

Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at Community level of
pitch, coal tar, high temp. (CTPHT)

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

Adopted

21 November 2011

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**OPINION OF THE COMMITTEE FOR RISK ASSESSMENT
 ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND
 LABELLING AT COMMUNITY LEVEL**

In accordance with Article 37(4) of the Regulation (EC) No 1272/2008 (CLP Regulation), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name: *pitch, coal tar, high temp. (CTPHT)*

EC Number: *266-028-2*

CAS Number: *65996-93-2*

The proposal was submitted by *the Netherlands* and received by RAC on *01 October 2010*.

The proposed harmonised classification

	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC
Current entry in Annex VI CLP Regulation	Carc. 1B; H350; Note H	Carc. Cat. 2; R45, Note H
Current proposal for consideration by RAC	Carc. 1A; H350 Muta. 1B; H340 Repr. 1B; H360FD Aquatic Acute 1; H400 Aquatic Chronic 1; H410	Carc. Cat. 1, R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 N; R50/53
Resulting harmonised classification (future entry in Annex VI of CLP Regulation)	Carc. 1A; H350 Muta. 1B; H340 Repr. 1B; H360FD Aquatic Acute 1; H400 Aquatic Chronic 1; H410	Carc. Cat. 1, R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 N; R50/53

PROCESS FOR ADOPTION OF THE OPINION

The Netherlands has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at http://echa.europa.eu/consultations/harmonised_cl/harmon_cl_prev_cons_en.asp on *01 October 2010*. Parties concerned and MSCAs were invited to submit comments and contributions by *15 November 2010*.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: *Helmut Greim*

Co-rapporteur, appointed by RAC: *Jose Luis Tadeo*

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37(4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on **21 November 2011**, in accordance with Article 37(4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

The RAC Opinion was adopted by *consensus*.

OPINION OF RAC

The RAC adopted the opinion that CTPHT should be classified and labelled as follows:

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific 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)		
648-055-00-5	Pitch, coal tar, high temp. (CTPHT)	266-028-2	65996-93-2	Carc. 1A Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H360FD H400 H410	GHS08 GHS09 Dgr	H350 H340 H360FD H410		# Acute M=1000 # Chronic M=1000	

[#]This substance is an UVCB (Unknown or Variable composition, Complex reaction products or Biological materials), and the M-factor is based on the typical composition of the substance. It is possible to adjust the M-factor if the exact composition of the UVCB is known

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	No tes
648-055-00-5	Pitch, coal tar, high temp. (CTPHT)	266-028-2	65996-93-2	Carc. Cat. 1; R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 N; R50/53	T; N R45-46-60-61-50/53 S45-53-60/61	^{##} N; R50/53: Cn ≥ 0.025 % ^{##} N; R51/53: 0.0025 % ≤ Cn < 0.025 ^{##} R52/53: 0.00025 % ≤ Cn < 0.0025 %	

^{##}This substance is an UVCB (Unknown or Variable composition, Complex reaction products or Biological materials), and the specific concentration limits are based on the typical composition of the substance. It is possible to adjust the specific concentration limits if the exact composition of the UVCB is known.

SCIENTIFIC GROUNDS FOR THE OPINION

Substance for which a harmonised health classification and labelling has previously been agreed at TC C&L

The classification of CTPHT for human health endpoints has been agreed in October 2006. The TC C&L agreed to the following classification proposal: Carc. Cat. 1; R45, Muta. Cat. 2; R46, Repr. Cat. 2; R60/61 - Xi; R41 – R43, further Note H should be deleted. The labelling would be: Symbol: T; R-phrases: 45–46–60–61–41–43 and S-phrases: 53–45. No new data were added since the discussion by the TC C&L, including during the public consultation period.

The opinion relates only to those hazard classes that have been reviewed in the proposal for harmonised classification and labelling, as submitted by *the Netherlands*. RAC notes that the C&L does not apply to bitumen, which in contrast to coal tar pitch is manufactured from crude oil.

