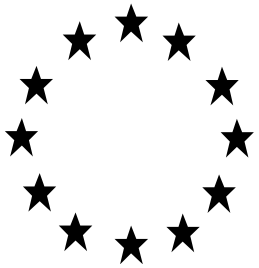
Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Creosote

Product-type 8
(Wood preservatives)

December 2010

Annex I - Sweden

Creosote (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 17.12.2010 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of creosote as product-type 8 (wood preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Creosote (CAS no. 8001-58-9) was notified as an existing active substance, by Creosote Council Europe, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 2032/2003of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) of that Regulation, Sweden was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for creosote as an active substance in Product Type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 28 March 2004, Swedish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 7 December 2004.

On 31 October 2007, the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 8 November 2007. The competent authority report included information that inclusion or non-inclusion of creosote in Annex 1 to the Directive for product-type 8 could not be recommended at that time.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 21 November 2007. This

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1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 2032/2003of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of creosote in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 17.12.2010.

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 17.12.2010.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include creosote in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain creosote. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing creosote for the product-type 8, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

3 http://ec.europa.eu/comm/environment/biocides/index htm

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Creosote [CAS No. 8001-58-9], a brownish-black oily liquid, used as wood preservative, is a distillation product of coal tars which themselves are by-products of the high-temperature destructive distillation of bituminous coal to form coke.

The distillation process generally produces several oil cuts starting from 80°C to 450°C. Creosote is the intermediate cut, ranging from 200 to 355°C as described in the European Standard EN 13991.

The common product is called Grade B and is intended for treatment of timber by vacuum-pressure impregnation. Grade C excludes the lower boiling fraction allowable in Grade B, and because of the lower volatility a reduction in odour is achieved. Furthermore the term creosote Grade B composite is used throughout the dossier/report and it is a mixture of single Grade B creosote batches produced by the European producers and mixed at equal parts in order to achieve an average representative Grade B creosote. It also served in more recent testing to cover some data gaps (e.g. the algae test, mouse lymphoma test).

Creosote is a complex mixture of hundreds of distinct compounds, including bi- and polycyclic aromatic hydrocarbons, phenols, as well as heterocyclic, oxygen-, sulphur- and nitrogen-containing compounds. The chemical composition is influenced by the origin of coal and also by the nature of the distillation process, and as a result, the composition of different batches may vary to a great extent. 106 compounds have been analysed for in the creosotes applied for.

Active substance/product properties

Some of the physical and chemical properties are claimed to have been tested in internal studies of the creosote manufacturers and these parameters were only addressed in Document III-AB (i.e. no study reports were provided in Document IV) of the competent authority report (CAR). This has been considered acceptable as the results are reasonable and in some cases also supported by results on other/undefined types of creosote. The parameters for which no study summaries were provided are summarised in the first section below.

Parameters only addressed in Document III-AB

The two grades of creosote under evaluation (i.e. Grade B and Grade C) are brown liquids with an aromatic odour. Creosote is considered soluble in benzene, toluene, acetone and quinoline. Creosote is not considered auto-flammable, highly flammable or to possess oxidizing properties. It is claimed not to be explosive but it is also stated that the vapours of creosote may produce explosive mixtures with air. It is considered thermally stable, stable upon storage and not reactive towards any container material. The viscosity is claimed to be <25 mm^2/s for both grades and is probably also within the range 13-16 mm^2/s (i.e. experimentally determined for US-type creosote). The great majority of the components of creosote are not able to dissociate and creosote is thus not considered to be significantly affected by pH.

Parameters for which study-reports were provided

A study was provided to show that the evaluated batches of Grade B, Grade B composite and Grade C comply with the specification requirements according to European Standard EN 13991:2003. The batches tested, all passed the criteria as shown in the table below:

Criteria according to EN 13391:2003				Results according to RÜTGERS 2008b		
Parameters	**Unit**	**Grade B**	**Grade C**	**Grade B composite batch ATE 8300**	**Grade B batch ATE 8515**	**Grade C batch ATE 8470**
Density (20°C) (DIN 51 757)	g/ml	1.02-1.15	1.03-1.17	1.057	1.082	1.101
Water content (DIN 51777)	%	max. 1	max. 1	0.2	0.14	0.18
Crystallization temperature (EN 13991)	°C	max. 23	max. 50	-5	0	30
Water- extractable phenols (EN 1014-4)	%	max. 3	max. 3	2.8	1.3	1.2
Matter insoluble in toluene (BS 144-annex G)	%	max. 0.4	max. 0.4	0.02	0.01	0.01
Boiling range (EN 13991):						
Distillate to 235 °C	%	max. 20		7	0	0
Distillate to 300°C	%	40-60	max. 10	59	57	0
Distillate to 355°C	%	min. 70	min. 65	88	90	77
Benzo[a]pyrene (EN 1014-3)	ppm	max. 50	max. 50	20	10	<10
Flash point Pensky-Martens (EN 22719)	°C	min. 61	min. 61	87	120	>120

The vapour pressure of the creosotes applied for is extrapolated to be 0.7 Pa and 0.5 Pa at 25°C for Grade B and Grade C respectively. Vapour pressure data for several of the components of creosote is also available from the open literature. Henry‟s law constant is not considered relevant for the creosote mixtures but individual figures for several of the components are available from the open literature. The water solubility expressed as TOC (total organic carbon) was found to be dependent on the initial creosote loading and was determined as 2.2-8.1 mg/l for all grades at a loading of 100 mg/l. At a loading of 10 g/l the TOC was ~30 mg/l for Grade B and Grade C and 191 mg/l for Grade B composite. The difference is probably due to the larger fraction of low molecular components in Grade B composite. Moreover, water solubility data is also available from the open literature for several of the components.

Log P_{ow} was determined for US-types P1/13 and P2 creosote and the results are considered valid also for the EU-creosote under evaluation. The result was shown to be dependent on the octanol concentration with increasing log P_{ow} with decreased octanol:water ratios. The log P_{ow} was found to be in the range 2.7-3.7 for the tested creosotes. However, due to uncertainties in the validity of the experimentally derived log P_{ow}, it has not been used in the evaluation of fate and behaviour (see section 2.2.2.1 further below).

Analysis of the active substance as manufactured

The method provided for characterisation of the creosote under evaluation is based on GC-FID and it was able to determine 65%, 63% and 57% (w/w) of the total content in the Grade B-composite, Grade B and Grade C respectively.

No validation data was provided for the method except for some linearity data. However, due to the complex nature of creosote and as it falls under the definition of substances of unknown or variable composition, complex reaction products or biological materials (i.e. a UVCB-substance) according to the REACH Implementation Project (RIP) 3.10 no further validation data is considered required.

Nevertheless, provided characterisation data on the US-types P1/13 and P2 creosote indicates higher analytical closures. However during the peer-review it was decided that it is not considered justified requiring further data as it is not anticipated to significantly improve the characterisation of the creosote under evaluation.

Formulation analysis

See above. The active substance and the product are the same.

Residue analysis

Numerous methods were provided for the analysis of components of creosote in different compartments, mostly from the open literature.

Soil and sediment

For soil the applicant stated that the provided US-EPA standard for extraction of PAHs, phenols and heterocycles could be used in connection with any of the methods used for characterisation of creosote. However, the RMS considers that some validation data is required in support of this statement and therefore proposes that this should be set as a data requirement.

A method based on GC-MS from the open literature was submitted to address the analysis of 24 PAHs in sediment. However the study is only considered acceptable as supplementary information as the reporting and the validation data is insufficient.

Air

Several methods were provided for the analysis of PAHs in air, which are considered to be the most relevant components of creosote to be monitored in air. The method considered most suitable for monitoring in air is based on GC-FID and has been sufficiently validated.

Water

Two acceptable standard methods based on HPLC-FD and GC-FID were provided for the analysis of PAHs in drinking and surface water.

Moreover, a GC-FID method for water using the same principles as in the characterisation of the creosote under evaluation was provided. This method was able to also quantify the polar components of creosote, which is considered required as these substances are more likely to end up in the water compartment. No sufficient validation data was provided. However, the data derived by the method was in good agreement with the results obtained in a study by an independent laboratory using the same method.

Animal and human body fluids and tissues

An acceptable method based on GC-FID/MS for the analysis of three PAHs (phenanthrene, pyrene and chrysene) and the corresponding OH-metabolites in faeces and urine was provided. No sufficient validation data was provided in the studies used to address the analysis of blood and tissues. However

the presence of PAHs and corresponding OH-metabolites in urine and faeces is widely used as an indicator of creosote exposure and no further data is therefore considered required.

Food and feeding stuffs

No method is considered required due to the use pattern of creosote where food and feed items are not likely to be contaminated.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s)

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Since the active substance and the biocidal product are identical they have the same classification and labelling requirements.

The current harmonised classification and labelling for creosote according to Annex VI to Regulation (EC) 1272/2008 applies only to the dangerous property shown, as indicated by Note H.

Classification in Annex VI, Table 3.2 (in accordance with the criteria in Directive 67/548/EEC)

Carc. Cat. 2; R45 May cause cancer

Labelling in Annex VI, Table 3.2

T

R: 45

S: 53-45

Additional classification provisionally by the manufacturer

Xi, R36/38	Irritating to eyes and skin
N, R51-53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Additional labelling

N

R: 36/38

S: 60-61

Additional classification proposed by RMS

R38	Irritating to skin
R43	May cause sensitization by skin contact
Repr. Cat. 2; R60	May impair fertility
Repr. Cat. 3; R63	Possible risk of harm to the unborn child
N, R50-53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
SCLs	N; R50-53: C ≥ 2.5 %
	N; R51-53: 0.25 % ≤ C < 2.5 %
	R52-53: 0.025 % ≤ C < 0.25 %

No additional labelling.

N

R: 60-38-43-63

Classification in Annex VI, Table 3.1 (in accordance with the criteria in Regulation (EC) 1272/2008)

Carc. 1B; H350 May cause cancer

Labelling

GHS08

Dgr

H350

Additional classification in accordance to the criteria in Regulation (EC) 1272/2008

Repr. 1B; H360F	May damage fertility
Repr. 2; H361d	Suspected of damaging the unborn child
Skin Irrit. 2; H315	Causes skin irritation
Skin Sens. 1; H317	May cause an allergic skin reaction
Aquatic acute 1; H400	Very toxic to aquatic life
Aquatic Chronic 1; H410	Very toxic to aquatic life with long lasting effects

M=10

Additional labelling

GHS07, GHS09

H360F, H361d, H317, H315, H410

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effects assessment

Toxicokinetics and metabolism

Creosote is a complex mixture and is composed of several hundreds and probably several thousands different compounds. Standard toxicokinetic studies according to guidelines are therefore not possible to perform. The submitted database consisted of published literature describing some parts of Absorption, Distribution, Metabolism and Excretion (ADME) of some of the key components of creosote. Great caution has to be taken when interpreting the ADME results obtained with individual components of creosote. The ADME of a complex mixture like creosote can be vastly different even with respect to the single components themselves.

The absorption from the gastrointestinal tract was relatively rapid following oral administration of phenanthrene and pyrene in the rat and was estimated to be higher than 90% based on the presence of the mother compound in the faeces. The oral route is, however, of minor importance in human exposure. Dermal exposure has been shown to account for about 90% of human exposure, and inhalation exposure accounts for the remaining part. Dermal absorption of creosote is, however, extremely difficult to assess depending on a large number of variables. Please see Doc II-B, section 9.1, for a discussion on this matter.

Information regarding distribution of creosote into tissues is scarce. Results regarding the persistence of creosote in the body over a long period are inconclusive. The total recovery of the mother compounds and their metabolites were in some studies very low. For phenanthrene only about 10% was excreted following oral administration and for pyrene only about 50% of pyrene and its metabolites that were analysable with the technique used in the study, were excreted. Either this depends on, as the applicant suggests, that different species of metabolites are formed and excreted, but they are not analysable by the experimental conditions used. Alternatively, substantial parts of phenanthrene and pyrene, and metabolites of the respective compounds, are retained and possibly accumulated in the body. A combination of these two scenarios is also possible. In contrast, other studies show almost complete elimination of benzo(a)pyrene following dermal administration. Only about 0.5% was retained in the body after 7 days. Generally, metabolites of 2-3 ring aromatic compounds are mainly excreted into urine or to similar extent into urine and faeces, while metabolites of 4–6 ringed PAH are mainly excreted into the faeces.

Aromatic compounds are metabolized by microsomal oxidative enzyme systems in a first step, in particular by the cytochromes P450 system (CYP1A1, CYP2E1 and CYP3A) in liver, lungs and other tissues. Thereby, the PAHs form reactive intermediates (epoxides) that can bind to macromolecules and cause specific toxic effects. Generally, the epoxides are hydrolysed, thereby forming hydroxy-/dihydroxy compounds or are directly conjugated with glutathione. Dihydrodiols may undergo conjugation with glucuronic acid or sulphate. Hydroxylated species may be further oxidised and form quinones. Conjugates of phenols, dihydrodiols, quinones, and anhydrides have been the principal metabolic products identified. The metabolic profile varies with compound and species tested.

