volatilisation

BgP has a vapour pressure at 1.4×10^{-8} Pa and a Henry's law constant at 0.027 Pa m³/mol. The values indicate that BgP has a very low volatilisation rate from a water body or soil (The Netherlands, 2008).

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 (equal and continuous release to water, soil and air). Calculation revealed a distribution of BgP mainly to the soil and sediment phase.

Table 3: Level III Fugacity Model calculation of BgP (EPI Suite, version 4.11)

Distribution	Mass amount (%)
Air	0.06
Water	4.4
Soil	48.6
Sediment	47

3.2.4 Summary and discussion of environmental distribution

The environmental distribution of BgP is determined by a low vapour pressure, a low water solubility and a low Henry's constant. In the atmosphere, BgP will be 100% associated with particulate matter. Further modelling of the fugacity reveals that BgP is mainly distributed to the soil and sediment compartment.

3.3 Bioaccumulation

3.3.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

Experimental data on the bioaccumulation of BgP are sparse. In a detailed review of the bioaccumulation of PAH compounds (RIVM, 2009) a study with *Daphnia magna* was evaluated and considered as reliable. The study showed a bioconcentration factor (BCF) at 28288 in a static exposure system using an actual water concentration of 0.2 µg/L (also cited in ECHA, 2009). Invertebrate species may have a lower metabolic capacity than fish species, e.g. as is the case for polycyclic aromatic hydrocarbons (Bleeker and Verbruggen, 2009). Bioaccumulation in these invertebrates may therefore be higher than in fish under the same exposure conditions and this situation should be considered in a *Weight-of-Evidence* approach. In another study with the aquatic crustacean *Azellus aquaticus*, a BCF of 16000 was observed. However, the study was rated as non-reliable.

No experimental bioaccumulation studies of BgP in fish have been found. Experimental accumulation studies with higher PAH compounds in fish include only a few studies with a high reliability (Klimisch score 1 or 2). A BCF value of 200-265 was observed for benz[*a*]anthracene in a static bioaccumulation study with fathead minnow (*Pimepales promelas*) (De Maagd, 1996 and 1998 cited in The Netherlands 2008). A flow-through bioaccumulation study of benzo[*a*]pyrene with the bluegill sunfish (*Lepomis macrochirus*) showed a BCF at 608 (Jiminez et al 1987, cited in The Netherlands 2008). The bioaccumulation of higher PAH compound in fish are in general lower than expected from the substance properties (log K_{ow}) and lower than found in other aquatic organisms. This is probably due to metabolism of PAHs, which plays an important role in fish but is not observed in other aquatic organisms, e.g. mollusks, and oligochatae (The Netherlands 2008).

The log K_{ow} value at 6.22 indicates that BgP may have a significant potential for bioaccumulation. For hydrophobic compounds, the BCF shows a linear relationship with log K_{ow} up to a value of 5 or 6. At higher log K_{ow} values the BCFs tend to level off and can even decrease considerably (The Netherlands, 2008).

Results from experimental studies of the bioaccumulation in crustaceans of PAH compounds with four aromatic rings or more report BCF values in the range 2440 – 50119. Examples of experimental BCF values obtained in tests with crustaceans are summarised in the table below. The studies are discussed in further details in the CTPHT Transitional Documents (The Netherlands 2008).

Table 4: Summary of bioaccumulation studies with crustaceans discussed in the CTPHT transitional document (extract from The Netherlands 2008)

Substance	Study type	BCF
Benz[<i>a</i>]anthracene	Static tests with <i>Daphnia magna</i> and <i>Daphnia pulex</i>	2920 – 10226
Chrysene	Static tests with <i>Daphnia magna</i>	6088
Benzo[<i>a</i>]pyrene	Static tests with <i>Daphnia magna</i>	2440-5770
	Flow through tests with the gammarid arthropod <i>Pontoporeia hoyi</i>	48582
	Flow through tests with the crustacean <i>Mysis relicta</i>	8496
	Static tests with the crustacean <i>Acartia erythraea</i> (NB: reliability score = 3)	25
Benzo[<i>k</i>]fluoranthene	Static tests with <i>Daphnia magna</i>	13225
Benzo[<i>ghi</i>]perylene	Static tests with <i>Daphnia magna</i>	28288
Dibenzo[<i>a,h</i>]anthracene	Static tests with <i>Daphnia magna</i>	50119

3.3.2 Summary and discussion of bioaccumulation

The experimental observation of the bioaccumulation of BgP is very limited. One study has reported a BCF value of 28288 in a static test with *Daphnia magna*.