Carcinogenicity

Based on experimental and epidemiological data on the carcinogenicity of CTPHT and CTPVsHT (coal tar pitch volatiles, high temperature) and the evaluation of these data by the IARC, classification of CTPHT and CTPVsHT as a category 1A carcinogen (H350) is proposed according to the CLP Regulation and as a category 1 carcinogen (T; R45) is proposed according to Directive 67/548/EEC.

Studies in animals reveal that inhalation of CTPHT caused lung tumours in rats and mice, while dermal exposure to CTPHT caused skin tumours in mice. Although the available experimental animal studies were not conducted according to EU or OECD guidelines, they clearly indicate that CTPHT is carcinogenic following inhalation and dermal exposure. This is further supported by oral studies with coal tar in mice, which resulted in increased tumour incidences in liver, lung, and forestomach. Oral studies with benzo[a]pyrene, a constituent of CTPHT, resulted in increased tumour incidences in, among others, the liver, forestomach, and epidermal structures in rats and the forestomach and the upper digestive tract in mice.

With respect to human data RAC concludes, that the accumulated evidence from workers exposed to CTPHT and workplaces with PAH, esp. benzo[a]pyrene exposures justify the proposed classification as Carc. 1A. Statistically non-significant increased lung cancer risks were observed in the three available cohort studies on coal tar distillation. In two of these three studies non-significant increased bladder cancer risks were observed. None of the studies contained data on exposure and one of the studies was not solely related to tar distillation but also to asphalt and roof felt processing.

Among aluminium production workers the lung and bladder have been the most common sites for excess cancer. In several studies excess risks of stomach, kidney, prostate, pancreas, lymphatic and haemopoietic cancer and leukaemia were also noted.

In one of the studies on the use of CTPHT as a binder and impregnation of electrodes, a statistically significant increased lung cancer risk was observed. In the other studies non-significant increases in lung and bladder cancer risks were observed.

Among roofers and asphalt workers excess lung and skin cancer risks were observed although the data were insufficient to specifically address the carcinogenicity of the different exposures, including coal tar derived exposures.

The meta-analysis of Armstrong *et al* (2003; 2004) on lung and bladder cancer risk after exposure to PAHs further adds to the evidence of human carcinogenicity.

Mutagenicity

Numerous genotoxicity studies with coal tar, coal tar waste, coal tar products, and individual PAHs (including benzo[a]pyrene) demonstrate the genotoxicity of these substances. Results on genotoxic endpoints in human blood cells after occupational exposure to CTP(V) (Coal tar pitch volatiles) are inconsistent except in heavily PAH-exposed people, where increased DNA-adduct levels have been reported. Since DNA adducts are marker of exposure and only indicate genotoxicity category 1A classification is not warranted. Therefore, and since the amount of category 1B mutagenic PAHs in CTPHT is estimated to be more than 0.1% (on a weight/weight basis) in almost all these products, classification of CTPHT as a category 1B mutagen is proposed (H340) according to the CLP Regulation (EC) 1272/2008 and as a category 2 mutagen is proposed (T; R46) according to Directive 67/548/EEC. RAC agrees with this proposal.

Reproductive Toxicity

No valid experimental animal studies are available which addressed the potential reproduction toxicity of CTPHT. However, high-boiling coal liquid had effects on fertility in a repeated dose inhalation toxicity study (13 weeks): statistically significant increased testis weights were observed in rats from a concentration of 140 mg/m³ (NOAEC 30 mg/m³). At the highest tested concentration (690 mg/m³) also decreased ovary weights and loss of luteal tissue were observed.