The primary metabolic reaction of acenaphthene starts with the oxidative cleavage of the 5-membered ring in acenaphthene in rat.

The metabolites following administration with phenanthrene were phenolic and dihydrodiol compounds. In vitro experiments show that a single metabolite, trans-9,10-diOH-9,10-dihydrophenanthrene (K-region oxidation), was formed by liver microsomes from non-induced rats while various inducers stimulated the formation of additional metabolites. Creosote contains several of these potential monooxygenase inducers. Observations by others show that also conjugation with glutathione, may occur to a high degree. Conjugation with methionine may also occur, resulting in methylthioesters. These types of metabolites escaped analysis under the experimental conditions employed in the investigations outlined above.

In the metabolism of fluoranthene mainly 3-dihydro-2,3-diOH-fluoranthene was formed but also 3-OH-fluoranthene, and 1-OH-fluoranthene were identified. The metabolism of fluoranthene in human and rat liver microsomes was qualitatively roughly similar, but the spectra of metabolites differed a lot. While the trans-2,3-dihydrodiol was the major metabolite in both the human and rat systems, many more metabolites were seen in the rat samples. Rat liver microsomes were also more proficient at metabolising fluoranthene. Variability was seen in the human samples, with respect to both the extent of metabolism and the metabolite spectra. This probably reflects interindividual differences. There were also differences between the human and rat systems in the formation of R,R enantiomers of the major metabolite, which may have an impact on the mutagenic potency. The main metabolite following administration of pyrene is 1-OH-pyrene.

Acute toxicity

Creosote has low acute toxicity when administered orally, dermally and via inhalation to rats.

Creosote is a skin irritant. Furthermore, creosote should, despite the negative results from the eye irritation study, on a precautionary basis, be considered to be potentially irritating to eyes, especially since practical experience with hot vapours of creosote has shown that it may display irritating properties to the eyes. However, the results of the eye irritation study does not warrant a classification with R36, “irritating to eyes”.

Creosote should be labelled with **Xi, R38 “Irritating to skin”.**

In the sensitisation studies creosote proved to be sensitising in the Maximisation test (M&K test), and considerations should therefore be taken if creosote should be labelled with **R43 “May cause skin sensitisation by skin contact”**.

Short-term toxicity

For repeated administration of creosote via the dermal and inhalational routes the studies did not reveal any evidence for cumulative toxicity in rats. Most of the changes observed in the dermal and inhalational studies were mild and did not persist after the recovery periods.

Genotoxicity

The mutagenic potency of creosote was studied *in vitro* in bacteria and mammalian cells and *in vivo* test systems in rats and mice. The results show that the creosote types tested were mutagenic in 2 out of 4 *in vitro* tests in the presence of a metabolising system (S9), while creosote was negative in the *in vivo* test systems with respect to genotoxicity. It has to be kept

in mind that there was significant cytotoxicity in most of the experiments. This can eventually mask a mutagenic potential of creosote in these assays.

Different creosote types have been shown to display large differences in genotoxic potency and the composition of creosote today has drastically reduced amounts of genotoxic components compared to former creosote types. However, the overall results from this evaluation regarding the genotoxic potency of the creosote types tested are inconclusive. Risk mitigation procedures are important since no threshold can be said to exist for substances containing genotoxic compounds.

The complex composition of creosote includes several mutagenic components, and the results in genotoxicity assays varies, depending on for example, cell type, concentration, metabolising capacity etc.

Long-term toxicity and carcinogenicity

One dermal carcinogenicity study was submitted. In addition of oncogenicity a limited number of other endpoints with respect to long-term toxicity were investigated. The results show that there was a dose-dependent increase in the number of tumours, and the tested creosote types produced 3-5 times more tumours than what could have been expected based on their BaP content. A threshold cannot be said to exist, and it is generally agreed that there is no threshold for genotoxic substances. Creosote is a complex mixture which contains several substances that are regarded as carcinogenic and mutagenic. A NOAEL could therefore not be set.

Creosote is classified as **Carc. Cat. 2, R45**.

Regarding other endpoints following long-term exposure, some parameters, in addition of carcinogenesis, were investigated. None of these gave rise to significant findings. Carcinogenesis can, however, be regarded as the most severe endpoint after long-term exposure.

Reproduction toxicity

In the teratology studies in rats there was an increase in post-implantation loss (early resorptions) in the high dose group. There was no difference in maternal body weight and body weight gain between the dose groups and the control when corrected for gravid uterine weight. It seems that creosote has an impact on early intrauterine development (seen as post-implantation loss) under very mild maternal toxicity.

In the developmental toxicity study performed in rabbits there was an increase in abortions and a reduction in the number of live foetuses in the high dose group. This can either be a result of maternal toxicity or reflect a reproductive/developmental toxicity effect of creosote.

All together these results indicate that creosote has an impact on early intrauterine development. It is unlikely that the increases of post-implantation losses are coupled to the decreased maternal food consumption, and there were virtually no other maternal toxic signs. Creosote should therefore be labelled with **R63 – "Possible risk of harm to the unborn child".**

In the two-generation reproduction study, a significant reduction in the number of live F1 offspring in the mid and high dose groups was observed. There was also a decrease in litter size and in offspring viability in F2, and this effect was even clearer than in F1. The body weight of live pups was decreased among all dose groups (on day 14 and 21 after birth) and showed a

clear dose response (less than 10 % in the low dose group). However, there was no difference in body weight on the day of birth.

Overall, the results of the reproduction studies indicate that creosote has an impact on reproduction and fertility under the influence of very mild maternal toxicity (maternal toxicity mainly seen as salivation and reduction of body weight and body weight gain (up to 20%) during gestation and lactation, and note, no corrections were made for gravid uterine weight). The decrease of maternal body weight gain during gestation may therefore be an effect of the decreased number of viable offspring.

It should therefore be considered if creosote should be labelled with **R60 "May impair fertility".**

Neurotoxicity

No specific data submitted. The results from the other studies do not indicate any neurotoxic potential of creosote.

Medical data

Creosote has been used for more than 100 years. Clinical findings thought to result from occupational exposure have mainly been restricted to the presence of various types of skin rashes, such as pustular folliculitis, tar warts, dermatitis, including phototoxic dermatitis after subsequent or simultaneous exposure to sunlight.

Epidemiologists have attempted to determine whether people who are occupationally exposed to creosote are at a greater risk than the general population for certain cancers. In a historical cross-sectional occupational survey, skin tumour incidences over 26 years amounted to 35 cases for which "creosote oil" was nominated as causal agent out of a total of 3753 skin cancer cases (about 1 %/26 years), notified by the "British Medical Inspector of Factories" in the first half of the 20th century. This low incidence has to be seen in relation to the less stringent working standards and application of creosotes with much higher PAH levels than today.

Studies conducted in Norway and Sweden and in the United States show conflicting results. Some studies point to a connection between creosote exposure and various forms of cancer and there are also a number of studies that fail to show such an association between occupational creosote exposure and any cancers. Simultaneous exposure to sunlight was a confounding factor.

The significance of the results of the epidemiological studies and exposure studies are difficult to interpret. Many of these studies are limited by their date and/or by uncertainty over the composition of the creosote in use at the time. The latter is a problem even for the more recent studies. Some of the studies were based on questionnaires on past occupational activities, giving rise to uncertainty about the reliability of the information gathered maybe several years after exposure occurred. Furthermore, the number of workers available for the studies were uncertain or few. The studies were also hampered by the lack of follow-up and control of confounders.

A recent cohort study which included creosote-exposed workers of 11 wood-treating plants in the USA from 01 Jan. 1979 through 31 Dec. 1999 failed to reveal any exposure-related mortality increases.

A large risk assessment was conducted for creosote pressure-treating workers using probabilistic distributional methods. This was not a single study, and it was based on reviews of animal data, case reports, cohort studies, case control studies, cross-sectional studies, and exposure studies. It included some of the studies mentioned above. The estimates of occupational cancer risk from creosote in this study gave the result that the largest part of the cancer risk distribution fell within acceptable risk levels (1×10^{-6} to 1×10^{-4}) traditionally employed for regulatory purposes by the US EPA. However a small part (95^{th} %-ile) (result of cancer potency factors: $1.5x10^{-4}$ with probabilistic analysis included, and $3.1x10^{-4}$ with probabilistic analysis excluded) actually falls above the acceptable risk (that is $1x10^{-4}$), giving a reason for concern.

Overall, the body of epidemiological data does not indicate an apparent elevated cancer risk for creosote workers.

Direct observations, e.g. clinical cases and poisoning incidents

Fatal cases after ingestion of creosote involve the amount of about 7 g for adults and 1-2 g for children. Death occurs 14 to 36 hours after ingestion of such amounts, and is mainly coupled to cardiovascular collapse. Symptoms of systemic exposure and illness are salivation, respiratory difficulties, vomiting, headache, irregular pulse, vertigo, hypothermia, cyanosis, and mild convulsions.

Acceptable daily intake (ADI) and acute reference dose (ARfD)

By definition, ADI gives a safety level of daily intake of a substance via ingestion. Therefore, the setting of ADI for creosote would be considered irrelevant, since creosote is used as wood preservative (PT8) and should not be consumed.

The route of exposure to creosote is primarily via dermal exposure, and to some extent via inhalation. Creosote is only used by professional users. The exposure to creosote via food or drinks would be practically non-existent. In addition, creosote is a complex mixture and contains several components that are regarded as carcinogenic and mutagenic, and creosote is classified as carcinogenic Cat.2. An ADI cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated. Creosote is regarded as a complete carcinogen (i.e., it has both initiating and promoting capacity with respect to tumour formation). The RMS is therefore of the opinion that an ADI or a long-term reference value cannot be established for creosote.

The ARfD of a chemical can, according to the EU guidance, 7199/VI/99/rev 6, be defined as "an estimate of a substance in food and/or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer on the basis of all the known facts at the time of evaluation". By this definition, the setting of ARfD for creosote which is used as wood preservative (PT8) is considered not to be relevant by RMS, since there will be no exposure of creosote to food or drinking water.

Acceptable Operator Exposure Level (AOEL)

Creosote is a complex mixture and contains several components that are regarded as carcinogenic and mutagenic, and creosote is classified as carcinogenic Cat.2. According to the EU Guidance for the setting and application of acceptable operator levels (AOELs) (revision 10), an AOEL cannot be set for substances that are genotoxic and/or carcinogenic unless a

threshold mechanism clearly has been demonstrated. Creosote is regarded as a complete carcinogen (i.e., it has both initiating and promoting capacity with respect to tumour formation). The RMS is therefore of the opinion that an AOEL or a long-term reference value cannot be established for creosote.

2.2.1.2. Exposure assessment

Data on exposure for operators

Wood preservation with creosote is restricted to professional users. Several worker exposure studies from industrial impregnation plants have been submitted, two of which were more appropriate for European conditions. In addition, a follow-up study was submitted in October 2008, and a study on down-stream users was submitted in November 2008. The studies focused on work tasks known to result in the highest exposure levels at the impregnation plants and among down-stream users, and are considered to adequately represent exposure for a whole and typical working day, while the plants were run at full capacity.

Since creosote is a complex mixture consisting of several hundreds, and maybe thousands of different compounds, the exposure cannot be measured directly. Instead, pyrene served as a marker substance for skin exposure and 15 of the EPA prioritised PAHs were monitored in the inhalational exposure measurements in the exposure studies.

The main conclusions were that worker exposure occurs primarily via the dermal route and is dominated by hand exposure, and is clearly connected to the proximity of the treating cylinder.

The estimated fraction of total body deposition arising from dermal creosote deposition ranged from 40-57 µg/kg bw/day in one study, and from 72 µg/kg bw/day with additional protection to 210 µg/kg bw/day without additional protection in another study.

Inhalational exposure was measured to be up to 13 µg/kg bw/day (0.13 µg/kg bw/day with PPE) (sum of detectable PAHs, dominated by naphthalene at >60 %). The inhalational exposure was measured outside of the respiratory protection, i.e., the resulting systemic exposure was reduced by the respiratory protection with 95-99%. Furthermore, the concentration of naphthalene in air is far below the existing Occupational Exposure Limit (OEL).

The study on down-stream users was focused on installation operations on treated wooden poles for in-service preparation, such as furnishing and cutting of electricity poles, installation of conductors, and installation of a separator. The work also involved setting up poles, climbing of poles by using climbing irons, sawing and drilling. The results show that the exposure is, for most job tasks, at approximately the same level or lower as at the impregnation plants. A value of 10 % dermal absorption is used in the quantitative risk characterisation.

The results of the risk characterisation is that there are sufficient Margin of Exposures (MOEs) at European impregnation plants and for down-stream users (pole installers), and the exposure levels are below a Derived Minimal Effect Level (DMEL) that represents a risk level, that according to the Reach R.8 Guidance, is of low concern (10^{-5}).

