



Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at Community level of
pitch, coal tar, high temp.

ECHA/RAC/CLH-O-0000001380-85-03/A2

Adopted
21 November 2011

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

[ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.]

Substance name: Pitch, coal tar, high temp.

CAS number: 65996-93-2

EC number: 266-028-2

General comments

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment
29/10/2010	Germany / Member State	The German CA supports the NL in their Proposal for Harmonized Classification of Pitch, coal tar, high temp.	The support is noted.	Noted
03/11/2010	UK / The Morgan Crucible Company plc / Company-Downstream user	P.19 The section on the use of pitch as a binder in Refractory Brick should be expanded to cover pitch as a binder in the production of Foundry Products, such as crucibles for the melting and casting of ferrous and non-ferrous metals and alloys. Coal tar pitch, heated to 60-100°C, is mixed with various granulated minerals to form a bound mixture which may be pressed or rolled into shape, e.g. crucibles. The formed shape is subsequently fired at high temperature, about 1200°C, to carbonise the binder pitch and it is this carbon which then forms a solid bond between the mineral constituents. Approximately 2000tonnes/annum of such products are manufactured in the EU, about 50% of which are exported to the Americas and Asia.	This detailed information is appreciated as background information, but considering the broad scope and outline of the paragraph on Refractory Brick on pages 21-22 in the Annex VI dossier, we believe that also the use of coal tar pitch in foundry products is sufficiently covered.	Agree with the response of DS
10/11/2010	France / Elodie Pasquier / Member State	- Health hazards For CMR properties, the recommendations agreed at the TC C&L regarding the classification of coal tar pitch,	The support is noted.	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		high temp. are supported in absence of any new study since the TC C&L discussions and in agreement with the classification proposed in the CLH report.		
12/11/2010	Ireland / Health & Safety Authority	<p>We note that CTPHT is included on the list of the 87 TC C&L handover substances for which the human health classification was agreed and that the current proposal for human health is the same as that previously agreed by the TC C&L.</p> <p>The dossier submitter has indicated that non-CMR health endpoints were not proposed for harmonised classification since the classification and labelling of CTPHT as a carcinogen will limit the risks for other health effects. While we agree with this approach, we query whether the full human health classification could have been proposed, given it was previously agreed in full at TC C&L.</p>	<p>A proposal for harmonised classification for all endpoints, agreed by the TC C&L, was considered. However, this requires a justification for the non-CMR/RS endpoints. The fact that it was already agreed at the TC C&L is not considered as a justification by the commission: the minutes of the 10th RAC meeting state that “The Commission also confirmed the need for providing a specific justification for non-CMR/RS hazard classes in the CLH dossier and report for the TC C&L agreed substances.”</p> <p>In our view, all concerns regarding the other human health endpoints are sufficiently covered by the proposed classification. Therefore, no harmonised classification for the other human health endpoints was proposed.</p>	Due to the need for specific justification for the non-CMR/RS endpoints, we support the harmonised classification proposed.
12/11/2010	Belgium / Eurobitume / Industry or trade association	<p>These comments are submitted by Eurobitume, the European bitumen association. However, we have consulted with the Bitumen Waterproofing Association and the European Asphalt Pavement Association and the views represented below are supported by those organisations</p> <p>A general comment is that the document refers to the use of coal tar and coal tar pitch in road and roofing products as if the use was normal practice in today's technologies. This is not the case and has not been for</p>	We agree that some further emphasis on the fact that pitch is no longer used in road and roofing products in the EU may be necessary, in addition to	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>decades. Furthermore, the text suggests that bitumen and coal tar are equivalent in respect of their properties and, due to their use in similar applications, might be in some way associated. This is not the case and any potential confusion should be removed.</p> <p>What is the difference between bitumen and coal tar? Bitumen and coal tar are often confused. Bitumen is manufactured from crude oil by distillation (under vacuum). Crude coal tar is a residue, derived from coal by destructive pyrolysis at high temperatures. Coal tar or coal tar pitch (depending on the softening point) is a residue of crude coal tar after distillation. Coal tar is quite different from bitumen, in terms of its physical characteristics, chemical composition and the nature and degree of hazard it presents to the user. Many coal tars are classified as carcinogenic, whereas bitumens are not. Coal tar can be identified by its characteristic smell.</p> <p>Page 16; Reference to pitch in combination with bitumen for use in road paving. Since the 1960s the use of coal tar products in road construction applications has declined dramatically and since the end-1990's is almost entirely absent from road surfacing mixtures except for highly specialised applications such as anti-skid layers for runways, but even this use of tar in anti-skid layers for airfields, has decreased significantly because alternatives have become available.</p> <p>Page 20; Binder for road construction and roofing This section suggests that the use of coal tar and its derivatives in conjunction with bitumen is routine. This is not the case and has not been so for several decades. The types of mixtures referred to in the text reflect</p>	<p>that already in the text, so the text on page 22 has been adapted.</p> <p>We appreciate the clear explanation of the difference between bitumen and coal tar. Yet, when bitumen is mentioned in the dossier it is being indicated as part of a mixture of tar and bitumen, which in our opinion clarifies the differences between the different mixtures, without suggesting that bitumen is equivalent to coal tar.</p> <p>On page 16 the reference is used only as an illustration of a formulation in which different PAH-containing substances are used, but we agree that a slight adaptation appeared necessary to emphasize that such a formulation is no longer used in road construction.</p> <p>On Page 22 the section on "Binder for road construction and roofing" has been adapted to further emphasize that this use is now very minor if existing at all.</p>	

