EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Coal tar pitch, high temperature

Human Health Part

CAS No: 65996-93-2

EINECS No: 266-028-2

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCHER adopted this opinion at its 22nd plenary on 12 March 2008

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

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SCHER

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Reports the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Reports?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1. General comments

The document is of good quality. The RAR follows the TGD as has been feasible.

Coal tar pitch, high temperature (CTP(ht)) is the solid fraction produced during the distillation of coal tars. It is produced by ten companies at eleven sites in nine countries in EU, 817 800 tonnes in 2004. CTP(ht) is a complex hydrocarbon mixture consisting thousands of compounds, mainly (90%) of three- to seven-membered polycyclic aromatic hydrocarbons (PAHs) and their (poly)methylated derivatives and in minor amounts phenolic compounds and nitrogen bases. Because the composition of the coal tar pitch depends on the distillation temperature and the nature of the coal used, no two coal tar pitches, and the PAH patterns of emissions are identical.

The RAR concerns specifically the coal tar pitch, high temperature with the CAS number 65996-93-2.

Few effect data has existed specifically on CTP(ht) and the associated coal tar pitch volatiles (CTPV). The risk assessment is largely based on data on PAHs, especially on benzo(a)pyrene (B(a)P), in coal tar, creosote and other related products. Because the composition of CTP(ht) is variable and no single representative composition/data exist, this is an acceptable approach. PAHs are the most relevant components in terms of toxicity, there are most data on B(a)P and it serves as a relevant indicator (in addition to references in the RAR, Spinelli et al., 2006, Friesen et al., 2008).

As to details of the RAR, in the tables of the exposure assessment section (4.1.1) the "N" should be defined. In a summary table of exposure (Table 4.16) the figures for "production" and "cleaning" have been mixed up for the use scenario 7 (Binder in coal briquetting) and the value for skin exposure in scenario 8 (Binder for clay pigeon) is modelled. In the summary table on occupational exposure (Table 4.16) it should be indicated that the exposure figures are for (B(a)P).

3.2. Specific comments

3.2.1. Exposure assessment

When coal tar pitch is heated, coal tar pitch volatiles (CTPV) are released most of them being PAHs. Large molecule PAHs are known to bind to particles and exposure occurs

also in particles. As to individual PAHs, only concentration data on (B(a)P) has been given, to be usually between 0.1 % and 1.5 % in CTP(ht).

Only inhalation and dermal exposure are assessed, in occupational use of CTP(ht). No data exist on consumer exposure but the exposure has been considered insignificant. Therefore, risk assessment has not been done for consumers. SCHER agrees with these decisions. Human exposure via environment has been suggested in the RA to occur only occasionally (e.g. road roofing). However, no information on the fate of CTPV in the environment in local industrial scenarios is given. Possible human exposure via environment in industrial scenarios should also be evaluated.

Coal tar pitch, high temperature is mainly used (90 % of total sales) as a binding agent in the production of carbon electrodes for metal industry (especially anodes for aluminium and other metal production). Refractories, clay pigeons, active carbon, coal briquetting, road construction and roofing represent minor use. In several EU countries the use of coal tar pitch has already been limited due to their PAH content but the use for electrode production is predicted to continue.

Eight use scenarios are created for occupational exposure assessment. They cover the main use categories. Both published and industrial exposure data were used. In general, measured data (of B(a)P) was used for inhalation exposure assessment. In the absence of measured data, the concentration of 1 % in CTP(ht) was used for B(a)P as a RWC.

For the most common exposure scenarios (production of coal tar pitch, binder for electronics) the typical, full-shift inhalation exposure levels of B(a)P were below 2.6 $\mu g/m^3$. The RWC levels, full-shift have been below 7.5 $\mu g/m^3$. For other scenarios the RWCs have been higher (about 10-fold).

In the absence of relevant measured data, dermal exposure levels were modelled by EASE. The few measured data available suggest that the modelled skin exposure data is in the same range. High dermal exposure of B(a)P (100 mg/day, RWC) was modelled for the use of CTP(ht) as a binder in asphalt work (road construction, roofing) but in other industrial environments the exposure was assessed notably lower (0.4-0.6 mg/day).

Altogether, the exposure assessment part describes in detail exposure patterns, addresses relevance of the data and is transparent. For some scenarios the data was only from one place but the data was considered representative. It comes out from the RAR that several industrial processes are under development to reduce CTP(ht)/PAH emissions or the use of CTP(ht) is phasing out which may decrease the exposure in the future.

3.2.2. Effect assessment

There are few specific data on CTP(ht) and data related to coal tar, different products and PAHs in general are described and used to a large extent. Only few experimental studies comply with the testing guidelines. However, the image created very likely reflects the toxicity qualitatively.

There are no ADME data specifically on (CTP(ht). Dermal absorption 30 % was considered as a worst case estimate on the basis of information on a PAH mixture and a conservative default value 100 % for absorption via inhalation. The final RA is based on risk of cancer and is not dependent on the selected values.