Furthermore, it is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure. Protective measures not mentioned below can also be of importance and hence be applied as well:

- Stringent adherence of the protecting measures that are already in place.
- The PPE should be changed frequently, and immediately after contamination. Inhalational PPE shall be changed at required intervals.
- The personal hygiene shall be strict, and washing with suitable cleaning solutions shall be performed as soon as possible after each work task where there is a risk of exposure.

Risk of exposure means direct skin contact or inhalation of the vapours. However, risks vary depending on the construction of the plant and during non-routine activities. Risks can, for example, occur when opening and maintaining of the vessel or entry into treating or preservative storage vessels. In these cases, aditional protection can be advised:

- Respiratory protection, such as a full face mask with particle filter P2 or preferably P3 in combination with gas filter A (brown) should be worn at critical work tasks when there is a risk of inhalation exposure
- Chemical resistant (coated) coveralls, or equivalent, should be worn over the regular work clothes at critical work tasks when there is a risk of exposure, and a thinner pair of (cotton) gloves should be worn under the chemical resistant gloves.
- Whenever possible, mechanical or automated processes should be used to avoid manual handling of treated timber (including down-stream work, for example during work with poles in service).
- Creosote-resistant boots should be worn when entering the vessel (e.g. for cleaning or maintenance).
- In order to ensure efficient protection, tight sealings (sleeve capes) may be used at the border of different garments, e.g., at the border of gloves and sleeves and at the border of trousers and boots.

In addition:

- The working areas such as the treatment/equalisation hall shall be cleaned when judged necessary based on monitoring or inspections. Other areas such as changing and washing rooms, break rooms and control rooms shall be cleaned weekly. Relevant equipment and tools shall be cleaned in case of contamination.
- Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.

It is estimated that the above mentioned protective requirements or measures would reduce the exposure substantially, and hence, lead to even larger MOEs than those already obtained in the current risk assessment.

Data on exposure for bystanders

Creosote is exclusively used by professional users, and there are sufficient MOEs for workers. Any occasional exposure by the public by for example touching a pole can never exceed the exposure for workers, and such possible exposure would consequently lead to very large MOEs. Exposure to non-professionals is therefore considered to be of minor relevance.

Furthermore, the exposure has been shown to be clearly connected to the proximity of the treating cylinder, and inhalational exposure account for only a small part of the total exposure levels. Investigations regarding emissions to ambient air at two American pressure treatments

plants have shown the ambient air emissions for naphthalene, which is the most significant PAH air emission, are close to background concentrations. Other, more high-molecular weight PAHs are below detection levels. Consequently, there is no apparent elevation in health risks for people living nearby creosote treatment plants.

2.2.1.3. Risk characterisation

In the revised risk characterisation, the revised dermal absorption value of 10% and 5% (as agreed at TMII 2008) and the exposure values from the European plants are used. Furthermore, two different MOE are presented for some of the toxicity endpoints. One MOE in which the major route of exposure (dermal) is taken into account is presented and one MOE in which the inhalational exposure (with PPE) is included. However, it has to be understood that the toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, it can be questioned if the volatile fraction really should be included. Moreover, the workers use respiratory protection at critical work tasks. The volatile fraction consists of a few detectable light-boiling PAHs with naphthalene as a major component (60->90%). More toxic and carcinogenic PAHs (e.g., BaP) seem not to volatilize.

Furthermore, it has to be taken into account that experimental data have been developed for the oral route in some studies. Utilising the oral route may be considered as a worst case compared with the relevant dermal exposure route in humans.

Table 2.2.1.3-1 Summary of the potential creosote exposure to operators with respect to different time frames and toxicity endpoints

	NOAEL	**Exposure**	**MOE [1, 2]**
Subchronic dermal toxicity test	400 mg/kg bw/day (revised NOAEL, see commenting table)	3.2 µg /kg bw/day (64 µg /kg bw/day x **5%** dermal absorption) 6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 125000** **MOE = 62500** **MOE = 29411**
Subchronic inhalation toxicity test	22 mg/m^3 corresponds to 5.5 mg/kg bw per rat[3)]	Sum of detectable PAHs: 0.13 µg /kg bw/day (with PPE) (Σ15 PAH, with >60 % naphthalene)	**MOE = 42307**
Teratogenicity test (rat, rabbit: oral)	50 mg/kg bw/day (rat)	Dermal exposure 3.2 µg /kg bw/day (64 µg /kg bw/day x **5%** dermal absorption) Dermal exposure 3.2 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs:: (Σ15 PAH, with >60 % naphthalene) = 3.33 µg /kg bw/day	**MOE = 15625** (rat NOAEL. Oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 15015

	9 mg/kg bw/day (rabbit)	Dermal exposure 6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs:: (Σ15 PAH, with >60 % naphthalene) = 6.33 µg /kg bw/day 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 7812** (rat NOAEL. Oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 7657 **MOE = 3676** **MOE (rabbit) =1406** (rabbit NOAEL. Oral vs. dermal bioavailability to be considered) MOE (rabbit, inhalation included)[1] = 1378
Two generations reproduction study	25 mg/kg bw/day	Dermal exposure 3.2 µg /kg bw/day (64 µg /kg bw/day x **5%** dermal absorption) Dermal exposure 3 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs: (Σ15 PAH, with >60 % naphthalene) = 3.33 µg /kg bw/day Dermal exposure 6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs: (Σ15 PAH, with >60 % naphthalene) = 6.53 µg /kg bw/day 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 7812** (rat NOAEL. Oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 7507 **MOE = 3906** (rat NOAEL. Oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 3828 **MOE = 1838**

1) Abbreviations: MOE = Margin of Exposure (NOAEL/Exp.) Generally a MOE of >100 is considered to be adequate. Moreover, an additional factor of 10 should be used, since creosote is classified as Canc. Cat 2. This results in a factor of 1000, i.e., the MOEs should preferably be at least 1000.
2) The use of respiratory protection has been taken into account when inhalational exposure has been included.
3) The dose (mg/kg bw) received by the rats in the 90-day study
NOAEL = 22 mg/m^3 = 0.022 mg/L
Rat breathing rate =175 ml/min = 10.5 L/h = 63 L/day (6 h in this study)
Rat weight = 250 g

Dose received at NOAEL= 0.022 mg/L x 63 L/day) /0.25 kg = 5.5 mg/kg bw/day

All MOEs can be considered to be acceptable.

For the short-term (90 day) studies, it can be noted that most NOAELs are derived based on mild effects at the LOAELs. Basically, all findings in the short-term studies were mild and of reversible nature. Creosote is also not considered to be acutely toxic. It exhibits, however, irritation properties to skin (as shown by the studies), and to the eyes and to the respiratory tract (as shown by practical experience). This can be overcome by more stringent use of the best available PPE, including chemical-resistant gloves, coveralls, sturdy boots and respirators.

For inhalational exposure the situation is complex. On one hand, inhalational exposure has proven to be of minor importance quantitatively in comparison with dermal exposure. Inhalational exposure accounts for about 10% of the total exposure. The high-molecular weight PAHs seem not to volatilise and are not considered to be problematic from an inhalational exposure point of view. On the other hand, coal tar creosote constituents such as naphthalene, methylnaphthalenes, acenaphthene, phenanthrene, and fluorene have been detected in emissions at pressure treatment facilities.

This is particularly the case for naphthalene, which accounts for more than 50 % of the emissions. This is problematic and may be of toxicological significance, because naphthalene has recently been identified as a potential carcinogen by the inhalation route in rodents. In two long-term inhalation carcinogenicity studies, naphthalene proved to be carcinogenic to the lung tissue of mice and to the nasal tissue in rats at exposure concentrations of 50 mg/m^3 and above. The relevance to humans is obscure. Air-borne naphthalene concentrations in wood-treatment plants in Finland and USA ranged between 0.04 – 5.7 mg/m^3.

Emissions to air may occur at several points in the treatment process, such as when cylinder doors are opened after a treatment cycle, or when creosote is transferred from the heater to the cylinder at the beginning of the impregnation process.

However, all emissions can be led to incineration and proper inhalational PPE are used at work tasks with a risk of inhalational exposure. Furthermore, dermal exposure has proven to be the most significant exposure pathway.

Risk characterisation of different working scenarios with respect to cancer risk

At TMII-2008 it was decided that 10% dermal absorption shall be used, and that figures obtained using 5 % dermal absorption shall be presented as well. This is used in conjunction with the highest exposure values from the European plants.

For systemic cancers, it is clear that dermal absorption should be taken into account. Even for skin cancer this may very well be the case since several of the components need to penetrate the skin in order to be metabolised and thereby exhibit any potential carcinogenic properties. In any case, the substances need to penetrate into the cells in order to be genotoxic.

A risk characterisation of the working scenarios with respect to cancer risk can (instead of using a NOAEL, which according to the RMS, and other bodies, cannot be identified in the cancer study) be performed by calculating the MOE by using the T25 value. The dose descriptor T25 gives an indication of the dose of a chemical resulting in a fixed incidence of tumours (in this case 25%). The T25 approach has been used for creosote by other bodies (Scientific Committee for Toxicity, Ecotoxicity and the Environment, CSTEE) and for non-threshold carcinogens by the Scientific Committee on Consumer Products (SCCP), and also by

EFSA, as well as for other substances within the EU and is also recommended in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8) to be used for non-threshold carcinogenic responses and when a linear dose-response can be assumed. In the ECHA Guidance, the use of T25 is described but also the use of the Benchmark dose (BMD). The BMD usually represents a 10% increase of the tumour incidence. The T25 value was chosen in the present case for the following reasons:

The T25 is recommended in the ECHA Guidance when there is a linear dose-response, as is the case with creosote. Furthermore, the T25 has been used quite extensively in the EU, especially for non-threshold carcinogens. Moreover, a T25 value calculated for BaP in creosote was already available and has previously been used in risk assessment for creosote by CSTEE (1999). In addition, the results obtained with the two procedures (T25 and BMD) are in most cases, when there is a linear dose-response, virtually identical.

The T25 value has been estimated by CSTEE (1999), based on BaP as a marker of carcinogenic potency of creosote using the data from a dermal cancer study in mice, (see DOC III A6/B6, point A6.7) to be 13 µg/kg bw/day BaP, corresponding to 1300 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). This is corrected by a factor of 5, since the creosote types were 5 times more potent than the control based on BaP content, resulting in 260 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). Please note that the detection limit for BaP in the analysis of the components of creosote is 10 ppm, and BaP was not detectable (i.e., below 10 ppm) in European creosotes WEI type B and C, meaning that the following risk characterisation based on a content of BaP is over-conservative. The T25 value is also corrected to account for differences in exposure conditions in order to obtain a corrected T25 or human T25. Guidance is to be found in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8.

In the present case the following modifications are made:

2/5 x 24/3 x 75/40 x 52/48 = 6.5

The figures 2/5 are due to the fact that the animals in the dermal cancer study (Fraunhofer, 1997) were exposed 2 times per week and creosote workers work five days per week and may thus be exposed five days per week.

The figures 24/3 are due to the fact that the animals were exposed continuously, while workers are exposed at maximum 3 hour per day. Workers at impregnations plants are in fact exposed at maximum 1 hour per day, while down-stream users, e.g., pole installers, may occasionally be exposed more than 3 hours per day, but not every day for the whole working year. Time is also spent, for instance, for travelling to the areas where work with poles has to be done and for collecting necessary equipment. Therefore, the 24/3 numbers are considered adequate.

It could be argued that first two factors should be combined into one factor, hours per week: 7 x 24 = 168 hours per week for the mice and 5 x 3 = 15 hours per week for workers.

This would then lead to about 3 times higher MOEs and about 3 times higher DMEL.

However, there is no assurance that creosote stayed on the skin of the mice entirely until the next application (two applications per week), since the site of application (on the skin of mice) was not covered. The more conservative option of keeping the first two factors (2/5 and 24/3) is therefore chosen. These factors have also been agreed on at the TMs.

There has been discussions whether the first two factors (2/5 and 24/3) should be used or not. Arguments have been raised that the factor 2 in 2/5 already has been taken into account in the

calculation of the T25 and that the factor 24/3 (hours) is not relevant, since the dose metric for the T25 value is per day. There is still no complete consensus if these factors should be applied or not. However, the *differences* in exposure conditions in the animal study and the human exposure situation have to be corrected for. Regardless of the total dose per day, there is a higher risk if the substance in question stays on the skin (as was the case in the mice study) compared to if it is removed immediately or as soon as possible. If these two factors are not used then the MOEs would be slightly less than half compared to the present situation (Table 2.2.1.3-2). On the other hand, the RMS has received a follow-up exposure study in November 2008 that showed exposure values that were about 1/3 of those that have been used in Table 2.2.1.3-2 below. The follow-up exposure study has not been used in any other respect than to show that risk mitigation measures are effective. If the follow-up exposure study is used in the cancer risk characterisation, then the MOEs would be about three times *higher*. Hence, these two issues (if the factors 2/5 and 24/3 really should not be used and if the follow-up exposure study would be used) more or less balance each other. The final result would still be that there are very large MOEs.