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>historic practice, as the vast majority (more than 99.9%) of road and all roofing materials are now manufactured with pure bitumen. A few products containing coal tar pitch and its derivatives remain in use in specialised applications where no other technical solution is feasible. However, their use is restricted due to their carcinogenic potential and the volumes involved are very small.</p> <p>In particular, in this section we are concerned about the use of the terms;</p> <p>" 'pitch'/ 'road tars'/ 'normal pitch with middle oils (boiling range 170-270 °C), heavy oils (270-300 °C), and anthracene oils (boiling range > 300 °C)'/ 'anthracene oil II (boiling range > 350 °C) and anthracene oil II (boiling range up to 350 °C) /Pitch-bitumen / Carbobitumen is a blend of soft pitch and hard bitumen, containing 20-30% of a special pitch, "</p> <p>The above text implies that the road paving industry is routinely using coal tar materials, which is clearly incorrect.</p> <p>In respect of the following text please see our comments;</p> <p>“Roofing tars used as impregnating, coating, and adhesive material for tarred felts and tarred sealing webs and are usually blends of pitch and filtered anthracene oil; by using plasticised pitches or by adding extenders the plasticity and temperature stability of roofing tars is improved considerably (Collin & Höke, 2002).”</p> <p>It is reported that in the 1970s the amount of roofing membranes produced with coal tar was extremely low. In 1979 coal tar disappeared completely from the production of roofing membranes, at that time the product standards for these tar products were withdrawn. [Technische Regeln für die Planung und</p>	<p>Also in this section we have further emphasized that this paragraph focuses on former use of coal tar.</p>	

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>Ausführung von Abdichtungen mit Polymerbitumen- und Bitumenbahnen, vdd Indistrieverband Bitumen dach- und Dichtungsbahnen e.V., Frankfurt,Germany 2002, ISBN 3-9801831-4-9]. Today a ban of the usage of coal tar in the roofing area exists e.g. Germany, France.</p> <p>All European standards for roofing products in CEN/TC 254 clearly state that they are only applicable for products made out of bitumen, the use of tar in these products is not permitted (e.g. EN 13707 art5.3, EN 13969 art.5.15 etc...). To our knowledge there are no local/national standards in existence for more than 30 years.</p>		
12/11/2010	Spain / Member State	We are in agreement with the environmental classification proposal submitted by the Dutch Competent Authority	The support is noted.	Noted
15/11/2010	Belgium / European Carbon and Graphite Association asbl / Industry or trade association	<p>The carbon and graphite industry is committed to reduce any of its effluents and emissions as a continuous effort and has made considerable progress of the years. The major and dominant sources for PAH emissions are power stations, incineration processes like heating systems and traffic. The carbon & graphite industry is a minor contributor like the producers and users of paste material i.e. as Soederberg Paste at Al-electrolysis plants. The only sources of PAH emissions from carbon & graphite manufacturing facilities are from mixing, baking and impregnation facilities, which are equipped with adequate abatement systems. Details on the manufacturing process of carbon & graphite are described in the Non Ferrous Metal Bref Note and the VDI 3467 guideline. In the Non-Ferrous Metal Bref Note also data of typical actual emissions are described, whereas achievable values might show the tendency of the long-term future development. Regarding additional</p>	The efforts by the carbon and graphite industry to reduce PAH emissions are appreciated, but for classification and labelling the focus is on hazard only, not on risk and thus not on exposure and emissions.	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>information on the use of pitch, typical data of emissions profiles and ambient air profiles in the neighbourhood of C&G sites are available and could be discussed on the basis of a database prepared by the ECGA. The C&G industry is certainly willing to evaluate and discuss required data, considering basics given in section 3 Hazardous assessment.</p> <p><i>ECHA's comment: The text below was submitted as an attachment (ECGA pp coal tar pitch public cons.doc) with the comments, and includes almost the same text than in the text feeds.</i></p> <p>ECGA position paper on: Environmental risk assessment of high temperature coal tar pitch and proposal for Harmonised classification and labelling</p> <p>1. Introduction The carbon and graphite industry is committed to reduce any of its effluents and emissions as a continuous effort and has made considerable progress of the years.</p> <p>2. Sources of PAH The major and dominant sources for PAH emissions are power stations, incineration processes like heating systems and traffic. The carbon & graphite industry is a minor contributor like the producers and users of paste material i.e. as Soederberg Paste at Al-electrolysis plants.</p> <p>3. Carbon and Graphite industry The only sources of PAH emissions from carbon & graphite manufacturing facilities are from mixing, baking and impregnation facilities, which are equipped with adequate abatement systems. Details on the manufacturing process of carbon & graphite are described in the Non Ferrous Metal Bref</p>		

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		<p>Note and the VDI 3467 guideline. In the Non-Ferrous Metal Bref Note also data of typical actual emissions are described, whereas achievable values might show the tendency of the long-term future development.</p> <p>Regarding additional information on the use of pitch, typical data of emissions profiles and ambient air profiles in the neighbourhood of C&G sites are available and could be discussed on the basis of a database prepared by the ECGA.</p> <p>The C&G industry is certainly willing to evaluate and discuss required data, considering basics given in section 3 Hazardous assessment.</p> <p>4. Monitoring of PAH</p> <p>Before any risk classification of sources can be established, a clear and common definition of methods of monitoring PAH constituents is urgently needed. Due to the fact, that quite different monitoring and analytical techniques are used (i.e. adsorption VDI and condensate fraction OSPAR), resulting in significantly different results of PAH; a common assessment of pollution data is not reliable at all.</p> <p>5. Hazard assessment</p> <p>It is doubtful whether properties of coal tar pitch, high temp. can be derived from properties of individual compounds like Benz(a)pyrene or EPA 16 list.</p> <p>Bioavailability and especially the impact of coal tar pitch on the environment (esp. in the media of water) needs to be considered. The carcinogenic properties of a material as such, do not give any indication of any bioavailability or environmental impact during production or application.</p> <p>The classification of coal tar pitch needs further discussions and the consideration based on available data contributable by the C&G industry. Especially the</p>		

