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: Chrysene

EC Number: 205-923-4

CAS Numbers: 218-01-9

Submitted by: Germany

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TABLES

FOREWORD

Chrysene (CHR) 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 CHR, 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).

CHR 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 chrysene fulfils the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, CHR 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 CHR is a SVHC is summarised 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 CHR in this current dossier is mainly based on the information provided in that support document.

In the following, the abbreviation CHR is used for the substance chrysene.

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

Substance Name: Chrysene

EC Number: 205-923-4

CAS number: 218-01-9

- 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 1B[1].

- 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):

Chrysene is covered by index number 601-048-00-0 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 CHR has already been carried out by the MSC in the context of the identification of CTPHT as SVHC, as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). Additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (NL, 2008). Both reports support the conclusions on the PBT and vPvB properties of CHR already drawn in the MSC Support Document on CTPHT. The information leading to the identification of CTPHT as SVHC is still valid and allow compact assessment of the substance properties with a focus on PBT/vPvB.

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

Persistence

Based on the available information from experimental and estimated data, CHR 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 CHR 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)

CHR is classified in the hazard class carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH Annex XIII 1.1.3 b) is fulfilled.

Overall conclusion

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

Registration dossiers submitted for the substance? No

PART I

Justification

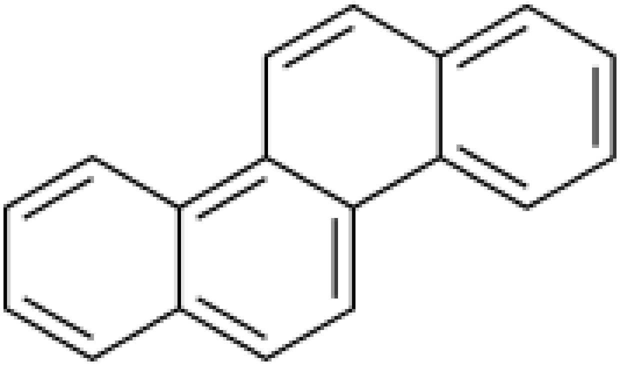
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	205-923-4
EC name:	Chrysene
CAS number (in the EC inventory):	218-01-9
CAS number: Deleted CAS numbers:	
CAS name:	chrysene
IUPAC name:	chrysene
Index number in Annex VI of the CLP Regulation	601-048-00-0
Molecular formula:	$C_{18}H_{12}$
Molecular weight range:	228.29
Synonyms:	Benzo[a]phenanthrene 1,2-Benzphenanthrene 1,2-Benzophenanthrene Chrysen (CHR) Chrysene

Structural formula:



1.2 Composition of the substance

Name: chrysene

Description: Chrysene (CHR) belongs to the group of Polycyclic Aromatic Hydrocarbons (PAHs). CHR is not produced intentionally but does occur as constituent in UVCB[2] - often together with other PAHs - mainly derived from the coal and petroleum stream. The dossier addresses the substance CHR as a substance itself and not in the context of its original occurrence in UVCB.

Substance type: mono-constituent

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

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		*solid*	*GSBL database, accessed at Mar-23-2017*
Melting/freezing point		*255.5°C*	Mackay, 2006
Boiling point		*448 °C*	Mackay, 2006
Vapour pressure	reported vapour pressure values are within the range between of the two indicated values (3rd column)	8.4 x 10^{-7} Pa at 25°C (effusion method) 1.7 x10^{-4} Pa at 20°C (supercooled liquid P_L)	Mackay, 2006
Density		e.g. 1.274 g/m^3 at 20°C	Mackay, 2006
Water solubility	reported water solubility values are within the range of the two indicated values (3rd column)	1.0 µg L^{-1} - 3.3 µg L^{-1}	Mackay, 2006
Partition coefficient n-octanol/water (log value)		log Kow 5.73 at 25°C	Mackay, 2006

2. Harmonised classification and labelling

Chrysene is covered by Index number 601-048-00-0 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)		
601-048-00-0	Chrysene	205-923-4	218-01-9	Carc. 1B Muta. 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H341 H400 H410	GHS08 GHS09 Dgr	H350 H341 H410			

3. Environmental fate properties

3.1 Degradation

The data provided on degradation of CHR 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.*

3.1.1.3 Oxidation

The oxidation of PAHs was summarised 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 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).