The figures 75/40 are based on that the animals were exposed their whole lives (75 years is a default figure for a human life time), while workers may at maximum be exposed a whole working life, i.e., 40 years. The figures 52/48 are based on the fact that the animals were exposed 52 weeks per year, while creosote workers work at maximum 48 weeks per year.

The following corrected T25 is obtained and used in the risk characterisation:

CorrT25 = 6.5 x 260 = 1690 mg/kg bw/day

The risk characterisation is presented in three ways: By using the MOE approach and also by using the linearised approach and the large assessment approach as described in chapter 4.1 of the TNsG for Annex 1 inclusion, and in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8.

The resulting MOEs are presented in the table below. It should be noted that the MOEs should preferably be 25 000 (in addition of the conventional 10 x 10, an additional factor of 10 should be used, since creosote is classified as Carc. Cat 2, and an extra additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL. An extra factor of 2.5 is used for the fact that the T25 value represents a 25 % level of the number of tumours (in comparison with the BMD that usually represents a 10% increase). A MOE of 25000 is obtained if an interindividual factor of 10 (i.e., not a factor of 5 for workers) is used in combination with the extra factor of 2.5.

Table 2.2.1.3-2 Summary of the creosote exposure to operators with respect to different exposure scenarios and cancer risk using 5% and 10% dermal absorption for comparison as decided at TMII 2008

Exposure scenario[1]	**Potential exposure**	
	µg/kg bw/day [2]	**MOE** [3]
Management Operator (MO, who exhibited the highest exposure in the FIOH study.) Changing the creosote buggy wheels and replacing a creosote cylinder door gasget.	Dermal: 6.8 (**5%** dermal absorption used)	**248529**
	13.6 (**10%** dermal absorption used)	**124264**

Worker (WO, who exhibited the second highest exposure value next to the MO in the FIOH study) Unloading/loading and charging of the cylinders, repair and maintenance. Load changes included the removal of processed pole buggies from the impregnation/after-treatment cylinder (unloading) and the charging of new buggies into the cylinder (charging). The change took approx. 15-30 minutes, of which a few minutes were spent in the vicinity of the impregnation/after-treatment cylinder.	Dermal: 2.8 (**5%** dermal absorption used) 5.6 (**10%** dermal absorption used)	**603571** **301786**
Worker (WO, who exhibited the highest exposure value in the van Rooij study). Controlling the process, transport of the wood into and out of the cylinder on rail trucks, opening and closing if the covers of the cylinder.	Dermal: 9.5 (**5%** dermal absorption used) 19 (**10%** dermal absorption used)	**177895** **88947**
Worker. Average exposure at impregnation plants for the two studies (64 µg/kg bw/day)	Dermal: 3.2 (**5%** dermal absorption used) 6.4 (**10%** dermal absorption used)	**528125** **264062**
Down-stream users (pole installers)		
Pole installers. Furnishing of poles. With the use of light chemical resistant overall	Dermal: 1.3 (**5%** dermal absorption used) 2.6 (**10%** dermal absorption used)	**1300000** **650000**
Pole installers. Furnishing of poles. Without the use of light chemical resistant overall	Dermal: 1.8 (**5%** dermal absorption used) 3.7 (**10%** dermal absorption used)	**938888** **456756**
Pole installers. Installation of conductors. With the use of light chemical resistant overall	Dermal: 0.56 (**5%** dermal absorption used) 1.1 (**10%** dermal absorption used)	**3017857** **1536363**
Pole installers. Installation of conductors. Without the use of light chemical resistant overall	Dermal: 0.85 (**5%** dermal absorption used) 1.7 (**10%** dermal absorption used)	**1988235** **994117**
Pole installers. Installation of a separator With the use of light chemical resistant overall	Dermal: 70.5 (**5%** dermal absorption used) 141 (**10%** dermal absorption used)	**23971** **11985**
Pole installers. Installation of a separator Without the use of light chemical resistant overall	Dermal: 100 (**5%** dermal absorption used) 200 (**10%** dermal absorption used)	**16900** **8450**

1) It has to be noticed that a distinction between different job categories and scenarios is difficult to make, since many of the workers perform several job categories. For pole installers the use of and non-use of a light chemical resistant

overall, respectively, is assumed to represent a situation equal to that in the exposure study by van Rooij (see DOC2.10 and DOCII-B, in where the use of an additional overall reduced the exposure considerably.

2) The exposure values are obtained from the study reports, see new study summaries in revised DOCIII A2.10, point A2.10.1, and revised DOCII-B, and the systemic exposure is obtained by accounting for 5 and 10% dermal absorption. Please note that the highest exposure values have been used. Furthermore, At TMII-2008 it was decided that 10% dermal absorption shall be used, and that values for 5% should be presented as well for comparison.
3) The inhalation exposure is not included since only a few PAHs were detectable in the volatile fraction and naphthalene accounted for > 60%. The large molecular weight PAHs (and most toxic and carcinogenic, e.g., BaP) were not detected, presumably due to low volatility. The toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, the volatile fraction was therefore not included. Moreover, the workers wear respiratory protection at critical work tasks.
4) The exposure to creosote can be considered to be chronic, since the workers can be exposed every working day for the entire working life. The MOEs have been calculated by comparing the exposure with the T25 value (corresponds to a dose of BaP in creosote resulting in a 25% increased incidence of tumours over a life span) (identified by CSTEE (1999)) of 13 BaP µg/kg bw/day, corresponding to 1300 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). This is corrected by a factor of 5, since the creosote types were 5 times more potent than the control based on BaP content, resulting in 260 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). The T25 value is also corrected to account for differences in exposure conditions in order to obtain a corrected T25 or human T25. The corrected T25 is 1690 mg/kg bw/day (see text above the Table). The MOEs should preferably be 25000 (an additional factor of 10 should be used, since creosote is classified as Carc. Cat 2, and an additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL, and a further extra factor of 2.5 is used when T25 (and not BMD) is used).

Derivation of DMEL

The derivation of a Derived Minimal Effect Level (DMEL) is described in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8. It should be pointed out that, although there is theoretically no safe exposure level for non-threshold carcinogens, the DMEL obtained represents a risk level that is considered to be of very low concern. This acceptable risk level is usually 10^{-5} for workers and 10^{-6} for the general public. Since creosote is only used by professionals and exposure for the general public can be considered to be negligible, the level of 10^{-5} is considered to be the adequate. This is especially the case since it can be noted that lower risk levels ($<10^{-3}$, $4 \cdot 10^{-3}$) have sometimes been used for workers.

In the linearised approach the reference value, in this case the corrected T25 value, is divided by a factor of 25000 in order to obtain a DMEL representing a risk level of 10^{-5}. This factor of 25000 is thought to adequately cover also intra and interspecies differences. Sometimes an extra factor for allometric scaling is needed. In this case that would be 7, since mice were used in the dermal cancer study (giving an overall factor of 7 x 25000). However, in the ECHA R.8 guidance, it is stated that a factor for allometric scaling should not be applied when the response in question (in this case skin tumours) is induced at the local port of entry. That was the case in the mice dermal cancer study from where the T25 value is derived. If the T25 value was based on systemic tumours in that study, then allometric scaling should be considered.

The overall factor in the linearised approach is in this case therefore 25000.

In the large assessment approach the corrected T25 is simply divided by the assessment factors. In the case of creosote the conventional 10 x 10 are used, and an additional factor of 10 should be used, since creosote is classified as Carc. Cat 2, and an extra additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL. An extra factor of 2.5 is used for the fact that the T25 value represents a 25 % level of the number of tumours (in comparison with the BMD that usually represents a 10% increase). A MOE of 25000 is thus obtained in the large assessment approach as well.

If the overall assessment factor of 25000 is applied, the equation is then:

DMEL = CorrT25 1690 mg/kg bw/day/25000 = 68 µg/kg bw/day

The DMEL obtained is considered to represent a risk level, which according to available Guidance, is of low concern (10^{-5}).

It is concluded that there are sufficient MOEs at the European impregnation plants, and that the exposure levels are below a DMEL that represents a risk level, that according to available Guidance, is of low concern (10^{-5}).

Acceptable uses are identified as far as acceptable uses can be said to exist for a genotoxic carcinogen.

The only exception is for pole installers during a special time-consuming work task of installing a separator. Strict risk reduction measures are to be applied. PPE was used in an inadequate way during the study. Gloves were, for example contaminated already before the work shift. Proper use of PPE will reduce the exposure considerably. It can also be noted that this kind of work is not performed every day all year around. This special work task can be dealt with on MS level.

A MOE of 10000 (25000 if T25 is used) has been considered to be of low concern by EFSA and other bodies, for example with respect to genotoxic carcinogens in food. It should, as explained above, be noted that the MOE of at least 25000 for creosote in the present risk characterisation is obtained by using the conventional 100 and adding an additional factor of 10, since creosote is classified as Carc. Cat 2, and by adding a second additional factor of 10 since an effect dose, i.e., T25 is used and not a conventional non-effect dose, i.e., a NOAEL), and by adding an extra factor of 2.5 for the fact that the T25 value represents a 25 % level of the number of tumours (in comparison with the BMD that usually represents an 10% increase).

It has also to be kept in mind that, although BaP has long been used as a marker for carcinogenic potency, the appropriateness for a complex mixture like creosote can be considered not to be fully clear.

Moreover, the suitability of the mouse cancer study for estimating cancer risk in humans can be questioned. The data from the mouse study are likely to over-estimate cancer risk in humans. The conditions used in mouse skin painting study were not representative of those that are common to humans (workers). In the study in mice, a solvent (toluene) was continuously applied at the same site, which may have impaired the integrity of the skin barrier function. Furthermore, a permissive effect of solvents on skin penetration of PAH is well known in the scientific literature. However, the use of a solvent does not rule out the fact that there was a dose-dependent increase in the number of tumours in the study. Workers are exposed to undiluted creosote, i.e., 100% creosote, which is not mixed with any solvent.

It has also to be taken into account that an increased cancer incidence among creosote workers is not evident despite the long history of creosote use, and despite the fact that former creosote types were “dirtier”, e.g., had higher contents of for instance BaP, and despite the fact that the working conditions have been much less stringently regulated historically compared to working conditions used today. Furthermore, American creosote oils still contain about 100-1000 times higher content of BaP. A recent cohort study by Wong and Harris in 2005, which included about 2000 creosote-exposed workers at 11 wood-treating plants in the USA failed to reveal any exposure-related mortality increases.

The epidemiological and medical data are, however, difficult to interpret. This does not rule out the fact that creosote is classified as carcinogenic, Cat 2.

Furthermore, it is estimated that the exposure situation can be further improved by extra protecting measures during work tasks where there is a risk of exposure. These are presented in section 2.2.1.2, Exposure assessment.

It is estimated that these protective measures would reduce the exposure substantially, and hence, lead to even larger MOEs than those already obtained in the current risk characterisation.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Creosote is made up of hundreds of aromatic compounds and from this fact it can be understood that a selection has to be made concerning which and how many compounds that can be studied regarding their fate and distribution in the environment. Since most compounds in creosote are polycyclic aromatic hydrocarbons (PAHs), the data submitted is almost exclusively on PAHs.

Abiotic degradation

No data was submitted on hydrolysis of creosote components. The justification given was that the components of creosote do not have hydrolysable groups and this was considered to be acceptable.

In water, PAHs present in creosote are rapidly photolysed under best case, laboratory conditions and an increasing trend in photoreactivity with increasing molecular weight was indicated. Due to effects of light attenuation, simulated realistic case half-life values for photolysis in natural waters were approximately two orders of magnitude longer than best case half-lives and varied between approximately half a day and 300 days depending on the PAH studied. Regardless of water type, direct photolysis is much more important than photosensitized oxygenation of PAHs. One major transformation product from aqueous photolysis of PAHs seemed to be quinone derivatives. It was indicated that photolysis of alkylated PAHs generated a greater number of transformation products than photolysis of parent PAHs.

For volatile PAHs, gas phase reaction with OH radicals is an important removal process. The half-lives of the selected PAHs ranged from approximately 1 to 7 hours. The mean half-life for the selected PAHs was estimated to approximately 3 hours. It should be mentioned that the OH radical concentration assumed was twice as high as the value suggested in the Technical Guidance Document on Risk Assessment (TGD) and from this follows that care must be taken if the half-life values should be used in PEC calculations (i.e. calculations of the predicted environmental concentrations) or compared to those of other substances for which the OH radical concentration suggested in the TGD have been used. For some PAHs, reactions with NO_3 radicals are very important but for PAHs in general this transformation pathway is of less importance compared to the OH radical-initiated reactions.

Biodegradation

A majority of the compounds present in creosote contain fused polycyclic aromatic ring systems (e.g. PAHs) which are very stable chemical structures, but a wide variety of bacteria, fungi and algae do have the ability to metabolise these compounds.