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		<p>bioavailability and environmental impact has to be evaluated before any conclusions are made.</p> <p>6. Summary Assuming that the overall contribution to the environment of the C&G industry is insignificant in comparison to power stations, heating systems and traffic any measures of handling restrictions would not lead to any measurable improvement.</p> <p>ECGA does not agree</p> <ul style="list-style-type: none"> • with the proposal that the C&G industry is not exempted like the production of coal tar pitch and the coal tar production in cookeries; • with the proposal to include coal tar pitch, high temp. (CAS number 65996-93-2 in the PBT list or classify as PBT respect. vPvB based on properties of individual PAH; • with the fact that the risk assessment is based on the properties of individual constituents and not on the actual properties of pitch and the bioavailability and – impact of coal tar pitch, high temp. <p>ECGA sees the need</p> <ul style="list-style-type: none"> • for further evaluation in the ESR framework; • for consideration of available data within the C&G industry; • for the necessity of further discussion. 		
15/11/2010	Portugal / Portuguese Environment Agency / National Authority	Considering the present proposal, we agree to establish an harmonised Classification & Labelling for CTPHT.	The support is noted.	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

Carcinogenicity

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment
12/11/2010	Ireland / Health & Safety Authority	According to Annex VI of CLP, benzo[a]pyrene is classified as Carc. 1B, Muta. 1B, Repr. 1B and Skin Sens. 1. There is a specific concentration limit of $C \geq 1\%$ for carcinogenicity. Information presented in the dossier suggests that the approximate concentration of benzo[a]pyrene in CTPHT is 1 – 1.3%. Therefore, based on the concentration of benzo[a]pyrene in CTPHT, and the animal studies with CTPHT, we can agree to a minimum classification of Carc 1B. We note the previous agreement of the TC C&L of Carc. Cat 1 R45.	The support is noted.	Noted
12/11/2010	Belgium / Eurobitume / Industry or trade association	<p>Page 21. Reference to bitumen carcinogenicity. This section includes the following statements: “Binding agents such as pitch, tar, and bitumen were formerly used for low volatile coals. Because of their carcinogenic effect (which is particularly pronounced if such binding agents are based on hard coal), they are being replaced by other binding agents, e.g. biomass materials (for example molasses).” We are not aware of any evidence to support this statement, particularly in relation to the reference to bitumen binding agents being carcinogenic. In fact, a further study by Boffetta et al* confirmed the confounding of the 2003 and 2004 references by coal tar amongst other agents.</p> <p>“On the whole the amount of pitch used for these two applications decrease as it is replaced by petroleum pitch...” The above statement refers to petroleum pitch (CAS 68187-58-6), but we believe the statement should refer to bitumen. Bitumen should not be confused with petroleum pitches, which are often highly aromatic residues, produced by thermal cracking, coking or</p>	<p>We believe that their carcinogenic effect, or at least their suspected carcinogenic effect, was the main reason why these binding agents were replaced by other materials. Yet, we see the validity of your comment and adapted the text by adding the word “suspected”.</p> <p>The statement was taken from the Risk Assessment Report that was compiled in the framework of Council Regulation (EEC) 793/93. We realize now that this statement may not be right and have changed it accordingly.</p>	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>oxidation from selected petroleum fractions. The composition of petroleum pitches differs significantly from bitumen and petroleum pitches are not a CAS n° accepted in bitumen manufacture. To our knowledge, 'Petroleum pitch' is not used in the road and roof industries.</p> <p>Referenced Studies</p> <p>We are concerned with the referencing of studies carried out on bitumen workers in a coal tar classification and labelling document. These studies did not study coal tar workers but bitumen workers. The inappropriate references are:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Boffetta et al, 2003 <input type="checkbox"/> Boffetta et al, 2004 <p>* A Case-Control Study of Lung Cancer Nested in a Cohort of European Asphalt Workers; Ann Olsson, Hans Kromhout, Michela Agostini, Johnni Hansen, Christina Funch Lassen, Christoffer Johansen, Kristina Kjaerheim, Sverre Langård, Isabelle Stücker, Wolfgang Ahrens, Thomas Behrens, Marja-Liisa Lindbohm, Pirjo Heikkilä, Dick Heederik, Lützen Portengen, Judith Shaham, Gilles Ferro, Frank de Vocht, Igor Burstyn, and Paolo Boffetta; available at http://dx.doi.org/, 2010</p>	<p>We are aware of the fact that these studies focus on bitumen workers, but we believe that these studies can be used in a weight of evidence approach (as has been done).</p>	
15/11/2010	Belgium / European Carbon and Graphite Association asbl / Industry or trade association	<p>It is doubtful whether properties of high temp coal tar pitch can be derived from properties of individual compounds like Benz(a)pyrene or EPA 16 list. Bioavailability and especially the impact of coal tar pitch on the environment (esp. in the media of water) needs to be considered. The carcinogenic properties of a material as such, do not give any indication of any bioavailability or environmental impact during production or application.</p>	<p>Considering the risks of high temp coal tar pitch we believe that the risks of the individual PAHs are indicative as it is shown that PAHs can be released from pitch into water.</p>	noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

Mutagenicity

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12/11/2010	Ireland / Health & Safety Authority	The studies presented demonstrate that CTPHT is mutagenic in bacteria but that occupational exposure to CTPHT or PAHs (and other confounding factors) have no mutagenic effect in humans. The classification proposal of Muta 1B H340 is based on $C \geq 0.1\%$ benzo[a]pyrene, which we are in agreement with.	The support is noted.	Noted

Toxicity to reproduction

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment
12/11/2010	Ireland / Health & Safety Authority	The studies presented indicate that high-boiling coal liquid, coal tar derived products and creosote have no effect on fertility or development. The classification proposal of Repr 1B H360FD is based on $C \geq 0.3\%$ benzo[a]pyrene, with which we are in agreement with.	The support is noted.	Noted