Coal tar derived products and coal tar creosote had no effects on fertility in mouse studies (with NOAELs of 344 mg/kg_{bw}/day and 100 mg/kg, respectively). In a multigeneration study creosote had effects on fertility in rats (at a dose level of 25 mg/kg_{bw}/day) below maternal toxic doses (75 mg/kg_{bw}/day) (Springer *et al*, 1982; Hackett *et al*, 1984; Springer *et al*, 1986b; Springer *et al*, 1987; Zangar *et al*, 1989; CCE, 2004). These data are seen insufficient for classification. As supporting argument for classification the Netherlands refer to the CLP Regulation, which recommends to classify as toxic for reproduction those substances containing more than 0.3% of a substance (impurity) being classified as toxic for reproduction in category 1B. Since CTPHT may contain up to 1.5% benzo[a]pyrene, which is classified as toxic for reproduction (Repr.1B, H360FD) it is proposed to classify CTPHT as toxic to reproduction (Repr.1B, H360FD) according to the CLP Regulation and as category 2 reprotoxic (T, R60/61), according to Directive 67/548/EEC.

As there are no sufficiently valid experimental or epidemiological studies available which address the potential reproduction toxicity of CTPHT itself, RAC agrees to the proposed classification (Repr.1B, H360FD) according to the CLP Regulation, and as category 2 reprotoxic (T, R60/61), according to Directive 67/548/EEC, based on benzo[a]pyrene content.

Respiratory Sensitisation

Not applicable

Environmental Hazards

CTPHT is a UVCB substance (Unknown or Variable composition, Complex reaction products or Biological materials) and very difficult to classify on the basis of its individual

components. In addition, not all the components can be analyzed when diluted in water. Furthermore, the different CTPHT components influence each other's solubility in the water phase and consequently the composition in water will not be the same at different loadings. The water-accommodated fraction (WAF) approach is considered most appropriate to classify CTPHT, as recommended for oil products and products such as creosote in the OECD *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures* (OECD, 2000).

Nevertheless, all the toxicity data for CTPHT from the WAF studies are obtained in the absence of UV irradiation. Several PAHs are known to be phototoxic and also having the lowest EC₅₀ values in the presence of UV irradiation in comparison to other non-phototoxic PAHs. In addition, only analytical data at a loading of 100 mg/L are available from the chronic *Daphnia* study after a 48 hours period of extraction. In absence of data at different loadings, it is not possible to make a comparison between the dissolved PAH concentrations at different loadings and the toxicity data obtained for the individual PAHs.

Therefore, an alternative approach for the environmental classification of CTPHT was taken, considering CTPHT as a 'mixture'. For the classification of mixtures two approaches are described in the CLP Regulation, a classification based on summation of classified components and one based on toxicity test data. For CTPHT the classification based on summation is preferred, because apart from toxicity test data, this method also takes into account the persistence and bioaccumulation potential of the mixture.

The 16 individual EPA-PAHs were analysed with respect to their acute aquatic effects data and the lowest available EC₅₀ or LC₅₀ was chosen as a point of departure for acute aquatic hazard classification. These lowest acute toxicity data were combined with degradability and bioaccumulation data to come to a classification for each individual PAH. Due to the entry into force of the 2nd ATP of CLP (Commission Regulation (EU) 286/2011), amending the CLP Regulation, the classification for the long-term aquatic hazards are based on chronic toxicity data when available, basing either on NOEC or EC₁₀ values.

For thirteen of the 16 EPA-PAHs the classification is N;R50/53 and Aquatic Acute 1; Aquatic Chronic 1, for one PAH (*i.e.* acenaphthylene) this classification is N;R51/53 and Aquatic Chronic 1, for one PAH this classification is N;R50/53 and Aquatic Chronic 1 (*i.e.* benzo[ghi]perylene); and for one PAHs the conclusion is 'not classified' due to non-occurrence of effects up to the limit of water solubility (*i.e.* benzo[b]fluoranthene).

Since all the PAHs to which an M-factor could be assigned are classified as Aquatic Acute 1, all their contributions were summed to come to an overall contribution (in %) to the toxicity of CTPHT, *i.e.* 14521%. Since this value is (far) above the 25% limit from Regulation (EC) 1272/2008, it is proposed to classify CTPHT as Aquatic Acute 1; according to CLP Regulation.