Mineralisation half-lives (DT_{50} values) in sediment-water systems can be summarised as follows: For non-alkylated PAHs with two rings; $DT_{50} \approx 30$ d, for alkylated PAHs with 2 rings and PAHs with 3 rings; $DT_{50} = >60$ d and finally, for PAHs with four rings, $DT_{50} \approx$ several years - ∞ (all at 22 °C). The rate of aerobic and anaerobic degradation of creosote components like PAHs increase in previously contaminated sediment water environments compared to pristine environments. In pristine, anaerobic sediment water environments mineralisation rates of PAHs are indicated to be too slow to be measured.

Dissipation half-life in the water phase of all PAHs (and creosote) was estimated to one month. The dissipation of creosote components from the water can most likely be ascribed to a combination of removal processes like volatilisation, adsorption, uptake by biota, photolysis and biodegradation.

Results of additional aquatic tests (non-key studies) showed that under favourable microbial conditions PAHs show significant degradation with rapid or gradual adaptation. This is true for compounds with three rings or less but among compounds with four rings some PAHs do not degrade even under favourable conditions. The rate of degradation in water for PAHs with three rings or less seemed to be enhanced when the water had been previously contaminated with hydrocarbons and/or PAHs. Alkylated PAHs seemed to degrade slower than parent PAHs. The acceptability of degradation results obtained with adapted inoculum cannot be considered as high as results obtained with non-adapted.

Soil degradation half-lives at 20 °C ranged from approximately two days for two ringed PAH compounds to more than a year for the four ringed PAHs. Shorter degradation half-lives were measured for PAHs when incubated as constituents in creosote. No degradation could be measured in anaerobic soil. PAHs may however be microbially degraded in soil under anaerobic, denitrifying conditions. The rate of degradation under anaerobic denitrifying conditions was slower than under aerobic conditions. Data on route of degradation in soil and the extent and nature of bound residues was missing in the dossier.

Distribution

For compounds present in creosote, the log K_{oc} values (i.e. values of the organic carbon - water partition coefficients) are found in the following approximate intervals; aromatic hydrocarbons range from 2.5 to 5.4, phenolic compounds from 1.0 to 1.8, nitrogen containing heterocycles from 1.1 to 3.0, sulphur containing heterocycles from 2.7 to 3.9 and finally, for the oxygen-containing heterocycle, dibenzofuran, the log K_{oc} is approximately 3.6. All K_{oc} values have been estimated from literature values of K_{ow} (i.e. octanol – water partition coefficients) by using the following correlation between the two partition coefficients; $K_{oc} = 0.35\ K_{ow}$.

If the log K_{ow} and log K_{oc} values of single compounds are weighted by their content in creosote (in percent), the log K_{ow} and log K_{oc} values of the different creosote oils can be estimated. The results of such calculations indicate that the composite sample of Grade B type (log K_{oc} 3.67) shows less tendency to partition to organic matter than the single Grade B creosote oil (log K_{oc} 3.97). Since the content of low molecular weight PAHs is lower in Grade C creosote oil its log K_{oc} is higher (4.17) than that for Grade B.

Accumulation

It is not possible to determine a single value for bioaccumulation potential of creosote, since the individual components of creosote all have different bioaccumulation potential. In bioconcentration tests with fish, the measured bioconcentration factors (BCFs) of some PAHs in creosote (phenanthrene, fluorene, fluoranthene, and pyrene) ranged from 78 to 540. However, some other components of creosote had higher BCFs, e.g. anthracene showed a BCF of 2500. The depuration rate in fish was rather rapid with 95% of the accumulated substance eliminated within 2-5 days for most PAHs. Since data was missing for many components of creosote, the BCF-values were also calculated using the mean log K_{ow} values. These calculated BCFs ranged from 61 to 17660 for individual aromatic hydrocarbons. For the creosote oils BCF-values of 634, 1163, and 1720, were calculated for composite Grade B, Grade B, and Grade C, respectively, using estimated log K_{ow} values. The bioaccumulation potential of creosote components in terrestrial organisms was low.

The results from the bioaccumulation studies in the aquatic environment show that most PAHs that are constituents of creosote are rapidly taken up and bioaccumulated in organisms. Biomagnification in food webs are not to be expected, though, since vertebrates and also some invertebrates have efficient metabolism and/or excretion of PAHs. There are species, however, that metabolise PAHs to little or no extent, like algae, oligochaetes, molluscs, and the more primitive invertebrates (protozoans, porifera, and cnidaria), which can accumulate high concentrations of PAHs. Therefore, predatory organisms may be exposed to significant levels of PAHs when feeding, but organisms from higher trophic levels are expected to eliminate these PAHs rather rapidly. An assessment of the risk of secondary poisoning is presented in section 2.2.2.3.

2.2.2.2. Effects assessment

Creosote has very high toxicity to aquatic invertebrates and fish and moderate toxicity to algae. Predicted No-Effect Concentration (PNEC) in surface water was estimated to 0.1 µg/l based on the lowest NOEC from chronic studies with fish and invertebrates (1µg/l) and an assessment factor (AF) of 10. $PNEC_{sw}$ values were also calculated for some individual components of creosote. These PNECs were in general in the same range as the PNEC for creosote, ranging from 0.042-0.3 µg/l, although a higher AF of 50 was used since only data for two trophic levels were available for these PAHs.

PNECs were also calculated for marine water with the same data set as for surface water, which also included short-term tests for creosote with two taxonomic marine invertebrate groups. The $PNEC_{marine}$ for creosote was estimated to 0.02 µg/l by using an AF of 50, and the $PNEC_{marine}$ for individual PAHs were estimated to 0.0044-0.03 µg/l with an AF of 500 for fluorene, phenanthrene, and anthracene and 1000 for fluoranthene.

The effects of creosote-treated pilings on sediment dwelling organisms were assessed in long-term field studies investigating benthic infaunal community composition. The $PNEC_{sediment}$ for creosote normalised to standard sediment organic carbon content was estimated to be 2 mg/kg ww sediment, based on threshold effect levels of measured concentrations of 15 PAHs (assumed to be equivalent to creosote). $PNEC_{sediment}$ derived for two individual PAHs, phenanthrene and fluoranthene, were estimated to be 0.4 and 0.6 mg/kg ww, respectively, with normalisation to standard sediment. If no normalisation to organic carbon content was made,

the $PNEC_{sediment}$ for creosote, phenanthrene, and fluoranthene was 0.4, 0.08, and 0.12 mg/kg ww, respectively.

The EC_{50} for inhibition of microbial activity in activated sludge by creosote was estimated to be 13 mg TOC/l and the $PNEC_{STP}$ was set to 0.13 mg creosote/l.

Terrestrial toxicity of creosote was studied in three trophic levels (microorganisms, plants, and earth-worm/springtail). The $PNEC_{soil}$ for creosote was estimated to be 0.3 mg/kg ww, based on the NOEC from a long-term test (28d) with creosote Grade B and springtails and an AF of 10. There was also data available to calculate $PNEC_{soil}$ for some individual PAHs with an AF of 50. These were in the same range as the $PNEC_{soil}$ for creosote, with a value of 0.34 mg/kg ww for 1-/2-methylnaphthalene, and between 0.24 and 0.55 mg/kg ww for five PAHs with increasing molecular weight from phenanthrene to pyrene.

2.2.2.3. PBT assessment

The PBT assessment made according to the criteria described in the TGD concluded that some creosote components fulfil one or more of the P, B or T criteria while other components do not. Anthracene has been reviewed by the PBT working group under the Technical Committee for New and Existing Substances (TC NEC) which concluded that this compound fulfils the PBT criteria. According to the data in the dossier for creosote no other compounds fulfils the PBT criteria. Fluoranthene and pyrene fulfils the P and T criteria and when theoretically estimated; also the B criterion why these compounds may be considered as *potential* PBT substances.

In the document by ECHA,"Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern", from 2007 it is stated that a multi-constituent substance composed of one or more constituents in individual amounts of ≥0.1 % but <80 % having PBT- or vPvB properties should be named "the substance contains PBT, or vPvB constituents". Since the content of anthracene which has documented PBT properties is approximately 1% in creosote RMS proposes that creosote should be described as a substance containing PBT constituents.

Some of the PAHs in creosote have, during the peer-review process, been considered by the Committee for Risk Assessment of the European Chemicals Agency as PBT (anthracene) or vPvB (fluoranthene, phenanthrene and pyrene) in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006.

2.2.2.4. Exposure assessment

The environmental exposure assessment of creosote has been performed following the general guidance in the OECDs emission scenario document (ESD) for wood preservatives and the Technical Guidance Document on Risk Assessment (TGD) in order to calculate the relevant PECs (i.e. predicted environmental concentration) for the different environmental compartments. The exposure assessment of creosote includes the estimation of local emissions to various receiving environmental compartments from only two stages of the life cycle, i.e. industrial product application and treated wood in-service in use classes 3, 4 and 5.

The leaching data used in the exposure assessment originates from experimental data, almost exclusively on pine. For the calculations of PECs, creosote retentions up to 150 kg/m^3 have

been taken into consideration since this was the highest retention applied for. Other types of wood as well as higher creosote retentions will have to be assessed by Member States at product authorisation stage.

Exposure to groundwater has been assessed for use class 3 and 4a by simulation with FOCUS PEARL. Groundwater assessment for use class 4a was simulated in two different ways with FOCUS PEARL. The first was done according to the same principles as for use class 3, i.e. the „house" scenario, and the second simulation made use of a special feature in PEARL called soil incorporation. The results of the simulations are given below in section 2.2.2.5. „Terrestrial compartment – In-service use".

2.2.2.5. Risk characterisation

The risk characterisation for the industrial use and for treated wood in-service has been performed both for creosote and for a selection of a few single creosote components (mostly PAHs).

It should be noted that all PEC values determined for creosote which have been generated from leaching rate data, are more uncertain than corresponding PEC values for single creosote components since the leaching rates for creosote are extrapolations from single creosote components, i.e. PAHs. Also, in some cases the predicted no-effect-concentration (PNEC) for creosote is more uncertain than corresponding PNECs for individual creosote components.

Aquatic compartments

Sewage treatment plant (STP) – industrial and in-service use

There is a risk posed to micro-organisms in a sewage treatment plant (STP) when an industrial application plant is connected to a STP. The PEC/PNEC ratio was 28 for creosote. It is therefore proposed that industrial application facilities should not be connected to a local STP.

The second exposure scenario for a STP is in-service leaching from a noise barrier (use class 3). For this scenario the PEC/PNEC ratio for creosote was <1, i.e. no risk was indicated.

Surface water – industrial use

The industrial use of creosote generates two exposure pathways to surface waters, emissions from the application entering a local STP followed by discharge into a local surface water and surface runoff from the storage site for creosote treated wood. PEC/PNEC ratios >>1 showed that there is a risk posed to aquatic organisms when exposed to creosote and creosote components via STP outlet. Therefore, it is proposed that industrial application facilities where wood is treated with creosote should not be connected to a local STP.

PEC/PNEC ratios <1 indicate that no risk is posed to aquatic organisms via exposure to runoff from the storage site. The discharge from a local STP and runoff from the storage site should be assumed to enter the same surface water. In the present case however, there is no point in making this worst-case assumption since the contribution from the storage runoff is negligible compared to the emissions from the application process. In conclusion, the added risk will be the same as the risk for the applications process scenario.

Surface water – in-service use

No risk is expected to be posed to aquatic organisms from exposure to in-service leaching from a creosote treated noise barrier (via STP outlet) since all PEC/PNEC ratios were <1.

There is risk for aquatic organisms when exposed to in-service leaching from a creosote treated bridge over a small pond (use class 3). The PEC/PNEC ratios for creosote were >1 but for individual creosote components however, the long-term PEC/PNEC ratios indicated no risk to aquatic organisms when removal processes (dissipation) were assumed to affect the creosote components in the water.

For the jetty-in-lake scenario (use class 4b), PEC/PNEC ratios >1 for creosote showed that there is risk to aquatic organisms when exposed to in-service leaching. The ratios were >1 regardless of assessment period or if removal was considered or not. For individual creosote components however, the PEC/PNEC ratios indicated no risk to aquatic organisms when dissipation was assumed to affect the creosote components in the water.

Also measured water concentrations in large mesocosms mimicking the „jetty" scenario were used in order to assess the risk from in-service leaching. The result showed that there is a risk for aquatic organisms during the initial assessment period but for the long-term assessment period no risk was indicated.

There are risks for aquatic organisms when exposed to in-service leaching from creosote treated sheet pilings in a streaming waterway (also use class 4b). The PEC/PNEC ratios were >>1 for creosote and >1 for single creosote components.

For the wharf scenario (use class 5), all PEC/PNEC ratios for creosote and for individual creosote components showed that there are risks posed to aquatic organisms when exposed to in-service leaching in a sea water environment.