Respiratory sensitisation

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment

Other hazards and endpoints

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment
29/10/2010	Germany / Member State	Page 91, Table 7.6.1: In this table the Aquatic hazard classification of CTPHT	We agree and adapted the table accordingly. Consequently, values and calculations	Noted

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		<p>is derived. It seems that the Multiplying factors (M) for anthracene and fluoranthene are not in accordance with Regulation EC 1272/2008 (EU, 2008b).</p> <p>For anthracene a LC50 of 0.001 mg/L is estimated in figure 7.1.1. According to table 4.1.3 of the CLP-regulation the appropriate M-factor for a toxicity of equal or less than 0.001 mg/L results is 1000 and not 100.</p> <p>For fluoranthene a LC50 of 0.0001 mg/L is cited as the most sensitive one according to Spehar et al (1999). According to table 4.1.3 of the CLP-regulation the appropriate M-factor for a toxicity of equal or less than 0.0001 mg/L results is 10000 and not 1000.</p> <p>Please note that these changes do not change the overall assessment of CTPHT.</p>	<p>in the main text were adapted as well.</p>	
10/11/2010	France / Elodie Pasquier / Member State	<p>- Environmental hazards</p> <p>First of all, we thank the Netherlands for the well detailed bibliographic review for the environmental properties and for the environmental hazard assessment.</p> <p>Although it has no influence on the classification of the considered CTPHT, we have two remarks for the chapter 4.</p> <p>Firstly, in the 4.1.1 (stability) it would have been interesting to present at least the half life for photodegradation of naphthalene. Indeed, the lowest half life for degradation (anthracene) has been provided. This value comes from a study where the half life for 7 others PAHs have been determined and the highest value is observed for the naphthalene. Giving the half</p>	<p>We agree that this improves the text and have adapted it accordingly.</p>	

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>life for naphthalene will allow to have a range of half life for photodegradation for these PAHs.</p> <p>Secondly, the chapter 4.2 is appreciated, where the influence of the kind of organic matter has been well documented. It is also described studies where the Koc for several PAHs for different sites have been reported. It is mentioned that “In the absence of information on the black carbon content no relationship between Koc values and the black carbon content can be made”. We suggest to still interpret the data from these studies, taking into account of the total organic content in the different sites.</p> <p>We have also some comments for the environmental classification, even if we agree with the general conclusion on classification. However, we think that the M-factor should be indicated in the proposal. Indeed, you have determined an M factor of 1000, based on the ecotoxicological data on substances representing less than 10% of the CTPHT. Thus, it should be mentioned that the M factor is equal to or over 1000, unless the composition can be more clearly identified and the chemical items of concern have concentrations which induce a lower M-factor.</p> <p>1. Since in the absence of data on bioaccumulation, log Kow can be used for the classification according to the Annex IV table 3.1, we suggest to add that log Kow is over 4 in the bioaccumulation column when bioaccumulation data are missing</p> <p>2. According to the Table 4.1.3 from the Annex I of the Guidance on the application Regulation(EC) No 1272/2008, M factor should be 1000 for anthracene</p>	<p>We wonder what the added value will be of the exercise as it will not impact the classification of the substance. We therefore would like to keep the text as it is.</p> <p>As indicated in the text of paragraph 7.6 we believe that since the M-factor strongly depends on the exact composition of CTPHT (the derivation of an M-factor of 1000 is just illustrative). It therefore appears more reasonable to treat CTPHT as a mixture for which only part of the constituents are known, as is indicated in paragraph 7.6.</p> <p>We have added the remark in the footnote of table 7.6.1.</p> <p>The table and relevant text have been adapted.</p>	<p>As it has no influence on the proposed classification, we support to keep the text as it is.</p> <p>This issue was discussed during RAC-17. The agreement was to propose default M-factors of 1000 for both categories Aquatic Acute and Aquatic Chronic, based on the typical composition of binder pitch. Manufacturers and users should be able to modify this M-factor if the composition of the substance is known.</p> <p>Noted (but instead of Table 7.6.1, it is Table 7.6.2).</p>

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

Date	Country / Person / Organisation / MSCA	Comment	Response	Rapporteur's comment
		<p>(E/LC50 = 0.001) and 10000 for fluoranthene (E/LC50 = 0.0001).</p> <p>3. Although the Table 7.6.1 is already very informative, could you specify:</p> <p>a. Endpoints which have been determined with UV exposure</p> <p>b. When EC10 has been chosen for the classification determination, in the absence of validated EC50 (ex. fluorene, indeno[1,2,3-cd]pyrene)</p> <p>4. Two studied PAHs have not been classified due to non-occurrence of effects up to the limit of water solubility (benzo[b]fluoranthene benzo[ghi]perylene). However, please note that the E(L)C50 determined for benzo(a)pyrene, dibenz[a,h]anthracene and indeno[1,2,3-cd]pyrene (respectively 0.058 mg/L, 0.0018 mg/L and 0.00027 mg/L) are over the limit of solubility presented in the Table 1.3.4. (respectively 0.00154 mg/L, 0.00082 mg/L and 0.0001 mg/L). A brief argumentation could be developed to explain why, for these cases, the E(L)50 have been considered as relevant even if there is no consequence on the proposed classification.</p> <p>It is also noted that classification for environment is not considered as a priority under CLP. It is noted that additional guidance from the Commission on what are relevant justifications for harmonisation of classification of hand-over substances would be helpful to clarify these points.</p> <p><i>ECHA has removed this comment from the General comments.</i></p>	<p>We agree and have added this useful information in a table note. EC10 values have now been replaced by E(L)C50 values.</p> <p>We agree that it is not correct to include these E(L)C50 values, so they have been removed. For benzo(a)pyrene, however, the value is replaced by a value for Daphnia which was determined with UV-exposure (0.0012 mg/L).</p> <p>We like to point out though, that neither of your comments 1-4 changes the classification of CTPHT.</p> <p>Your comment is noted.</p>	<p>Noted</p> <p>Noted (but instead of Table 7.6.1, it is Table 7.6.2).</p> <p>Noted</p> <p>Noted</p>
12/11/2010	Ireland / Health &	Environment:	The support is noted.	Noted