This observation is supported by bioaccumulation studies of other PAH compounds with four aromatic rings or more where the reported BCF values lies in the range 2440 – 50119. In fish, PAH are metabolised and studies of the bioaccumulation of PAHs with more than four aromatic rings show relatively low BCF values at 200–608 BCF.

BgP has a log K_{ow} value at 6.22 and in general, the BCF shows a linear relationship with log K_{ow} up to a value of 5 or 6 for hydrophobic substances.

4. Human health hazard assessment

Not relevant for the identification of the substance as a PBT since the T criterion is fulfilled based on ecotoxicity data.

5 Environmental hazard assessment

5.1 Aquatic compartment (including sediment)

The Support Document for the identification of CTPHT as SVHC (ECHA, 2009) summarises the following on environmental hazard assessment of PAH for the aquatic compartment:

“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.” (The above section is cited from ECHA, 2009).

There are only few studies available on aquatic toxicity of BgP. In 2011, the Scientific Committee on Health and Environmental Risks (SCHER) reviewed the environmental quality standard (EQS) dossier prepared by the Working Group E of the Common Implementation Strategy for the Water Framework Directive (EC, 2011). The comments of SCHER did not necessitate any changes. The dossier is used here as the general reference to information on the effects of BgP in the aquatic compartment.

5.1.1 Fish

5.1.1.1 Short-term toxicity to fish

A semi static study (reliability score 2) with no exposure to UV-light in the first 24 hours with the freshwater fish fathead minnow (*Pimephales promelas*) (larvae) showed < 20 % mortality was observed after 120 hours of exposure to a concentration of BgP at 0.15

µg/L (EC, 2011). This concentration is close to the water solubility of the substance at 0.14 µg/L, thus the NOEC was higher than the water solubility of BgP.

5.1.1.2 Long-term toxicity to fish

In a long-term 42-days study (reliability score 2) with early life stages of zebra fish (*Brachydanio rerio*), a NOEC was reported at 0.16 µg/L or higher (EC, 2011). This concentration is close to the water solubility of the substance at 0.14 µg/L.

5.1.2 Aquatic invertebrates

5.1.2.1 Short-term toxicity to aquatic invertebrates

No effect was observed at a BgP concentration at 0.2 µg/L in a 48-hour immobilisation study with *Daphnia magna* (reliability score 2) (EC 2011). This concentration is close to the water solubility of the substance at 0.14 µg/L. Thus, the EC₅₀ (immobility) is higher than the water solubility.

5.1.2.2 Long-term toxicity to aquatic invertebrates

In a 7-days study with *Ceriodaphnia dubia*, the EC₁₀ (reproduction) of BgP was determined at 0.082 µg/L. The test concentration was verified with chemical analysis and the study received a reliability score 2 (EC, 2011). The study was selected as key study for the aquatic toxicity of BgP in the Support Document for the identification of CTPHT as SVHC (Bisson *et al.* 2000, cited in ECHA, 2009).

In a recent 7-day reproduction test with *Ceriodaphnia dubia*, Bragin *et al.* (2016) tested the effect of BgP in a limit test. A 6 % reduction ($P > 0.05$) was observed in neonate reproduction at 0.08 µg/L. The test was performed under conditions that excluded exposure to UV light. The biological significance of the observed effect corresponding to a response lower than 10 % was, however, questioned by the authors.