Data on measured (by semi-permeable membrane device, SPMD) water concentration adjacent to underwater constructions (piling sites) in a seawater environment was also used to assess the risk for aquatic organisms. The ratio between measured water concentration of creosote and ditto $PNEC_{marine}$ for creosote indicated that risk is posed to aquatic organisms.

Sediment– industrial use

In a similar manner as for surface water, the PEC/PNEC ratios showed that there is a risk posed to sediment living organisms when exposed to creosote and creosote components from the application process via a STP outlet. No risk is however posed to sediment living organisms via exposure to runoff from the storage site.

Sediment– in-service use

No risk is posed to sediment living organisms via exposure to in-service leaching from a creosote treated noise barrier (via STP outlet) since all PEC/PNEC ratios were <1.

The PEC/PNEC ratios for creosote and single creosote components for the long-term assessment period were all showing risk for the sediment in the three scenarios; bridge-over-pond, jetty-in-lake and sheet pilings-in-streaming water. For the short-term assessment period for the „bridge" scenario, a risk was however only indicated when the PNEC for creosote was not normalised to standard organic carbon content in the sediment.

For the sea water scenario (wharf), a risk was shown for the sediment for the short-term assessment period while for the long-term assessment period a risk was only indicated when

the PNECs for creosote and individual components were not normalised to standard organic carbon content in the sediment.

By comparing measured sediment concentration of creosote adjacent to underwater constructions (piling sites) in a seawater environment with the $PNEC_{sediment}$ for creosote (normalised to standard organic content) it was shown that for the initial assessment period there was a risk for sediment living organisms close (0.5 m) to the piling site made of newly treated wood. For the long-term assessment period, at the same piling site, the $PNEC_{sediment}$ for creosote was exceeded (i.e. indicating risk) in surface sediments collected in a gradient from close to the construction and up to a distance of >7.5 m - <10 m from the construction. For the piling site made with weathered pilings, the $PNEC_{sediment}$ for creosote was exceeded in sediments collected in a gradient from close to the piling site up to a distance of 2 m for the initial assessment period, and up to a distance of >5 m - < 10 m for the long-term assessment period.

Terrestrial compartment

Industrial use

There is risk posed to terrestrial organisms when exposed to leaching of creosote from treated wood at the storage site. It is therefore suggested that all treated wood should be stored on impermeable hard standing to prevent direct losses to soil and allow losses to be collected for re-use or disposal.

In-service use

There is no risk posed to terrestrial organisms by exposure to in-service leaching from creosote treated wood in use class 3 (e.g. house, fence, noise barrier and railway sleepers). All PEC/PNEC ratios were <1 when it was assumed that degradation is taking place in the soil. The use of railway sleepers is not represented in the ESD for wood preservatives as an in-service use scenario. But when examining the parameters affecting the in-service leaching behaviour, it is considered that the use of sleepers should be included in use class 3. Further, when considering the area of wood exposed to rain relative to the volume of the receiving soil compartment it can be concluded that the „sleeper scenario" is less worst case than the „house" scenario of use class 3.

There is risk posed to terrestrial organisms when exposed to creosote leached out into the ground from a transmission pole or a fence post (use class 4a). For the transmission pole scenario there is risk for both the initial and long-term assessment periods when assuming soil degradation, while for the fence post scenario the risk was only seen for the long-term assessment period (also when assuming degradation in the soil). For individual creosote components however, the PEC/PNEC ratios indicated no risk when degradation was assumed to affect the creosote components in the soil.

Measured concentrations of creosote (i.e. PAHs) at various distances and depths adjacent to a large number of utility (transmission) poles in service were compared to $PNEC_{soil}$ for creosote. The results indicate that there are risks posed to terrestrial organisms at distances up to at least 76.2 cm from the poles. The PAH concentrations measured at a distance of 122 cm from the poles were not elevated compared to background levels but still some of the samples collected at 122 cm from the poles showed ΣPAH concentrations that were above the $PNEC_{soil}$, i.e. indicating risk to soil organisms.

The exposure to groundwater for use class 3 was assessed by simulation with FOCUS PEARL using the „house" scenario. The results showed that the predicted levels of creosote and all individual compounds were <0.001 µg/l for all scenarios. Railway sleepers have been decided to be included in use class 3 and since the maximum sleeper wood surface area per hectare is lower than the wood surface area of houses per hectare the results of the simulation of the house scenario are also valid for the railway scenario. From this it can be concluded that the predicted levels in groundwater from in-service use in use class 3 will not exceed the maximum permissible concentration in drinking water.

Exposure to groundwater for use class 4a was assessed by two different simulations with FOCUS PEARL. The first simulation was done according to the same principles as for use class 3, with the only difference that the leaching rate input was the one appropriate for use class 4a. The results showed that the predicted levels of creosote and individual compounds were <0.001 µg/l for all scenarios. The second simulation made use of a special feature in PEARL called soil incorporation. This much more worst case simulation required that the actual wood leaching area of poles was estimated instead of using the default values of the house scenario. The results showed predicted groundwater levels <0.001 µg/l for all individual compounds modelled. For creosote, one scenario out of nine showed a predicted groundwater concentration >0.1 µg/l (0.1066 µg/l). It should be remembered however that the modelling tool (FOCUS PEARL) and the special feature with soil incorporation is an approximate way to assess groundwater exposure for poles in the ground. It is not developed specially to model the leaching of wood preservatives from poles placed in the ground. This in combination with the worst case wood area of poles in a hectare assumed in the simulation leads RMS to consider that exposure to groundwater from in-service use of creosote treated wood in use class 4a is not expected to be an area of concern.

Non compartment specific effects relevant to the food chain (secondary poisoning)

The risk for secondary poisoning via the aquatic and terrestrial food chain was assessed for the creosote constituents anthracene, fluoranthene, and pyrene, for which there were data available. The ratios for $PEC_{oral\ predator}/PNEC_{oral}$ were all <1 and thus the results of the assessment indicate that the risk for secondary poisoning is low from exposure to creosote components leaching from treated wood in service.

Atmosphere

Creosote released from the industrial application process and during storage and in-service use of creosote treated wood is not expected to result in air concentrations which can be considered to be of concern.

Summary of risk characterisation for industrial and in-service use

Table 2.2.2.5-1 Summary of the results of the risk characterisation for industrial and in-service use of creosote. Degradation/removal processes were not assumed for STP and sediment or for surface water in the industrial scenarios and the „noise barrier" scenario. For in-service use only the results of the long-term assessments are displayed in the table

		PEC/PNEC >1 (i.e. indicate risk), Yes / No				Measured concentrations indicate risk? Yes/No (Conc./PNEC ratio)
Industrial use scenario		**STP**	**Water**	**Sediment**	**Soil**	
Application		**Yes**	**Yes**	**Yes**	-	-
Storage		-	No	No	**Yes**	-
Use class	**In-service use scenario**					
3	"House/Fence/Rail -way sleepers"	-	-	-	No	-
	"Noise barrier"	No	No	No	No	-
	Bridge over pond	-	**Yes**	**Yes**	**-**	**-**
4a	"Transmission pole" and „Fence post"	-	-	-	**Yes**	**Yes** (24)[1]
4b	"Jetty in a lake"	-	**Yes**	**Yes**	-	No - water [2]
	"Sheet pilings in waterway"	-	**Yes**	**Yes**	-	-
5	"Wharf"	-	**Yes**	No [5]	-	**Yes** (4) -water [3] **Yes** –sediment [4]

[1] The ratio given is for soil at a distance of 45.7 cm from transmission/utility poles (long-term assessment).
[2] The ratio given is for water (large mesocosms) for the long-term assessment period.
[3-4] Equivalent to the long-term assessment period.
[5] The result in the table was obtained when using sediment carbon normalised PNEC for creosote. The result when using a non-normalised PNEC value indicated risk

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the decision

Health aspects

Creosote is a complex mixture which is classified as Carcinogenic, Category 2, R45, and is considered to be a non-threshold carcinogen.

For substances regarded as non-threshold carcinogens a qualitative risk characterisation is always performed as a first option. The use of creosote is already stringently restricted in the Reach Regulation (Annex XVII p. 31).The requirements of Reach and also the Carcinogens and Mutagens Directive 2004/37/EC shall be complied with. A quantitative risk characterisation may be performed on a case by case basis and such a risk characterisation has been performed for creosote. Guidance can be found in the revised and endorsed chapter 4.1 of the TNsG for Annex I inclusion, in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8, and in the Report by SCHER, SCCP, and SCENIR, (2008): Risk assessment methodologies and approaches for mutagenic and carcinogenic substances.

Generally, for biocides, the risk characterisation for human health is performed by a comparison of the exposure with the A(O)EL and also by the MOE (Margin of Exposure) approach (for calculation of MOEs the exposure is usually directly compared to a relevant NOAEL by dividing the NOAEL with the exposure value). However an A(O)EL cannot be set for creosote, since creosote is classified as Carcinogenic, Category 2, R45, and is considered to be a complete carcinogen, i.e., with both initiating and promoting capacity with respect to tumour formation. There is theoretically no safe exposure level for non-threshold carcinogens. Hence, a risk characterisation for creosote by comparison of the exposure in relation to an A(O)EL cannot be performed.

In cases where a NOAEL cannot be identified (i.e., for genotoxic and non-threshold carcinogenic substances), the MOE can instead be calculated by comparing the exposure with other reference points such as the dose descriptor T25. The dose descriptor T25 gives an indication of the dose of a chemical resulting in a fixed incidence of tumours (in this case 25%). The T25 approach has been used for creosote both in this risk assessment and by other bodies such as the Scientific Committee for Toxicity, Ecotoxicity and the Environment, CSTEE. It has also been used for assessments on other non-threshold carcinogens by the Scientific Committee on Consumer products (SCCP), and also by EFSA, as well as for other substances within the EU.

Occupational operators are the single group of the population that may be exposed to creosote on a daily basis. Exposure of the general public to coal-tar creosote [CAS 8001-58-9] can generally be excluded. In the European Union, coal-tar creosote is a restricted-use wood-preservative, regulated by the Reach regulation, which only permits creosote for professional use.

In the risk characterisation for human health it is concluded that there are sufficient Margin Of Exposures (MOEs) at European impregnation plants and for down-stream users, and that the exposure levels are below a Derived Minimal Effect Level (DMEL) that represents a risk level, that according to available Guidance is considered to be acceptable (10^{-5}).

Environmental aspects

Risks are posed to environmental compartments from exposure from the industrial application process and during storage of creosote treated wood. It is therefore proposed that industrial application facilities would not be connected to a local STP and that appropriate risk mitigation measures are taken in order to protect the soil from leaching from treated wood at the storage site.

For the in-service use of creosote treated wood in use class 3 (not covered and not in contact with soil), the risk assessment showed that no risk is posed to the terrestrial environment. In-service-leaching from

treated wood in contact with the ground (use class 4a) will, according to the risk assessment, result in a risk to terrestrial organisms. The risk assessment also showed that there is risk to the aquatic compartment due to in-service use of creosote treated wood as a bridge over a small pond (use class 3), in permanent contact with freshwater (use class 4b) as well as permanently exposed to sea water (use class 5).

The risks identified for the terrestrial and aquatic compartments, using the model scenarios of the OECD Emission Scenario Document for in-service use of creosote treated wood, can at product authorisation be further discussed in relation to risk assessment results obtained by the use of monitoring data.

The PBT assessment made according to the TGD showed that some creosote components fulfil one or more of the P, B or T criteria while other components do not. Anthracene has been reviewed by the PBT working group under the Technical Committee for New and Existing Substances (TC NES) which concluded that this compound fulfils the PBT criteria. According to the data in the dossier for creosote no other compounds fulfils the PBT criteria. Fluoranthene and pyrene fulfil the P and T criteria and, when theoretically estimated on basis of their log K_{ow} values, also the B criterion is fulfilled why these compounds may be considered as *potential* PBT substances.

In the ECHA document "Guidance for the preparation of an Annex XV (REACH) dossier on the identification of substances of very high concern" from 2007 it is stated that a multi-constituent substance composed of one or more constituents in individual amounts of ≥0.1 % but <80 % having PBT-, or vPvB properties should be named "the substance contains PBT, or vPvB constituents". Since the content of anthracene which has documented PBT properties is approximately 1% in creosote, the RMS proposes that creosote should be described as a substance containing PBT constituents.

According to the criteria for Annex I inclusion agreed in the Technical Notes for Guidance on Annex I inclusion, chapter 5 (April 2002), a substance that fulfilled the PBT criteria would not normally be included in Annex I unless other aspects such as benefit should influence the decision. No comment is made in the guidance about substances that contain PBT constituents.

Conclusions on health and environmental risks

As regards health aspects, the risks when using creosote for professional wood treatment and professional use of treated wood are, according to available guidance, within acceptable levels. No environmental risks were identified for the terrestrial compartment when treated wood is used without cover and without contact with soil (use class 3). However, creosote contains PBT constituents and is classified as carcinogenic, category 2, and should therefore not normally be included in Annex I.