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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	Safety Authority	<p>We agree with both the CLP and CPL proposed classifications, based on the need to treat the UVCB substance as a mixture. Therefore, C&L was obtained by the use of the summation method under 99/45/EEC and CLP looking at each individual component, i.e. 16 EPA-PAHs. Attempts to classify the substance as UVCB itself proved difficult as there were several controversial and unclear issues with regard to various tests.</p> <p>Note: the proposed labelling under CLP (page 6) proposes both H400 and H410 as labelling elements for environment. However, for this type of classification under CLP, H410 only is sufficient for the label.</p>	We agree that the H410 labelling is sufficient and have removed the proposal of the H400 label.	Noted
15/11/2010	Belgium / European Carbon and Graphite Association asbl / Industry or trade association	<p>ECGA does not agree with the proposal to include coal tar pitch, high temp CAS number 65996-93-2 in the PBT list or classify as PBT or vPvB based on properties of individual PAH or constituents and not on the actual properties of pitch and the bioavailability and impact of high temp coal tar pitch. Before any risk classification of sources can be established, a clear and common definition of methods of monitoring PAH constituents is urgently needed. Due to the fact, that quite different monitoring and analytical techniques are used (i.e. adsorption VDI and condensate fraction OSPAR), resulting in significantly different results of PAH; a common assessment of pollution data is not reliable at all. The classification of coal tar pitch needs further discussions and the consideration based on available data contributable by the C&G industry. Especially the bioavailability and environmental impact has to be evaluated before any conclusions are made.</p>	PBT assessment is not part of this dossier. This remark is therefore noted but not considered further.	Agree with the response of DS
15/11/2010	Netherlands / Coal Chemicals Sector Group (CCSG)	Comments on the environmental classification proposal of CTPHT		

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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	<p>representing European producers of chemicals derived from coal tar distillation / Industry or trade association</p>	<p>Summary: The Annex VI report (Version 0.2, 02-09-2010) for "Pitch, coal tar, high-temp.; EC Number: 266-028-2; CAS Number: 65996-93-2" hereafter: "CTPHT" proposes the harmonised environmental classification: N; R50/53 (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410).</p> <p>Industry (IND) justifies the environmental classification R53 (H413 Chronic 4) for CTPHT.</p> <p>Detailed comments on certain issues</p> <p>p.87/88 Discussion of repeated water extraction experiments on CTPHT powder [RÜTGERS VFT 1999a and 1999b]</p> <p>The Annex VI report is ambiguous regarding description and interpretation of IND experiments [RÜTGERS VFT 1999a and 1999b]. On p.13 "Multiple elution" the experiments are adequately described and evaluated whereas the interpretation on p. 87/88 is not clear. Therefore the background is explained again.</p> <p>These experiments - outside the scope of OECD test methods - were exclusively focussed on the availability of PAH constituents of CTPHT in water. The question was what maximum PAH concentrations in water would be expected in the event of a CTPHT release such as a ship accident. Another question was whether the obtained PAH concentration level in water would persist or reduce over time as no further PAH are emitted from the water/ CTPHT surface interface.</p>	<p>The justification is noted.</p>	

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		<p>Apparently, the authors of the Annex VI report identify the absence of UV-light as an essential short-coming of the experimental concept (page 87 last lines). Text: "The most important short-coming of these tests, however, is that they were not performed in the presence of UV irradiation in order to take into account possible phototoxic effects."</p> <p>IND, however, is convinced, that solubility tests have to be performed under the exclusion of light, as stability of the test substance is a primal requirement in any test. Phototoxicity was not addressed. In the presence of direct UV light, it is expected that dissolved PAHs will react rapidly, probably quicker than replenished by dissolution from the stock thus misleadingly reducing the measured PAH concentration.</p> <p>The influence of UV light on CTPHT in water is limited. CTPHT has a density of 1.3 g/cm³ and sinks to the bottom of the sea thus escaping from UV irradiation.</p> <p>RÜTGERS VFT 1999a and 1999b showed that PAHs can only be extracted from the particle surface to some extent, but the surface is exhausted after several water exchanges.</p> <p>The low solubility of PAHs bound in CTPHT was not expected by scientists who are unfamiliar with CTPHT and, therefore, was verified and confirmed in several studies (Table 1.3.2; UBA 1997 and UBA 1999).</p> <p>Extrapolation of PAH solubility to 1 mg/L</p>	<p>We agree that the discussion on these pages is not clear enough. We realize that it needs elaboration.</p> <p>What was meant here was that the concentrations from the WAF are less useful if based on these loading rates toxicity is to be assessed.</p> <p>Since toxicity of PAHs can be enhanced by (UV-)light this factor should be taken into account in assessment of toxicity of PAHs.</p> <p>The text has been adapted to clarify this.</p>	<p>Noted</p>