5.1.3 Algae and aquatic plants

The effect of BgP on the growth rate of the microalgae *Pseudokirchneriella subcapitata* was tested in a 72-hours study (reliability score 2). The photoperiod under the study was 16:8 hours light:dark at less than 500 lux. The EC₁₀ was higher than 1.6 µg/L, which is higher than the water solubility of the substance at 0.14 µg/L. Thus, the reported EC₁₀ > water solubility.

In a recent study, Bragin *et al.* (2016) tested the toxicity of BgP in a growth test with *Pseudokirchneriella subcapitata* using a passive dosing method. The EC_{50S} and EC_{10S} were above the exposure concentrations (maximum solubility attainable in test medium) delivered in a limit test.

5.1.4 Sediment organisms

No studies on the effects of BgP on sediment organisms are available.

5.2 Summary and discussion of the environmental hazard assessment

Only few data are available on the toxicity of BgP in the environment. Most test data obtained with aquatic organisms showed no effects at concentrations corresponding to the water solubility.

However, in a long-term study with the aquatic invertebrate *Ceriodaphnia dubia*, the EC₁₀ (reproduction) of BgP was determined at 0.082 µg/L. In a recent similar study with *Ceriodaphnia dubia*, a statistically significant effect (< 10 %) on the reproduction was observed at 0.08 µg/L.

The observed toxicity of BgP to aquatic organisms is supported by studies of the long-term toxicity of other higher PAH compounds (i.e. with four or five aromatic rings) where NOEC/EC₁₀ values are observed in the concentration range from 0.1 – 10 µg/L.

Table 5: Summary of toxicity studies with higher PAH compounds (extract from European Commission 2008 & 2011)

Substance	Properties	Study type	Endpoint	Value(µg/L)
Benz[<i>a</i>]anthracene	MW: 282 g/mol Log K _{ow} : 5.91 VP: 7.6 x 10 ⁻⁶ Pa Sw: 10.2 µg/L	Crustacean, (<i>Daphnia pulex</i>), 96h, static test, 12:12 h photoperiod to mixed fluorescent and natural light	EC ₅₀	10
		Crustacean, (<i>Daphnia magna</i>), 48h, static test, no light	EC ₅₀	>9.1
		Larvae of Iberian ribbed newt (<i>Pleurodeles waltl</i>) 6d study. Constant Irradiation with UVA light.	LC ₅₀	3.1-6.3
		Algae (<i>Pseudokirchneriella Subcapitata</i>) 72h growth test. Light intensity 6000 – 8000 lux	EC ₁₀ (growth)	1.2
Chrysene	MW: 228 g/mol Log K _{ow} : 5.81 VP: 5.7 x 10 ⁻⁷ Pa Sw: 1.65 µg/L	Crustacean (<i>Daphnia magna</i>). Lethal time (LT50) test. 24h	LT ₅₀	0.7
Benzo[<i>a</i>]pyrene	MW: 252 g/mol Log K _{ow} : 6.13 VP: 7.3 x 10 ⁻⁷ Pa Sw: 1.54 µg/L	Crustacean (<i>Daphnia magna</i>). 27h static test. 16:8 hour light:dark followed by 2 hour UV-A B radiation and 1 hour recovery	EC ₅₀	1.2
		Algae (<i>Pseudokirchneriella Subcapitata</i>) 72h growth test. Light intensity 6000 – 8000 lux	EC ₁₀ (growth)	0.78
		Pacific salmon (<i>Oncorhynchus Mykiss</i>) Early Life Stage test.1	NOEC	1.5
		Crustacean, (<i>Ceriodaphnia dubia</i>). 7d semistatic reproduction test. Photoperiod 16:8 h light:dark at less than 500 lux	EC ₁₀	0.5
		Oyster embryos (<i>Crassostrea gigas</i>). 48h shell development. 12:12 hour light:dark fluorescent light without UV.	EC ₁₀	1.1
		Oyster embryos (<i>Crassostrea</i>	EC ₁₀	0.22