The availability of alternatives

According to Directive 98/8/EC (Article 10(5)) entry of an active substance in Annex I may be refused if the evaluation of the substance gives rise to concern and if there is an alternative substance on Annex I for the same product type which presents significantly less risk, and that can be used without significant economic and practical disadvantages.

Creosote gives rise to concern because of its PBT characteristics. However, there are no substances on Annex I at this point in time, which can be seen as realistic alternatives when applying article 10(5) of Directive 98/8/EC. However, creosote is nevertheless a candidate for comparative assessment.

Benefits of using creosote

While the inclusion on Annex I of an active substance that contains PBT constituents cannot be desirable in itself, arguments have been made to the RMS and the European Commission that the continued availability of creosote-treated wood is needed to provide certain services, such as telephone communications and railway connections in several of the Member States. These arguments were

submitted during a public consultation by the European Commission and the contributions have been made public on the Commission‟s website (http://ec.europa.eu/environment/biocides/creosote.htm). The contributions have been summarised but the arguments have not been analysed in detail.

However, the contributions in the public consultation indicate that there would be severe economic and practical consequences for the European community if creosote treated wood cannot be used. The contributions further indicate that available alternatives are not any better from an environmental and health point of view. Consequently, socio-economic aspects need to be taken into account in the decision if creosote can be included in Annex I of Directive 98/8/EC.

It could be argued that if such necessary use areas exist, they would not necessitate the authorisation of creosote products within the EU since creosote-treated wood is, and could continue to be, imported from outside of the EU. Any large-scale import of treated wood and use of such wood within the EU in applications of concern may limit the effect of risk mitigation measures taken under Directive 98/8/EC. Such measures can only affect the use of creosote within the EU, not the use of imported wood. The limitations on uses that now apply according to the Reach Regulation (formerly Directive 76/769/EEC) would not be sufficient to deal with this. Given that import of treated creosote wood can continue, it could further be argued that a prohibition of the marketing of creosote and the treatment of wood with creosote within the EU would be a disproportionate measure on European industry that would not bring any benefits in terms of reduction of risks to the environment and, in terms of downstream users, to human health.

Conclusion

The RMS suggests that the inclusion of creosote in Annex I of the Directive should be considered.

3.2. Decision regarding Inclusion in Annex I

An inclusion of creosote in Annex I of Directive 98/8/EC as an active substance for use as a wood preservative, product type 8 may be considered, subject to the following conditions:

1. Biocidal products containing creosote may only be authorised for uses where no appropriate alternatives are available. Member States authorising such products shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission shall make these reports publicly available.
2. Creosote should be included in Annex I for five years only, and should be subject to a comparative risk assessment before its inclusion in this Annex is renewed.
3. The active substance creosote, as manufactured, must comply with the criteria for Grade B or Grade C as specified in European Standard EN 13991:2003
4. Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006 (the Reach regulation), and products containing creosote and used as wood preservatives shall not be authorised for the treatment of wood for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to the Reach regulation.
5. All possible measures to protect workers, including down-stream users, from exposure during treatment and handling of treated wood must be taken according to the Reach Regulation, and also the Carcinogens and Mutagens Directive 2004/37/EC.
6. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect these compartments. For instance, labels

and/or safety data sheets of products authorised shall indicate that treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.

7. Where relevant for the particular product, Member States shall assess at product authorisation stage the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the EU level risk assessment.

3.3. Elements to be taken into account by Member States when authorising products

1. Restrictions for the use and marketing of creosote in the Reach regulation must be taken into consideration in connection with product authorisation.
2. Losses during industrial treatment must be contained and recycled or collected and treated as waste in accordance with the national regulations of the Member State authorising creosote products.
3. The environmental exposure assessments have been based on a creosote retention in the wood of 40-150 kg/m^3. The use of wood with a higher retention must be assessed prior to authorisation at Member State level.
4. The leaching data used in the environmental exposure assessments was for creosote treated pine wood. Use of other types of treated wood must be assessed prior to authorisation at Member State level.
5. The environmental risk assessment for the terrestrial compartment should be re-assessed prior to product authorisation when data on route of degradation in soil and the extent and nature of bound residues are available at Member State level.
6. An assessment regarding the potential environmental and human health risks following in situ retreatment needs to be performed prior to product authorisation at Member State level.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of creosote in Annex I to Directive 98/8/EC.

The following data gaps were identified: Validation data for a monitoring method for soil and data on route of degradation in soil and the extent and nature of bound residues. This information should be submitted as part of applications for product authorisation.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of creosote in Annex I to the Directive.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Creosote
Function (*e.g.* fungicide)	Wood preservative: fungicide, insecticide, repellent
Rapporteur Member State	Sweden (Competent Authority: Swedish Chemicals Agency, KemI)

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	Creosote
Chemical name (CA)	Creosote
CAS No	8001-58-9
EC No	232-287-5
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	Not applicable to a UVCB substance. Specification for creosote is based on the criteria in European Standard EN 13991:2003
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	The term impurities does not apply to an UVCB substance. European Standard EN 13991:2003 specifies maximum content for (Grade B and C):: Water extractable phenols: max 3% Matter insoluble in toluene: max 0.4% Benzo[a]pyrene: max 50 ppm
Molecular formula	Not applicable to an UVCB substance (molecular formulas for individual components given in Document II-A, Appendix I-A)
Molecular mass	Not applicable to an UVCB substance (Molecular masses for individual components given in Document II-A, Appendix I-A)
Structural formula	Not applicable to an UVCB substance (structural formulas for individual components given in Document II-A, Appendix I-A)

Physical and chemical properties (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	Range: <30 °C (Crystallization temperature: 0°C and 30°C (grade B and grade C respectively)
Boiling point (state purity)	Range: ≥210 °C – 400 °C (grade B) ≥260-400°C (grade C)

Temperature of decomposition	none> 400°C
Appearance (state purity)	Brown liquid with aromatic phenolic odour (purity not applicable)
Relative density (state purity)	1.08 – 1.10 (Grade B and Grade C)
Surface tension	Not possible to determine for a complex mixture with a low solubility in water.
Vapour pressure (in Pa, state temperature)	Measurements in the range 164-255°C (Grade B) and 180-285°C (grade C). Extrapolated: 20 °C 0.4 Pa (Grade B) 0.3 Pa (Grade C) 25 °C 0.66 Pa (Grade B) 0.50 Pa (Grade C) 50 °C 4.88 Pa (Grade B) 3.41 (Grade C) 100 °C 120 Pa (Grade B) 72.6 Pa (Grade C)
Henry"s law constant (Pa m^3 mol^{-1})	Not possible to determine for the complex creosote mixture Range for single components (literature data for 18 PAHs): 0.007 (6 ring PAH) – about 150 (acenaphthylene) Pa*m^3/mol
Solubility in water (g/l or mg/l, state temperature)	For creosote expressed as TOC: <u>At a loading of 100 mg creosote/l water:</u> 2.25-8.11 mg/l (Grade B, Grade B-composite and Grade C) <u>At a loading of 10 g creosote/l water:</u> 191 mg/l (Grade B-composite) 30.3 mg/l (Grade B) 27.7 mg/l (Grade C) Range for single components (literature data for 18 PAHs): 0.26 µg/l (benzo[ghi]perylene) – 31.7 mg/l (naphthalene) Higher solubilites anticipated for the polar components (i.e. phenolics, N-, S- and O-heterocycles)

Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Completely miscible in benzene or toluene, >99.5 % in acetone, soluble in quinoline
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant as creosote is not used in any solvents
Partition coefficient (log P_{OW}) (state temperature)	Experimentally determined for US types creosote P1/13 and P2: 2.7 (o:w 8:1)-3.7 (o:w 1:1.25) o:w = octanol to water ratio The experimental value not used in the risk assessment (See Chapter 4)
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	See Chapter 4
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Not possible to determine for the complex creosote mixture Creosote is not anticipated to be significantly affected by pH, as the great majority of the components cannot dissociate.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No specific information due to complex mixture of aromatic compounds
Flammability	Flash point: >87 – >120 °C (Grade B and Grade C); ignition point >450 °C
Explosive properties	Not explosive
Oxidizing properties	Not oxidizing

Classification and proposed labelling (Annex IIA, point IX.)

According to the Annex VI to Regulation (EC) 1272/2008 and proposed.

with regard to physical/chemical data	none
with regard to toxicological data	Class of danger: T R phrases: 38, 43, 45, 60, 63
with regard to fate and behaviour data and ecotoxicological data	Class of danger: N R phrases: 50/53

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	GC-FID Able to quantify 106 components in the creosote under evaluation
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Not relevant as the term impurities does not apply to an UVCB-substance. The methods for the relevant components of creosote are given in European Standard EN 13991:2003

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	<u>Sediment</u> <u>24 PAHs in sediment</u> SEC for isolation and GC-MS for analysis. LOQ not stated. LOD: 1-4 ng/g dry sediment (i.e. µg/kg) for low-molecular weight PAH and 0.3-0.5 ng/g dry sediment (i.e. µg/kg) for high-molecular weight PAH. However, the reporting and the validation data are not sufficient. <u>Soil</u> No specific method has been submitted. Soxhlet extraction in combination with e.g. GC-FID analysis has been proposed. However, no validation data has been provided in support of the proposal.
Air (principle of method and LOQ) (Annex IIA, point 4.2)	<u>11 PAHs in air</u> GC-FID. LOQ: 19.1-25.8 µg/air sampling tube. Another study for slightly different PAHs indicated LOQs of 1.6-10.2 mg/m^3
Water (principle of method and LOQ) (Annex IIA, point 4.2)	<u>16 PAHs in surface and drinking water:</u> GC-FID or HPLC-UV/FD (US EPA method 610) LOQ not stated. LOD: Naphthalene, acenaphthylene, acenaphthene: 1.8-2.3 µg/l, Fluorene-pyrene, chrysene: 0.15-0.66 µg/l, remaning PAHs: 0.017-0.076 µg/l (LOD for benz(a)pyrene is above the EU-drinking water limit (98/83/EC)) <u>6 PAHs in drinking water</u> HPLC-FD (DIN 38407-8), LOQ: 0.005 µg/l <u>Components of creosote in water (deionized)</u> GC-FID, able to quantify 68 components of creosote, LOD: 1 µg/l, LOQ: 3 µg/l

Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Urine and faeces 1-OH-pyrene in urine HPLC-FD, LOQ: 8.73 µg/l Phenanthrene, pyrene and chrysene and corresponding OH-metabolites in urine and faeces GC-FID/MS, LOQ not stated, LOD: 0.1 ng injected Blood and tissues 10 PAHs in blood HPLC-FD, LOQ: 76 ng/l-10 µg/l. However, the reporting and the validation data are not sufficient 24 PAHs in tissues SEC for isolation and GC-MS for analysis. LOQ not stated, LOD: 5-50 ng/g dry tissue (i.e. µg/kg) for low-molecular weight PAH and 0.5-3.5 ng/g dry tissue (i.e. µg/kg) for high-molecular weight PAH. However, the reporting and the validation data are not sufficient.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required due to the use pattern of creosote
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required due to the use pattern of creosote

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	Considered as not relevant (impossible to assess, since creosote consists of several 100 compounds)
Rate and extent of dermal absorption:	2.1%. At TMII-2008 it was decided that 10% dermal absorption shall be used.
Rate and extent of inhalational absorption	100% used
Distribution:	Pyrene (as model PAH): highest levels in liver, kidney and fat (transient peaks)
Potential for accumulation:	no evidence, reactive metabolites of certain PAH may react with DNA
Rate and extent of excretion:	depending on compound: pyrene elimination rate constant (rat): 0.17 – 0.35/d, 70 – 80 % (6 d)
Toxicologically significant metabolite	epoxides, quinones, phenols

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	>3500 mg/kg
Rat LD_{50} dermal	>2000 mg/kg
Rat LC_{50} inhalation	>5000 mg/m^3 (aerosol)
Skin irritation	Irritating
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Positive (Maximization) negative (Buehler)

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target/critical effect	Rat / liver hypertrophy / inflammation in nasal cavity (inhalation)
Lowest relevant oral NOAEL/LOAEL	no data
Lowest relevant dermal NOAEL/LOAEL	400 mg/kg bw/d (90 d)
Lowest relevant inhalation NOAEL/LOAEL	22/128 mg/m^3 (90 d)

Genotoxicity (Annex IIA, point 6.6)

	Result	Creosote-type
• Bacterial reverse mutation test (Ames test)	Positive (+ S9) negative (- S9)	EU <50 ppm BaP
• In Vitro mammalian chromosome aberration test (human lymphocytes)	negative (+/- S9)	EU <50 ppm BaP
• In vitro mammalian cell gene mutation test (Mouse lymphoma L5178Y)	positive (weak, + S9)	EU <50 ppm BaP
• In vivo micronucleus assay (mouse, bone marrow)	negative	EU <50 ppm BaP
• Dominant-Lethal Test (rat)	negative	US ~5000 ppm BaP

Long term toxicity and Carcinogenicity (Annex IIA, point 6.7)

Species/type of tumour	Mouse (dermal): skin tumors (papilloma and squamous-cell carcinoma)
lowest dose with tumours	CTP1 (BaP content 10ppm): 3 mg (2x/wk) CTP2 (BaP content 270 ppm): 0.1 mg (2x/wk)

Reproductive toxicity (Annex IIA, point 6.8)

Species/Reproduction target/critical effect	Rat / fertility / decreased litter size in the high dose group, decreased live offspring, and decreased bw of live pups during lactation
Lowest relevant reproductive NOAEL/LOAEL	25/75 mg/kg bw/d
Species/Developmental target / critical effect	Rat, rabbit/ embryonal / post-implantation loss
Lowest relevant developmental NOAEL/LOAEL	50/175 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/target/critical effect	no data
Lowest relevant developmental NOAEL/LOAEL	--

Other toxicological studies (Annex IIIA, VI/XI)

No data

Medical data (Annex IIA, point 6.9)

	Fatal cases after ingestion of creosote involve the amount of about 7 g for adults and 1-2 g for children. Overall, the body of epidemiological data does not indicate an apparent elevated cancer risk for creosote workers.