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>p.87 5th paragraph states: “Since the DOC concentration (i.e. 0.3 mg/L) of pulverized CTPHT in the experiments by Rütgers VFT (1999a, b) was equal at loadings of 100 and 10,000 mg/L, it is assumed that at both loadings the concentrations of available PAHs is also equal.”</p> <p>..... “Since the concentration in the force percolate exceeds the LC50 for fluoranthene (i.e. 0.1 µg/L) by almost a factor of 100, it is plausible that at loading rates around 1 mg/L or lower CTPHT exerts toxic response and should be classified.”</p> <p>Comment: It is not clear which solubility test is meant to produce a WAF of PAHs of 0.3 mg C/L at a loading of 100 mg/L. Section 1.3 (Table 1.3.2) makes reference to a test with 100 g/L but not 100 mg/L. The referenced experiment RÜTGERS VFT 1999b) is a second report on the ongoing extraction experiment RÜTGERS VFT 1999a). Both reports used a loading of 10,000 mg/L.</p> <p>IND recently verified [Noack et al. 2009] that CTPHT generates a fluoranthene concentration of 0.3 µg/L at 100 mg/L loading compared to 9.3 µg/L fluoranthene at 10,000 mg/L loading [RÜTGERS VFT 1999]. This is not the same level as postulated in the Annex VI dossier. It is not plausible to predict a toxic response of dissolved fluoranthene at 1 mg/L CTPHT loading.</p>	<p>We incorrectly made reference to RÜTGERS VFT 1999a and b. The data were obtained from another study performed by order of UBA in 1996 (T, Weck, 1996, “Bewertung des ökotoxikologischen Potentials von Steinkohlenteerpech”), which was provided by industry. This has been corrected. Based on the additional studies that were provided (Aniol et al 2007ab and Noack et al 2009) section 7.6 has been extensively changed, and we think these data are no longer relevant.</p> <p>Based on the provided additional studies (including those by Aniol et al) we agree that it is not possible to predict a toxic response at 1 mg/L loading. Nevertheless, the measured concentration of both fluoranthene and pyrene are above the lowest reported EC₅₀ value based on which CTPHT should be at least be classified at a loading of 100 mg/L. The text in the Annex VI report has</p>	<p>Noted</p>

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		<p>LC50 for fluoranthene</p> <p>p.87 5th paragraph states the LC50 for fluoranthene to be 0.1 µg/L.</p> <p>Comment: The LC50 value of 0.1 µg/L is exceptional and relates to marine fish (winter flounder). The lowest EC50 value for fluoranthene in the presence of UV light is 1.6 µg/L in a common accepted test organism, in daphnia (Spehar et al. 1999). For comparison, the LC50 in a common, accepted fish species (Pimephales promelas), also in the presence of UV, was 12 µg/L(Spehar et al. 1999).</p> <p>As these studies were all conducted by the same work group, it can be expected that the very low toxicity value in winter flounder is reality rather than an outlier. But this strongly suggests that this exotic fish species would respond similarly towards other phototoxic substances in the presence of UV light. As there are no data for other substances, this fish cannot be used as a routine standard for environmental classification. For consistency and comparability, only acute toxicity results obtained from valid standard test conducted on acknowledged standard test organisms have to be applied. The winter flounder is not test organisms in routine test protocols. A proposal to use this data for classification is arbitrary.</p>	<p>been adapted by adding this argumentation.</p> <p>According to the CLP Regulation (Annex I, section 4.1.1.2.2) both freshwater and marine species toxicity data are considered suitable for use in classification provided the test method used are equivalent.</p>	<p>Agree with the response of DS</p>

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		<p>Proposal to classify the UVCB substance CTPHT as multicomponent mixture</p> <p>In view of the extremely low availability of PAHs from CTPHT, the proposal presented on page 88 2nd paragraph to use the composition of CTPHT for classification purposes, treating pitch as a PAH mixture, is far from reality and is based on the assumption that a high percentage of the constituents are freely available and are a potential source of emissions into the environment. None of these assumptions apply to coal-tar pitch due to its inert inherent properties. This mixture approach is therefore not considered applicable.</p> <p>Alternative approach based on experimental data and weight of evidence.</p> <p>Water hazard classification of CTPHT</p> <p>For the water hazard classification of a substance Regulation (EC) No. 1272/2008 applies.</p> <p>All European CTPHT producers had jointly prepared a composite sample representing the European market average of CTPHT. This sample is used for a variety of new studies performed for the REACH registration dossier of CTPHT registered in November 2010. Acute and chronic aquatic hazard were two endpoints to be addressed. The results are briefly compiled as follows. For a detailed description IND refers to the registration dossier for CTPHT (CAS-No. 65996-93-2).</p> <p>Acute (short-term) and chronic aquatic hazard</p>		

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		<p>assessment</p> <p>Fish OECD 203: Fish , Acute Toxicity Test [Tadokoro et al 1991]: => LL50 > 100 mg/L</p> <p>Crustacea OECD 202: Acute Daphnia sp. Immobilisation Test [Aniol et al 2007a]: => EL 50 >> 100 mg/L => NOELR = 100 mg/L (highest concentration tested)</p> <p>OECD 211: Daphnia magna Reproduction Test, Limit-Test (Semi-Static, 21 d) [Noack et al. 2009]: => NOELR (daphnia, 21 d) = 100 mg/L (highest concentration tested) => LOELR (daphnia, 21 d) >100 mg/L</p> <p>Algae OECD 201: Alga sp. growth inhibition [Aniol et al 2007b]: => ErL50 = 220 mg/L => EyL50 = 153 mg/L =>ErL10 = 10 – 100 mg/L (apparent inhibition of <10 %, no dose dependence)</p> <p>Average initial PAH concentrations in the saturated solution of CTPHT [Noack et al. 2009] as compared to acute EC50 values in daphnia in the presence of UV light</p> <p>The total of 18 aromatic substances leached from 100 mg/L of CTPHT resulted in 1.3 – 1.4 µg/L water-</p>		

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		<p>accomodated fraction (WAF). The concentrations of individual key PAHs in this WAF are compared with EC50/LC50 obtained under UV light irradiation.</p> <p>The following table compares the PAH concentrations achieved in the chronic daphnia study [Noack et al 2009] (1st data column) to the lowest EC50 values found in literature in the presence of UV-light (2nd data column). The daphnia represented the standard test organism with the highest number of search hits for acute test conditions including photoactivation and the same time with the lowest toxicity values as compared with findings from tests with other standard test organisms (alga and fish).</p> <p>The ratios of water concentrations-to-toxic values for single PAHs are significantly below 1, proving that toxic values will not be achieved. This finding provides strong evidence that acute aquatic phototoxicity is very unlikely to arise from CTPHT in contact with water.</p> <p>Mean (n = 5) [µg/L] EC50 daphnia [µg/L] EC50 : WAF ratio (mean) Naphthalene < LOQ 0.0 Acenaphthylene < LOQ 0.0 1-Methylnaphthalene < LOQ 0.0 2-Methylnaphthalene < LOQ 0.0 Acenaphthene 0.063 >1000 Wernersson 2003 0.0 Fluorene 0.054 >1000 Wernersson 2003 0.0 Phenanthrene 0.252 378 Wernersson 2003 0.0 Anthracene 0.056 1.2 Oris and Giesy 1984; Allred and Giesy 1985 0.05 Fluoranthene 0.318 1.6 Spehar 1999 0.20 Pyrene 0.240 1.4 Wernersson 2003 0.17</p>		