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		<i>gigas</i>). 48h shell development. 12:12 hour light:dark. UV A and B radiation.		
Benzo[<i>k</i>]fluoranthene	MW: 252 g/mol Log K_{ow} : 6.11 VP: 1.3×10^{-7} Pa Sw: 0.93 µg/L	Zebrafish Early Life Stage test (<i>Brachydanio rerio</i>) chronic 28d test	LC ₅₀	0.58
		Zebrafish (<i>Brachydanio rerio</i>) chronic 42d test.	LC ₅₀ EC ₁₀ (weight) EC ₁₀ (length)	0.65 0.31 0.17
Dibenzo[<i>a,h</i>]anthracene	MW: 278 g/mol Log K_{ow} : 6.5 VP: 3.7×10^{-10} Pa Sw: 0.82 µg/L	Crustacean <i>Daphnia magna</i> , 27h test. 16:8 hour light:dark followed by 2 hour UV-A B radiation and 1 hour recovery	EC ₅₀	1.8
		Crustacean <i>Daphnia magna</i> , 28h test. 16:8 hour light:dark followed by 2 hour UV-A B radiation and 2 hour recovery	EC ₅₀	4.6
		Algae (<i>Pseudokirchneriella Subcapitata</i>) 72h growth test. Light intensity 6000 – 8000 lux	EC ₁₀ (growth)	0.14

¹: Determined from presented data with log-logistic dose-response relationship (The Netherlands 2008)

6 Conclusions on the SVHC Properties

6.1 CMR assessment

Not relevant for the identification of the substance as SVHC in accordance with Articles 57 (d) and (e) of REACH.

6.2 PBT and vPvB assessment

6.2.1 Assessment of PBT/vPvB properties

Persistence

BgP is chemically stable and will not hydrolyse under environmental conditions. Photo-degradation is relevant for BgP attached to particles in the atmosphere. Overall, this degradation route is not considered to significantly influence the environmental fate of BgP.

Experimentally determined half-lives of BgP obtained in soil microcosms are reported in the range 365-535 days. Moreover, the observed half-life in a long-term field experiment was 9.1 years.

In general the biodegradation rate of PAH compounds decrease with increasing number of aromatic rings. It has been observed that substances with up to four aromatic rings are biodegradable under aerobic conditions, but that PAH with more than four aromatic rings, e.g. BgP biodegrades very slowly.

Based on estimated rates of biodegradation of PAH compounds in general, BgP has been placed in the group of high molecular weight PAH with a half-life in the aquatic environment water phase of 1000-3000 hours, corresponding to 42 – 125 days, and in sediments >30000 hours, corresponding to >1250 days.

Therefore it is concluded that BgP fulfils the P and vP criteria according to REACH Annex XIII as the degradation half-life is above 180 days. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC.

Bioaccumulation

BgP has been reported to have a BCF value of 28288 based on observations in a static test with *Daphnia Magna*.

This observation is supported by results from other studies of bioaccumulation in crustacean of PAHs with five aromatic rings or more showing BCF values in the range 2440 – 50119.

Therefore it is concluded that BgP fulfils the B and vB criteria according to REACH Annex XIII as the BCF is higher than 5000 in aquatic species. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC.

Toxicity

In a long-term study of the toxicity of BgP to reproduction of the aquatic invertebrate *Ceriodaphnia dubia*, the reported EC₁₀ value was 0.082 µg/L.

This observation is supported by another reproduction test with *Ceriodaphnia dubia* where a slight but significant effect was observed at 0.08 µg/L. Moreover, studies of other higher PAH compounds with a four or five ring structure have reported NOEC/EC₁₀ values in the concentration range 0.1 – 1 µg/L.

Therefore it is concluded that BgP fulfils the T criteria according to REACH Annex XIII as the EC₁₀ is below 0.01 mg/L. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC.

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

There are only few studies available on the persistency, bioaccumulation and toxicity of BgP in the aquatic and soil environment. The limited information is, however, supported by studies of other PAH compounds with a four or five ring structure with respect to the degradation, bioaccumulation and toxicity to aquatic organisms.