Acute oral and dermal toxicity of CTP(ht) in animals are low. Occupational exposure has caused different skin effects (pitch warts, acne etc.) and cutaneous photosensitivity and even severe eye irritation and effects which are aggravated by sunlight. Eye irritation has been confirmed in animals. No proper data exist on skin sensitisation of CTP(ht) but B(a)P is a known skin sensitizer.

Evaluation of repeated dose toxicity is limited to histopathological changes in carcinogenicity studies made with coal tar derived products. Data in previous reviews have also been addressed. Single PAHs have different primary target organs of toxicity

the liver being typically affected. NOAEL for repeated dose toxicity of CTP(ht) can not be drawn from those studies and was not attempted. No relevant human data was available related to repeated dose toxicity.

CTP and its extracts and other tar products have been mutagenic in bacterial tests in the presence of S9 mix but negative in its absence and most in vitro tests in mammalian cells have been positive. No relevant animal (in vivo) data exist on genotoxicity. In some occupational exposure situations, relevant for the RA, PAH-DNA adducts in blood cells have been demonstrated. The overall conclusion is that CTP(ht) should be regarded genotoxic. SCHER agrees with the conclusion. Genotoxicity supports cancer risk as an endpoint for RA.

CTP(ht) has been definitively carcinogenic in rats and mice causing lung tumours after inhalation exposure. CTP and CTP(ht) have been carcinogenic after dermal application in mice (and also after peroral administration in animals but that route is not relevant in the evaluation). The IARC has concluded already in 1985 that coal tar pitches are carcinogenic in humans. Association of lung cancer with CTP(ht) has been demonstrated in all main use and exposure categories of the RA and is stronger than for bladder cancer.

In the absence of valid studies with CTP(ht), data on reproduction toxicity of high-boiling coal liquid, coal tar derived products and creosote in animals have been summarized. All of them have produced reproduction toxicity by inhalation, oral and dermal routes. In general, the NOAELs have been above 25 mg/kg/day (by inhalation 80 mg/m^3). Developmentally toxic doses have been already on the border of maternal toxicity. As a single agent, B(a)P has adverse effects on female fertility and reproduction and cause developmental toxicity in animals. Valid data on humans for the evaluation of reproduction toxicity were not available. No quantitative evaluation of the risk could be performed.

3.2.3. Risk characterisation

The RAR clearly states that the database on possible health hazards induced by CTP(ht) is too limited to allow full risk assessment for all required endpoints. On the basis of the overall evidence, cancer risk was selected as the most serious end point for risk characterisation. Because CTP(ht) contains PAHs with high carcinogenic potency, limitation of the risks for cancer will automatically reduce risk for other possible effects. SCHER agrees with the decision and the concept.

Lung and bladder cancer risks were calculated for workers in all exposure scenarios, with risk factors of B(a)P derived from the meta-analysis of 39 occupational cohorts for lung cancer and 27 cohorts for bladder cancer. It was assumed that such summary evaluation describes best the overall risk of highly variable exposure for composition. The calculated excess lifetime risks at the RWC exposure levels vary in the order 10^{-1}-10^{-3} for lung cancer in the use scenarios and 10^{-2}-10^{-4} for bladder cancer, respectively. At "typical" (ordinary) exposure levels the cancer risk was at the same or an order lower. The calculated risks are high.

Because no NOAEL could be drawn for non-carcinogenic effects after repeated dosing, quantitative risk assessment on those effects could not be done.

CTP(ht) is classified in the RAR eye irritant ("irritant with risk of serious damage to eyes" proposed) and skin sensitizer. SCHER supports these proposals.

SCHER agrees with conclusion (iii) for skin sensitisation, mutagenicity and carcinogenicity in occupational use. SCHER also agrees with conclusion (ii) for acute toxicity, eye irritation, and corrosivity.

Conclusion (i) is proposed for skin irritation, systemic toxicity after repeated exposure, and effects on reproduction but put "on hold" to revisit the need after risk reduction strategy. Regulation of the cancer risk is considered to reduce these other risks. SCHER

supports the proposal. Further testing of the mixtures would not facilitate the RA but the RA is better to base on relevant data by read across-principle (as has been done).

Because there is no consumer exposure and human exposure via environment was considered insignificant, no risk was characterised. However, human exposure and risks via environment from local industrial sources should also be evaluated. The RAR should be completed for these parts.

4. LIST OF ABBREVIATIONS

ADME	absorption, distribution, metabolism, and excretion
B(a)P	Benzo(a)pyrene
CTP(ht)	Coal pitch tar, high temperature
CTPV	Coal Tar Pitch Volatiles
EASE	Estimation and Assessment of Substance Exposure
NOAEL	No Observed Adverse Effect Level
PAH	Polycyclic Aromatic Hydrocarbon
RAR	Risk assessment report
RWC	Reasonable Worst Case

5. REFERENCES

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