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>Benz(a)anthracene 0.072 3.4 Wernersson 2003 0.02 Chrysene 0.080 0.7 Newsted and Giesy 1987 0.11 Benzo(b)fluoranthene 0.0033 4.2 Wernersson and Dave 1997 0.01 Benzo(k)fluoranthene < LOQ 0.0 Benzo(a)pyrene 0.035 1.2 Wernersson 2003 0.03 Dibenz(a,h)anthracene < LOQ 1.8 Wernersson 2003 0.0 Benzo(ghi)perylene < LOQ 0.0 Indeno(1,2,3-cd) pyrene < LOQ 0.0 Sum of 18 PAHs approx. 1.33</p> <p>LOQ: limit of quantitation = 0.030µg/L; included in the total of 1.33 µg/L with LOQ/2 = 0.015 µg/L (8 values)</p> <p>IND conclusions on environmental classification</p> <p>CTPHT is not considered to be an environmentally hazardous substance due to its inert inherent properties: because of its poor water-solubility and its complex high-molecular aromatic structure, it is not bioavailable, hence can be neither biodegraded nor bioaccumulated.</p> <p>CTPHT failed to show acute and chronic aquatic toxicity. (Note: Daphnia and alga gave no evidence of chronic adverse effects up to a loading of 100 mg/L. Long-term studies in fish are not available. However, they are not supposed to generate chronic toxic effects that are relevant for classification. Furthermore, the classification proposal outlined below will include the aspect of chronic hazard. Phototoxic effects produced by certain PAHs under the influence of sun/UV-light can be waived by way of a</p>	<p>After the public consultation several new studies were made available by industry. Section 7.6 of the dossier has been adapted to accommodate these new studies.</p> <p>As indicated in this section 7.6, our evaluation of the studies identified a number of short-comings in the new studies.</p> <p>First, the toxicity was determined in the absence of UV irradiation, while several PAHs are known to be phototoxic. Hence, it proved to be impossible to draw any definitive conclusions on the aquatic classification of CTPHT based on the new WAF studies performed.</p>	<p>Due to the shortcomings observed in these new studies, we agree with the response of DS.</p>

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		<p>weight-of-evidence approach, namely by comparing water solubility and phototoxicity data of critical key components of pitch.</p> <p>As pointed out in the ANNEX-VI document by NL (p. 86/87), “the water-accommodated fraction (WAF) approach is considered most appropriate to classify CTPHT, as recommended e.g. for petroleum derivatives in the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD, 2000)”.</p> <p>Based on experimental evidence and weight of evidence, CTPHT requires no classification for environmental hazards in accordance to Directive (EU) 67/548/EEC. For precautionary reasons, taking into account that CTPHT may be a potential source of PAHs released into the environment, the labelling with R 53 is proposed.</p> <p>Also in accordance to Regulation (EC) No 1272/2008, there is no need to classify pitch for acute toxicity. Using the precautionary principle it is recommendable to classify CTPHT for long-term aspects as a potential source of environmental release of PAHs, which may be a cause of concern. This precautionary principle is covered by the “safety net” classification (Category: Chronic 4) [GHS Guidance, part 4, 4.1.2.12], hence H413 Chronic 4 is proposed.</p> <p>“Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable and have a log Kow ≥ 4, indicating a potential to bioaccumulate, will be</p>	<p>Second, the new WAF studies were performed at one loading only (i.e. 100 mg/L), while availability of the different PAHs may very well be dependent on the loading, At present, we have insufficient information to enable extrapolation to lower loadings. In addition, the loading time may not have been sufficient, especially for the chronic study (48 hrs). When following the transformation/dissolution protocol for metals, the CTPHT material should be stirred for 28 days for chronic classification (at a loading of 1 mg/L). In absence of relationships between the loading and time of extraction on the one hand and between loading and solubility of PAHs on the other, it is difficult at present to extrapolate the summation of all PAHs at 100 mg/L downwards to lower loadings (i.e. 1 mg/L). This strongly hampers the classification of CTPHT based on the new WAF studies presented. Based on these considerations we maintain our classification based upon the rules laid down in Annex I, section 1 of Regulation (EC) 1272/2008, considering CTPHT as a</p>	

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence would include an experimentally determined BCF < 500, or a chronic toxicity NOEC > 1 mg/l, or evidence of rapid degradation in the environment.</p> <p>References:</p> <p>Allred PM, Giesy JP (1985): Solar radiation-induced toxicity of anthracene to <i>Daphnia pulex</i>. Environ. Toxicol. Chem. 4, 219-226</p> <p>Aniol S, Blum Th, Honnen W 2007a: <i>Daphnia</i> sp., Acute Immobilisation Test according to OECD 202 of Pitch (Coal Tar). Report No. STZ 11-07-002, 15 Nov. 2007, Steinbeis-Transferzentrum (STZ), Germany (sponsored by Coal Chemicals Sector Group CEFIC (CCSG), Brussels)</p> <p>Aniol S, Blum Th, Honnen W 2007b: <i>Alga</i> sp., Growth Inhibition Test according to OECD 201 of Pitch (Coal Tar). Report No. STZ 11-07-001, 03 Dec. 2007, Steinbeis-Transferzentrum (STZ), Germany (sponsored by Coal Chemicals Sector Group CEFIC (CCSG), Brussels)</p> <p>Newsted JL and Giesy JP (1987): Predictive models for photoinduced acute toxicity of polycyclic aromatic hydrocarbons to <i>Daphnia magna</i>, Strauss Cladocera, Crustacea. Toxicol Chem, 6, 445-461</p> <p>Noack M, Stülten D, Noack U (2009): Pitch, coal tar, high-temp - <i>Daphnia magna</i> Reproduction Test, Limit-</p>	<p>'mixture'.</p>	