Persistence

The observed half-lives of BgP in soil microcosms are in the range of 365-535 days. Moreover, a long-term field experiment reported a half-life in soil of 9.1 years. As these half-lives in soil exceed the P- and vP-criteria (half-life of 120, respectively 180 days in soil), it is concluded that the P- and vP-criteria are fulfilled by BgP.

Bioaccumulation

A BCF value of 28288 has been reported in a static test with *Daphnia Magna*. This BCF value exceeds the B- and vB criteria (measured BCF values in aquatic species > 2000, respectively > 5000) and it is concluded that the B- and vB-criteria are fulfilled by BgP.

Toxicity

The EC₁₀ (reproduction) of BgP has been determined at 0.082 µg/L in a long-term study (7d) with the aquatic invertebrate *Ceriodaphnia dubia*. As the EC₁₀ is lower than the T criteria (the long-term no-observed effect concentration (NOEC) or EC₁₀ for marine or freshwater organisms is less than 0.01 mg/l) it is concluded that the T-criteria is fulfilled by BgP.

Overall conclusion

In conclusion, BgP is identified as a PBT and vPvB substance according to Art. 57(d) and (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Part II

7 Registration and C&L notification status

7.1 Registration status

BgP is not registered under REACH.

7.2 CLP notification status

Table 6: CLP notifications

	CLP Notifications ²
Number of aggregated notifications	2
Total number of notifications	19

8 Total tonnage of the substance

BgP is not produced intentionally and has not been registered as a substance on its own under REACH. In general, PAHs are introduced to the market via petroleum-based products. BgP is likely to occur as a constituent in a range of coal and petroleum-based UVCB substances (see list in Annex III of this report). The listed petroleum substances are all used in high volumes in the EU and the registered tonnage bands are shown in Annex III of this report. No information is available on the content of BgP (Concawe, 2017).

In addition, BgP is present in coal tar pitch (high temperature) (CTPHT), a petroleum-based compound not included in the list in Annex III. Data from 2004 show that the production of CTPHT in the EU was 817,900 tonnes, the EU import 91,600 tonnes and the export to outside EU was 355,600 tonnes. Assuming that the concentration of BgP in coal tar pitch is around 1 %, the marketed tonnage of BgP in 2004 in the EU as part of CTPHT was around 5539 tons (The Netherlands, 2008).

BgP is in the years up to 2003 reported in the Nordic SPIN database in preparations in tonnages of 0.0 tonnes per year indicating that the volume was below the limit of accuracy at 100 kg. From 2004 and on there are no registrations of BgP in chemical products in the Nordic countries (SPIN 2017).

The Spin database includes very limited data on the petroleum substances listed in Annex III. The only data on the consumed volume in 2015 is 189 tonnes of the substance 'Heavy fuel oil component; distillates (petroleum), intermediate vacuum (EC No. 274-683-0; CAS No. 70592-76-6).

² C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 23.10.2017)

9 Information on uses of the substance

The SPIN database (October 2017) contains data reported by industry in the content of substances in chemical products as well as their uses. The data are extracted from the national product registers in Sweden, Norway, Finland and Denmark. The database shows reporting of BgP used in 15 or 16 chemical products for corrosion inhibition marketed in Denmark up to 2004. Use of BgP was not reported in Sweden, Norway or Finland.

The uses of CTPHT are summarised in the CTPHT Annex XV transitional dossier (The Netherlands, 2008). Overall, the main uses of CTPHT are as anodes and electrode in the manufacturing of metals, calcium carbide and silicon carbide.

The reported uses in SPIN of the petroleum substance shown in Annex III includes fuel, intermediate, process regulators, cleaning/washing agents, fillers and vulcanising agents. In the SPIN database, CTPHT is registered as used in the following product groups: adhesives, binding agents, intermediates, process regulators, fillers, insulating materials, conductive agents.