CHR has 4 aromatic rings and a reported vapour pressure below 10^{-4} Pa. Therefore it is assumed that CHR 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 in the atmosphere was assessed in the EU risk assessment report (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, CHR is mainly particle associated. The degradation rate of PAHs, and therefore of CHR, 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 PAH 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 CHR does have representative lifetimes between 10 hr 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 PAHs degrade within a range of minutes to days by direct photolysis. The substance is however mostly particle-associated and when adsorbed onto fine particles, CHR may be more stable in the atmosphere. In water, CHR 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 CHR 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. CHR 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 CHR 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 been 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 a dissipation half-life for CHR in the range of 106 to 313 days in laboratory soil microcosms and under field condition a half-life of 8.1 years. Wild et al. (1991) summarized, *that biodegradation is the key process in PAH losses from these soils*.

In addition Mackay et al. (1992) as summarised by The Netherlands (2008) suggested a half-life for CHR 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) indicates that CHR 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 CHR that consists of four aromatic rings, standard tests for biodegradation in water demonstrated that CHR 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 CHR of more than 8.1 years under field conditions.

Hence, CHR biodegrades very slowly in sediments and soil.

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

CHR 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.

The predicted half-lives range between 42 and 125 days for water degradation and half-lives higher than 1250 days for sediment. Wild and Jones (1993) reported a dissipation half-live for CHR of 106 to 313 days in a laboratory soil microcosm study. For assessing the persistence of CHR, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Under field conditions Wild et al. (1991) demonstrated a half-life of more than 8.1 years in soil for CHR.

It is conclusive that CHR degrades very slowly in sediment and soil.

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 Kow and the organic carbon-water partitioning coefficient Koc has been demonstrated for PAHs in sediments and soil. The Log Kow 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)."

CHR has a Log Kow value of 5.73. It is therefore concluded that CHR has a high potential to adsorb to particles in the environment.

3.2.2 Volatilisation

CHR has reported vapour pressure values between 8.4 x 10^{-7} Pa at 25°C and 1.7 x10^{-4} Pa at 20°C (Mackay et al., 2006). It is therefore concluded that CHR 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 CHR is released at equal rates to air, water, soil and sediment) and default values of physico-chemical properties (done in April 2017). Calculation revealed a distribution of CHR to soil and sediment phase (table 4).

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

Distribution to:	Mass amount (percent)
Air	0.058
Water	4.33
Soil	47.6
Sediment	48

3.2.4 Summary and discussion of environmental distribution

CHR has a high potential to adsorb to particles and volatilisation of CHR is insignificant. Further modelling the fugacity reveals that CHR 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)

For CHR only one experimental BCF study was considered at the Support Document for the Identification of CTPHT as SVHC (ECHA, 2009).

Newstedt and Giesy (1987) studied an experimental BCF value at steady state in a static system and reported a BCF = 6088 for CHR in *D. magna*. In this study the bioconcentration factor was determined for a range of PAHs. The study was evaluated in the Support Document for the Identification of CTPHT as SVHC (ECHA, 2009).

The Octanol-water partitioning coefficient is used as indication for B or vB properties. A PAH with a $\log K_{OW}$ in a range similar to CHR ($\log K_{OW}$ = 5.73) is Benz[a]anthracene (BaA, EC: 200-280-6; $\log K_{OW}$ = 5.91). BaA was used in experimental studies for BCF more extensively. An overview of BCFs determined for aquatic organisms is given in ECHA (2009) and more detailed in The Netherlands (2008). Briefly, for BaA the following considerations on bioaccumulation in aquatic organism have been taken: The bioaccumulation potential of BaA differs between the organisms due to the organisms´ 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 mechanisms. 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 organisms of low trophic level could contribute to a constant exposure of predators and therefore hamper the integrity of aquatic ecosystems. Accordingly, Freitag et al. (1985) reported a BCF value for BaA in fish (*L. melanotus*) of 350, while for *Daphnia magna* Newsedt & Giesy (1987) reported a BCF of 10,226.