The classification for long-term aquatic environmental hazards depends on the amount of data available. Following this decision scheme, all individual PAHs are classified as Category Aquatic Chronic 1 (H410), with the exception of benzo[b]fluoranthene. Due to the absence of (reliable) chronic toxicity data for chrysene, the classification for chrysene is based on acute data (as described in section 4.1.2 of CLP). Based on these toxicity data and a typical content of the different PAHs, CPTHT should be classified as Category Aquatic Chronic 1 (H410), regardless of the species group considered (total percentages are all > 25%).

In Directive 1999/45/EC (EU, 1999) the summation method is based on specific concentration limits instead of M-factors. Since all the PAHs to which concentration limits

could be assigned are classified as N; R50/53 substances, all their contributions were summed to come to an overall contribution (in %) to the toxicity of CTPHT, *i.e.* 581%. Since this value is (far) above the 25% limit from Directive 1999/45/EC, it is proposed to classify CTPHT as a N; R50/53 substance according to this Directive (and Table 3.2 of Annex VI of Regulation (EC) 1272/2008).

The estimation of percentages of PAHs in CTPHT is made using the composition of binder pitch, as it is the main source for the production of anodes and electrodes.

M-factors and specific concentration limits for environmental classification

Although acute and chronic M-factors were derived for the typical composition of CTPHT, the classification proposed in the CLH report does not include any M-factor or specific concentration limits (SCLs) for this substance. Instead, the approach of the dossier submitter is to classify CTPHT-containing mixtures by the summation method by using the classification of the individual toxic components (*i.e.* the PAHs in CTPHT) to fix them case by case based on the composition of each individual batch of CTPHT used in a mixture.

However, the M-factor is in principle a legal requirement for substances classified Aquatic Acute 1 and/or Aquatic Chronic 1. Therefore, RAC agreed to suggest harmonised M-factors of 1000 for both categories Aquatic Acute and Aquatic Chronic, based on acute and chronic toxicity data of individual PAHs and the typical PAH composition of binder pitch. Similarly, R50/53 classification was defined and the SCLs were calculated by using acute toxicity data of individual PAHs (*i.e.* the calculated acute toxicity was in the range of $0.0001 < L(E)C_{50} \leq 0.001$ and set the SCLs as given in the table). Manufacturers and users should be able to modify the set M-factors and SCLs if the composition of the substance is known. Thus, RAC proposes the inclusion of a Note in the entry for CTPHT in Table 3.1 of Annex VI of CLP.

As a tentative text for the note, RAC suggested the following for M-factors:

“This substance is an UVCB (Unknown or Variable composition, Complex reaction products or Biological materials), and the M-factor is based on the typical composition of the substance. It is possible to adjust the M-factor if the exact composition of the UVCB is known.”

Similarly, the following tentative text for the SCLs is suggested by RAC:

“This substance is an UVCB (Unknown or Variable composition, Complex reaction products or Biological materials), and the specific concentrations limits are based on the typical composition of the substance. It is possible to adjust the specific concentration limits if the exact composition of the UVCB is known.”

Additional information

During the discussions on CTPHT at RAC, CCSG, representing European CTPHT producers, submitted the document 110627, pointing out some discrepancies with the environmental classification proposed in the first draft opinion.

The information provided in this document is basically the same as the one presented during the commenting round, which was already responded to by the dossier submitter in Annex 2 the RCOM.

Thus, this document does not change the RAC opinion for this classification. RAC supports the response given by the dossier submitter and the proposal of considering CTPHT as a “mixture” for classification purposes.

The Background Document, attached as Annex 1, gives the detailed scientific grounds for the Opinion.

ANNEXES:

Annex 1 Background Document (BD)¹

Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and rapporteurs’ comments (excl. confidential information)

¹ The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter. The original CLH report was changed as a result of the comments and contributions received during the public consultation(s) and the comments by and discussions in the Committees.