9.1 Alternatives

BgP as a component in CTPHT is mainly used in anodes and electrodes in metal industry and for manufacture of calcium carbide and silicon carbide. It seems very difficult to replace the use of CTPHT in these uses (ECHA 2009b). However, due to the concerns about PAH release in production and use of anodes, research to find and test materials with a lower PAH content has been reported (Boenigk et al. 2015).

9.2 Existing EU legislation

There are no direct regulations of the use of BgP. However, REACH Annex XVII (31) restricts the placing on the market and use of coal tar intended for the treatment of wood to only professional and industrial applications. The concentration of BgP in coal tar is about 1 %.

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Annex I - Data on tonnage, import and export

According to an inventory of petroleum substances data from Concawe (2017) PAH compounds like BgP with a 4 – 6 ring structure is present in a number of petroleum substances. The table below summarises the relevant substances.

CATEGORY	EC #	CAS #	Name	EC Description	Reg.	Tonnage band (tonnes /yr)
HEAVY FUEL OIL COMPONENT S	265-045-2	64741-45-3	Residues (petroleum), atm. tower	A complex residuum from the atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 000 - 100 000 000
HEAVY FUEL OIL COMPONENT S	265-058-3	64741-57-7	Gas oils (petroleum), heavy vacuum	A complex combination of hydrocarbons produced by the vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and boiling in the range of approximately 350°C to 600°C (662°F to 1112°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 000 - 100 000 000
HEAVY FUEL OIL COMPONENT S	265-063-0	64741-61-3	Distillates (petroleum), heavy catalytic cracked	A complex combination of hydrocarbons produced by the distillation of products from a catalytic cracking process. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C35 and boiling in the range of approximately 260°C to 500°C (500°F to 932°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000

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HEAVY FUEL OIL COMPONENT S	265-064-6	64741-62-4	Clarified oils (petroleum), catalytic cracked	A complex combination of hydrocarbons produced as the residual fraction from distillation of the products from a catalytic cracking process. It consists of hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
HEAVY FUEL OIL COMPONENT S	265-069-3	64741-67-9	Residues (petroleum), catalytic reformer fractionator	A complex combination of hydrocarbons produced as the residual fraction from distillation of the product from a catalytic reforming process. It consists of predominantly aromatic hydrocarbons having carbon numbers predominantly in the range of C10 through C25 and boiling in the range of approximately 160°C to 400°C (320°F to 725°F). This stream is likely to contain 5 wt. % or more of 4- or 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 - 100 000
HEAVY FUEL OIL COMPONENT S	265-081-9	64741-80-6	Residues (petroleum), thermal cracked	A complex combination of hydrocarbons produced as the residual fraction from distillation of the product from a thermal cracking process. It consists predominantly of unsaturated hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 000 - 100 000 000

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HEAVY FUEL OIL COMPONENT S	265-082-4	64741-81-7	Distillates (petroleum), heavy thermal cracked	A complex combination of hydrocarbons from the distillation of the products from a thermal cracking process. It consists predominantly of unsaturated hydrocarbons having carbon numbers predominantly in the range of C15 through C36 and boiling in the range of approximately 260°C to 480°C (500°F to 896°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
HEAVY FUEL OIL COMPONENT S	265-162-9	64742-59-2	Gas oils (petroleum), hydro-treated vacuum	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C13 through C50 and boiling in the range of approximately 230°C to 600°C (446°F to 1112°F). This stream is likely to contain 5 wt. % or more of 4- to 6- membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
HEAVY FUEL OIL COMPONENT S	265-181-2	64742-78-5	Residues (petroleum), hydrodesulfurized atmospheric tower	A complex combination of hydrocarbons obtained by treating an atmospheric tower residuum with hydrogen in the presence of a catalyst under conditions primarily to remove organic sulfur compounds. It consists of hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000