It might be likely, that the same mechanism leads to a bioaccumulation of CHR in organisms of lower tropic levels.

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

The European Union Risk Assessment Report on CTPHT (EC, 2008) reported a QSAR estimated BCF value for CHR in *Eisenia andrei* of $BCF_{earthworm}=7800$ 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

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

As for BaA it might be likely that CHR is transformed in fish, and to some extent also in molluscs, using enzymes belonging to the Cytochrome P450 enzymes (Cyt P450) and other mechanisms. 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 organisms of low trophic level could contribute to a constant exposure of predators and therefore hamper the integrity of aquatic ecosystems.

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 of CHR in Section 2 as Carc. 1B, H350).

PBT considerations regarding human health hazard assessment:

CHR is classified in the hazard class carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH Annex XIII 1.1.3 b) is fulfilled.

5. Environmental hazard assessment

5.1 Aquatic compartment (including sediment)

The Support Document for the identification of CTPHT as SVHC summarises the following on environmental hazard assessment 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.

5.1.1 Fish

5.1.1.1 Short-term toxicity to fish

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

5.1.1.2 Long-term toxicity to fish

No data on long-term toxicity to fish are available (search done April 2017).

There are only very few data available on CHR. Evaluation on long-term toxicity of CHR to fish was reported as following in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

The water solubility of chrysene is about 1.6 µg/l, with a range between 1.0 and 3.3 µg/l (Mackay et al., 2006). Around or below this value, no significant effects were observed for any species in a regular toxicity experiment, although chronic toxicity studies were performed with algae, crustaceans (including Daphnia) and fish.

5.1.2 Aquatic invertebrates

5.1.2.1 Short-term toxicity to aquatic invertebrates

There are only very few data available on CHR. Evaluation on short-term toxicity of CHR to aquatic invertebrates was reported as following in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

The only study, that showed a considerable effect of chrysene, was a determination of the median lethal time of neonates of Daphnia magna (Newsted & Giesy, 1987). In this experiment, the daphnids were exposed to one concentration of chrysene (measured concentration of 0.7 µg/l). After 24 hours of exposure with a 16:8 h light:dark photoperiod, the animals were exposed to a mix of UV A , UV B and visible light. The median lethal time after UV-radiation started was 24 hours. Thus, after 48 hours, of which the last 24 hours were with UV irradiation, 50% mortality of the daphnids occurred at 0.7 µg/l. This type of study is however not designed to determine dose-response relationships and hence quantitative data on toxicity or toxicity threshold values cannot be derived from the result.

5.1.2.2 Long-term toxicity to aquatic invertebrates

No standard test data on long-term toxicity to aquatic invertebrates are available.

There are only very few data available on CHR. Evaluation on long-term toxicity of CHR to aquatic invertebrates was reported as following in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

The water solubility of chrysene is about 1.6 µg/l, with a range between 1.0 and 3.3 µg/l (Mackay et al., 2000). Around or below this value, no significant effects were observed for any species in a regular toxicity experiment, although chronic toxicity studies were performed with algae, crustaceans (including Daphnia) and fish.

5.1.3 Algae and aquatic plants

There are only very few data available on CHR. Evaluation on toxicity of CHR to aquatic algae was reported as following in the Support Document for identification of CTPHT as SVHC (ECHA, 2009):

The water solubility of chrysene is about 1.6 µg/l, with a range between 1.0 and 3.3 µg/l (Mackay et al., 2006). Around or below this value, no significant effects were observed for any species in a regular toxicity experiment, although chronic toxicity studies were performed with algae, crustaceans (including Daphnia) and fish.