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>Test (Semi-Static, 21 d). Project-No. 070615HC, DR. U. NOACK-LABORATORIEN, Germany, 27 July 2009 (sponsored by Coal Chemicals Sector Group CEFIC (CCSG), Brussels)</p> <p>Oris JT, Giesy JP, Allred PM, Grant DF, Landrum PF (1984): Photoinduced toxicity of anthracene in aquatic organisms: an environmental perspective. Stud. Environ. Sci. 25 (Biosphere: Probl. Solutions, ed. Veziroglu TN), 639-658</p> <p>Spehar RL, Poucher S, Brooke LT, Hansen DJ, Champlin D, Cox DA (1999): Comparative toxicity of fluoranthene to freshwater and saltwater species under fluorescent light. Arch. Environ. Contam. Toxicol., 37, 496-502</p> <p>Tadokoro H, Maeda M, Kawashima Y, Kitano M, Hwang D, Yoshida T 1991: Aquatic toxicity testing for multicomponent compounds with special reference to preparation of the test solution. Ecotoxicol. Environ. Safety 21: 57-67</p> <p>Wernersson A-S (2003): Predicting petroleum phototoxicity. Ecotoxicol. Environ. Safety, 54, 355-365</p> <p>Wernersson, A.-S.; Dave, G. (1997): Phototoxicity identification by solid phase extraction and photoinduced toxicity to Daphnia magna. Arch. Environ. Contam. Toxicol., 32, 268-273</p>		
15/11/2010	UK / Member State	We note the CTPHT proposal uses an environmental classification for naphthalene that is different to the harmonised classification in Annex VI (section 7.6). We think there should be more explanation for why this	For the classification in table 7.6.1 we only used data gathered for this Annex VI dossier to ensure that all data in this table (including	Noted (but instead of Table 7.6.1, it is Table 7.6.2).

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		<p>harmonised environmental classification is not used in the CTPHT proposal. Do the Netherlands think the harmonised classification for naphthalene should be revised?</p> <p>*We note the indicative calculation of an M-factor for binder pitch (section 7.6). Whilst we appreciate the variability of CTPHT, we think it would be useful to consider including some indication of the potential range of the M-factor i.e. will the compositions produced for other known uses have very different M-factors or be broadly similar?</p>	<p>classification and M-factors) was derived in the same way and thus can be combined to classify CTPHT.</p> <p>We also like to point out that based on other comments we realized that the table contained some errors in the choice of toxicity data used. The table is therefore adapted to correct for this. Yet, this has no implications for the overall classification that is proposed for CTPHT.</p> <p>As indicated in paragraph 7.6 we believe that the summation method is preferred. Considering the variability of CTPHT this method is more flexible to calculate the hazard of different batches (if necessary). Based on the compositions of the two pitches in Table 1.2.1 the M-factor will probably not change much between different pitches.</p>	<p>This issue was discussed during RAC-17. The agreement was to propose default M-factors of 1000 for both categories Aquatic Acute and Aquatic Chronic, based on the typical composition of binder pitch. Manufacturers and users should be able to modify this M-factor if the composition of the substance is known.</p>
15/11/2010	Portugal / Portuguese Environment Agency / National Authority	<p>The proposed Environmental Classification fulfils the criteria established both in CLP Regulation and in 67/548/EEC Directive. Therefore, we support this proposal.</p> <p>We also support the proposed corresponding Labelling according to 67/548/EEC Directive.</p> <p>Nevertheless, regarding the proposed CLP Labelling, according to article 27 of CLP Regulation, we consider that the hazard statement H400 should be removed since</p>	<p>The support is noted.</p> <p>The support is noted.</p> <p>We agree that the H410 labelling is sufficient and have removed the proposal of the H400 label.</p>	<p>Noted</p> <p>Noted</p>

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON PITCH, COAL TAR, HIGH TEMP.

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		<p>the respective content is already included in the hazard statement H410.</p> <p>We also consider that, as a precautionary principle, a default M-factor of 1000 should be applied due to the high value of the estimated M-factor based on only 9.2% of known constituents.</p> <p>Additionally there seems to be a minor inconsistency with reference in point 7.6 of the proposal, page 89. The reference to “(see 4.1.3.5.2 in Annex I of Regulation (EC) 1272/2008)” should be replaced by “(see 4.2.3.5.2 in Annex I of Regulation (EC) 1272/2008.</p>	<p>Considering that we assume that all PAHs will be available and exert adverse effects we assume that the precautionary principle is sufficiently considered. In addition, as indicated in paragraph 7.6 we believe that the summation method is preferred. Considering the variability of CTPHT this method is more flexible to calculate the hazard of different batches (if necessary).</p> <p>We agree and have adapted the text.</p>	<p>This issue was discussed during RAC-17. The agreement was to propose default M-factors of 1000 for both categories Aquatic Acute and Aquatic Chronic, based on the typical composition of binder pitch. Manufacturers and users should be able to modify this M-factor if the composition of the substance is known..</p>

Attachments:

European Carbon and Graphite Association asbl: ECGA pp coal tar pitch public cons.doc

Coal Chemicals Sector Group (CCSG) representing European producers of chemicals derived from coal tar distillation: Submitted Comments on ECHA document on Coal Tar Pitch.doc