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HEAVY FUEL OIL COMPONENT S	265-189-6	64742-86-5	Gas oils (petroleum), hydrodesulfurized heavy vacuum	A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and boiling in the range of approximately 350°C to 600°C (662°F to 1112°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
HEAVY FUEL OIL COMPONENT S	269-777-3	68333-22-2	Residues (petroleum), atmospheric	A complex residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly greater than C11 and boiling above approximately 200°C (392°F). This stream is likely to contain 5 wt.% or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 000 - 100 000 000
HEAVY FUEL OIL COMPONENT S	274-683-0	70592-76-6	Distillates (petroleum), intermediate vacuum	A complex combination of hydrocarbons produced by the vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C14 through C42 and boiling in the range of approximately 250°C to 545°C (482°F to 1013°F). This stream is likely to contain 5 wt.% or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
HEAVY FUEL OIL COMPONENT S	274-685-1	70592-78-8	Distillates (petroleum), vacuum	A complex combination of hydrocarbons produced by the vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C50 and boiling in the range of approximately 270°C to 600°C (518°F to 1112°F). This stream is likely to contain 5 wt.% or more of	yes	10 000 000 - 100 000 000

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				4- to 6-membered condensed ring aromatic hydrocarbons.		
RESIDUAL AROMATIC EXTRACTS	295-332-8	91995-70-9	Extracts (petroleum), deasphalted vacuum residue solvent	A complex combination of hydrocarbons obtained by solvent extraction of a vacuum-deasphalted residue. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly greater than C30. This stream contains more than 5 wt. % of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10 000 - 100 000
UNTREATED DISTILLATE AROMATIC EXTRACTS	265-103-7	64742-04-7	Extracts (petroleum), heavy paraffinic distillate solvent	A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C20 through C50. This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	1 000 000 - 10 000 000
UNTREATED DISTILLATE AROMATIC EXTRACTS	265-104-2	64742-05-8	Extracts (petroleum), light paraffinic distillate solvent	A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C15 through C30. This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	100 000 - 1 000 000
UNTREATED DISTILLATE AROMATIC EXTRACTS	265-111-0	64742-11-6	Extracts (petroleum), heavy naphthenic distillate solvent	A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C20 through C50. This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	yes	10-100

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HEAVY FUEL OIL COMPONENT S	269-782-0	68333-26-6	Clarified oils (petroleum), hydrodesulfurized catalytic cracked	A complex combination of hydrocarbons obtained by treating catalytic cracked clarified oil with hydrogen to convert organic sulfur to hydrogen sulfide which is removed. It consists of hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	No	
HEAVY FUEL OIL COMPONENT S	269-784-1	68333-28-8	Distillates (petroleum), hydrodesulfurized heavy catalytic cracked	A complex combination of hydrocarbons obtained by treatment of heavy catalytic cracked distillates with hydrogen to convert organic sulfur to hydrogen sulfide which is removed. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C35 and boiling in the range of approximately 260°C to 500°C (500°F to 932°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	No	
HEAVY FUEL OIL COMPONENT S	272-187-9	68783-13-1	Residues (petroleum), coker scrubber, condensed-ring-arom	A very complex combination of hydrocarbons produced as the residual fraction from the distillation of vacuum residuum and the products from a thermal cracking process. It consists predominantly of hydrocarbons having carbon numbers predominantly greater than C20 and boiling above approximately 350°C (662°F). This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	No	

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TREATED DISTILLATE AROMATIC EXTRACTS	295- 338-0	91995- 75-4	Extracts (petroleum), light naphthenic distillate solvent, hydrodesulfu rized	A complex combination of hydrocarbons obtained by treating the extract, obtained from a solvent extraction process, with hydrogen in the presence of a catalyst under conditions primarily to remove sulfur compounds. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C15 through C30. This stream is likely to contain 5 wt.% or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	No	
UNTREATED DISTILLATE AROMATIC EXTRACTS	265- 102-1	64742- 03-6	Extracts (petroleum), light naphthenic distillate solvent	A complex combination of hydrocarbons obtained as the extract from a solvent extraction process. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C15 through C30. This stream is likely to contain 5 wt. % or more of 4- to 6-membered condensed ring aromatic hydrocarbons.	No	