5.6 Summary and discussion of the environmental hazard assessment

The environmental hazard assessment for CHR was previously done for the identification of CTPHT as SVHC (ECHA, 2009). It is reported that “*the only study, that showed a considerable effect of chrysene,* was a *determination of the median lethal time of neonates of Daphnia magna at a concentration of 0.7 µg/L (Newsted & Giesy, 1987). […] This type of study is however not designed to determine dose-response relationships and hence quantitative data on toxicity or toxicity threshold values cannot be derived from the result.*”

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Chrysene is covered by index number 601-048-00-0 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

CHR 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 the filed study (Wild et al., 1991). The study by Wild et al. (1991) was selected as the study having highest weight for the P assessment. Additionally, the study by Wild et al. (1993) reports a half-life values of CHR in soil between 106 to 313 days and is therefore above the P and vP criteria set in Annex XIII. Furthermore, model calculations done by Mackay et al. (1992) do confirm that CHR 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 CHR 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

An experimentally obtained BCF value above 5000 is reported for CHR in aquatic Crustacea. In accordance to REACH Annex XIII, CHR 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

CHR is classified in the hazard class carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH Annex XIII section 1.1.3 b) is fulfilled.

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

Art 57 (d) and (e):

An assessment of the PBT/vPvB properties of CHR has already been carried out by the MSC in the context of the identification of CTPHT as SVHC, as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). Additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (NL, 2008). Both reports support the conclusions on the PBT and vPvB properties of CHR already drawn in the MSC Support Document on CTPHT. The information leading to the identification of CTPHT as SVHC are is still valid and allow compact assessment of the substance properties with a focus on PBT/vPvB.

Persistence
Based on the available information from experimental and estimated data, CHR 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 CHR 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)
CHR is classified in the hazard class carcinogenicity category 1B according to EU Regulation 1272/2008. Thus, the T criterion of REACH Annex XIII 1.1.3 b) is fulfilled.

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

Part II

7. Registration and C&L notification status

7.1 Registration status

CHR is not produced intentionally and is not registered within the scope of regulation REACH.

7.2 CLP notification status

Table 5: CLP notifications

	CLP Notifications[3]
Number of aggregated notifications	9
Total number of notifiers	382

8. Total tonnage of the substance

CHR is not produced intentionally and is not registered within the scope of 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 CHR 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 CHR as a constituent.

9. Information on uses of the substance

There are numerous UVCB substances that contain CHR. Among the reported uses are: Uses in Coatings and paints, uses in road and construction application, in binders or release agents, uses in lubricants and in cleaning agents. The substances are also registered for consumer uses. Those uses are suitable to contribute to a significant environmental exposure. The low quality of registration dossiers were issued during informal meetings of authorities and industry. Therefore it is likely that more than these substances do contain CHR and are used wide dispersively.

Two UVCBs containing CHR are registered according to Art. 18 (transported isolated intermediate) with industrial uses in the production of other chemicals and rubbers.

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

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

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. As primary producers of UVBCs are organised in industry consortia like CONCAWE[4], Cefic[5], LOA[6] and other, this allows regulatory authorities to address specific questions and concerns to industry. However, according to information from an industry sector organisation the knowledge of uses decreases with the increase in the level of downstream uses.

11. Additional information

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

CHR 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 its PAH constituents. CHR was one of its constituents which lead 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 CHR-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.

11.3 Existing EU legislation

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

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[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

In addition to entry 28 CHR is further restricted by entry 50 of Annex XVII to Regulation REACH. 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 these 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 CHR. For toys the same applies but the limit of CHR content is 0.5 mg/kg.

CHR is listed in Annex II of EU Regulation 1223/2009 (Reference number 643) as a substance which is prohibited in cosmetic products.

11.4 Previous assessments by other authorities

CHR 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 CHR 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 based on their PBT/vPvB properties (anthracene, B[a]P) or on the intrinsic properties 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 CHR 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 proposed for formal SVHC identification and inclusion in the Candidate List.

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