Summary (Annex IIA, point 6.10)

ADI (if residues in food or feed)	By definition, ADI gives a safety level of daily intake of a substance via ingestion. Therefore, the setting of ADI for creosote would be considered irrelevant, since creosote is used as wood preservative (PT8). Furthermore, creosote is classified as R45 Carc. Cat.2. An ADI cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated.
AOEL (Operator/Worker Exposure/Bystander)	Creosote is classified as R45 Carc. Cat.2. According to the EU guidance on AOEL setting (rev 10), an AOEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated.
Drinking water limit	0.1 µg/L (As set by EU Drinking Water Directive (98/83/EC))
ARfD (acute reference dose)	The setting of ARfD for creosote which is used as wood preservative (PT8) is considered not to be relevant.

Acceptable exposure scenarios (including method of calculation)

Professional users	Creosote is classified as R45 Carc. Cat.2. There are sufficient MOEs at European impregnation plants and for down-stream users, and the exposure levels are below a DMEL that, according to available Guidance, represents a risk level of low concern (10^{-5}).
Workers (re-entry)	Creosote is classified as R45 Carc. Cat.2. There are sufficient MOEs at European impregnation plants and for down-stream users, and the exposure levels are below a DMEL that, according to available Guidance, represents a risk

	level of low concern (10^{-5}).
Non-professional users	Not relevant
Indirect exposure as a result of use	Not relevant

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Not applicable for creosote (PAH compounds not expected to be hydrolytically degraded).
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not applicable for creosote. Direct photochemical transformation (latitude 40°N, midday, midsummer) for different PAH compounds in creosote: Compound / DT_{50} (h) / Quantum yield x 10^3 Naphthalene 71 15±1 1-Methylnaphthalene 22 18±1 2-Methylnaphthalene 54 5.3±0.2 Phenanthrene 8.4 10±1.6 Anthracene 0.75 3.0±0.2 9-Methylanthracene 0.13 7.5±0.5 9,10-Methylanthracene 0.35 4.0±0.4 Pyrene 0.68 2.0±0.3 Fluoranthene 21 0.12±0.001 Chrysene 4.4 2.8±0.7 One major transformation product of PAHs seems to be quinone derivatives.
Readily biodegradable (yes/no)	No
Disappearance in water	Dissipation DT_{50} = 30 d for creosote and individual creosote components.
Biodegradation in water / sediment systems	Not applicable for creosote. Mineralisation half-lives (at 22 °C) and total percentage mineralised of ^{14}C-labelled PAHs after 56 days. Values in brackets for 2-methylnaphthalene and phenanthrene show estimated half-lives as given in the study report: DT_{50}, days / % mineralised Naphthalene 30.8 54.5 2-Methyl-naphthalene >56 (140) 18.8 phenanthrene >56(126) 22.3 Pyrene nd <0.2

	nd = no mineralisation detected.
Non-extractable residues	Not applicable for creosote. Between approx. 2% for naphthalene / methylnaphthalene to 7.5% for phenanthrene (56 days).
Distribution in water / sediment systems (active substance)	Not applicable for creosote. For naphthalene, methylnaphthalene, phenanthrene and pyrene: Between 3.1 and 8.4% was found in the water phase and between 8.2 and 75% was found in the sediment phase. (Measured as recovered ^{14}C in the water and sediment phases, respectively, after 56 d)
Distribution in water / sediment systems (metabolites)	No data (polar metabolites of PAHs accounted for 0.1 to 6% of the original PAHs).

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	No data
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not applicable for creosote. For PAHs the following half-lives were determined (highest value of two soils) at 20 °C: DT_{50} (d) Naphthalene 2.2 1-Methylnaphthalene 2.2 Phenanthrene 35 Anthracene 134 Fluoranthene 377 Pyrene 260 Benz[a]anthracene 261 Chrysene 387 The kinetic calculations resulting in first order rate constants and half-lives gave r^2 values ranging from 0.71-0.95 and 0.57-0.93 for the two soils, respectively
Field studies (state location, range or median with number of measurements)	No data
Anaerobic degradation	No degradation could be measured in anaerobic soil
Soil photolysis	No data
Non-extractable residues	No data

Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data

Adsorption/desorption (Annex IIA, point VII.7.7; Annex IIIA, point XII.1.2)

Ka, Kd

Ka_{oc}, Kd_{oc}

pH dependence (yes / no) (if yes type of dependence)

Data on log K_{ow}- and log K_{oc} values for 42 single components present in creosote have been compiled and presented in the report.

The log K_{ow}- and log K_{oc} values for single components were weighted by their content in creosote (in percent), in order to estimate the corresponding partition coefficients for the different creosote oils, respectively.

Creosote Oil	Log K_{ow}	Log K_{oc}	Proportion of creosote used in the estimate [a]
Composite Grade B	4.12	3.67	61%
Grade B	4.43	3.97	58%
Grade C	4.63	4.17	53%

[a] The total sum of all analysed/identified compounds in the oils were approx. 65, 63 and 57% for „composite Grade B", Grade B and Grade C, respectively (see Document III-A1-2).

No pH dependence of partition coefficients.

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	No data
Quantum yield of direct photolysis	No data
Photo-oxidative degradation in air	Not applicable for creosote. Half-lives of selected PAHs due to gas-phase reactions with hydroxyl (OH) radicals and nitrate (NO_3) radicals for hypothetical summertime conditions in clean air:

	DT_{50} (OH)	DT_{50} (NO_3)
Naphthalene	4.0 h	10 years
1-Methylnaphthalene	2.4 h	5 years
2-Methylnaphthalene	1.9 h	3 years
1-Ethylnaphthalene	2.8 h	3 years
2-Ethylnaphthalene	2.4 h	5 years
Dimethylnaphthalenes	1.2-1.7 h	0.1-3 years

Acenaphthylene	0.76 h	4.2 min
Acenaphthene	1.2 h	0.97 h
Fluorene	6.9 h	20 h
Phenanthrene	5.3 h	3.0 h

Volatilization

A laboratory study simulated emissions to air during storage of creosote treated timber. For this purpose, a climate–controlled enclosure was constructed into which test pieces of wood were placed. The air in the enclosure was circulated. There was constant supply of clean air and equal amount of air was extracted from the enclosure. The emissions were measured for their content of 21 PAHs by sampling the extracted air. The results showed that the loss rate of creosote (estimated from ΣPAH conc.) to air was approximately 8-74 mg/m² wood and day.

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)

No data for creosote.

PAH concentrations in soil at various depths and distances from creosote treated utility poles in service were determined in the USA (EPI, 1997; III- A2.10.2/12). The age of the poles ranged from less than 5 years to 40 years although most of the poles of the study were less than 20 years old. Twenty-two pole sites were investigated and from each site 40-44 samples were analysed for their content of 18 PAHs. Median ΣPAH concentrations of all maximum values at each distance (independent of depth) from each pole site:

Distance from the pole	Median creosote[1] concentration (mg/kg wet weight)
7.6 cm	3320
20.3 cm	973
45.7 cm	7.1
76.2 cm	4.0
122 cm	0.25 [2]

[1] Assuming that the proportion of the PAHs analysed was 40% of the creosote content.

[2] Background levels of ΣPAHs.

Surface water (indicate location and type of study)

No data for creosote.

In Sooke Basin, British Colombia, Canada, sea water concentrations of PAHs were measured with SPMD (semi-permeable membrane device)

	adjacent to underwater constructions (piling sites = dolphins) made of creosote treated wood (Goyette and Brooks, 1998 and 2002; III-A2.10.2/10). The highest water concentration of creosote (estimated from ΣPAH conc.) was 0.08 µg/l approx. 6 months after construction.
Sediment (indicate location and type of study)	In Sooke Basin, British Colombia, Canada, surface sediment concentrations of 16 PAHs were measured adjacent to underwater constructions (piling sites = dolphins) made of creosote treated wood (Goyette and Brooks, 1998 and 2002; III-A2.10.2/10). The following concentrations of creosote (estimated from Σ16PAH concentrations) were found (mg/kg wet weight):

Day from installation	Day 14	Day 384	Day 14	Day 384
Distance from site	*0.5 m*	*0.5 m*	*1.5 m*	*7.5 m*
Site-BMP*	12	31	1.5	6.3
Distance from site	*0.5 m*	*0.5 m*	*2 m*	*5 m*
Site-WP#	142	17	4.1	3.2

* Newly treated pilings
# Weathered pilings

Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Fish				
O. latipes (fresh water) *Pagrus major* (seawater)	creosote	96 h semi-static	LC_{50}	0.7 mg/l (measured conc. of 19 PAHs)
Brachydanio rerio	PAH-mixture	42 d	$NOEC_{growth}$	0.0021 mg Σ6PAHs/l (m)
Clupea pallasi	creosote from treated wood	9 d	$NOEC_{hatching\ success}$	0.001 mg creosote (Σ Aromatic compounds)/l
B. rerio	phenanthrene/ fluoranthene	28/41 d	$NOEC_{reproduction}$	0.011/0.0044 mg/l (estimated/m)
P. promelas	anthracene	77 d	$NOEC_{reproduction}$	0.006 mg/l (m)
Invertebrates				
Daphnia magna	creosote	48 h	EC_{50}	1.14 mg/l (n)
Mysidopsis bahia	creosote	96 h	LC_{50}	0.018 mg/l (n)
Daphnia magna	anthracene, fluorene, phenanthrene	21 d	$NOEC_{reproduction}$	0.002, 0.015, and 0.018 mg/l
zooplankton community	creosote from treated wood	83 d	$NOEC_{abundance}$	0.011 mg creosote (Σ15PAHs)/l
Algae				
(*Desmodesmus subspicatus*)	creosote	72 h	E_rC_{50} NOEC	2.1 mg/l (measured TOC) 0.9 mg/l (measured TOC)
Sediment dwelling organisms				
Benthic community	creosote from treated wood pilings	1-4 years	NOEC abundance/ diversity	creosote (Σ15PAHs): 10 mg/kg dw = 22 mg/kg ww phenanthrene: 2 mg/kg dw = 4.4 mg/kg ww fluoranthene: 3 mg/kg dw = 6.5 mg/kg ww

				(in ww after conversion to TGD standard susp. matter)
Microorganisms				
Activated sludge	creosote	3 h	EC_{50} resp. inhibition	13 mg/l (TOC/creosote, estimated conc.)

Effects on earthworms or other soil non-target organisms
(Annex IIIA, point XIII.3.2)

	Test substance	Endpoint/toxicity (mg/kg)
Acute toxicity to: earthworms (*E. fetida*)	PAH- or creosote-contaminated soil	LC_{50} (14d): 286-1354 (ΣPAH) (ww)
springtails (*F.candida*)	1-/2-methyl-naphthalene isomer mixture	LC_{50} (14d): 42 (ww)
earthworms (*E. fetida*)	fluorene/phenol	LC_{50} (14d): 51.2/56.6 (ww)
	chrysene	LC_{50} (14d): > 301 (ww) (after conversion to standard TGD soil)
Long-term toxicity to: springtails (*F. candida*)	creosote Grade B	$NOEC_{mortality}$ (28d): 10 (dw) = 3 (ww)
	1-/2-methylnaphthalene isomer mixture	$NOEC_{reproduction}$ (28d): 56 (dw) = 16.8 (ww)
	phenanthrene	$NOEC_{reproduction}$ (28d): <75 (dw) = 22.6 (ww)
potworm (*E. crypticus*)	naphthalene, fluorene, fluoranthene, pyrene, carbazole, dibenzofuran	$NOEC_{reproduction}$ (28d): 11- 36 (dw) = 12- 40 (ww)
	anthracene	$NOEC_{reproduction}$ (28d): >897 (dw) = >690 (ww) (in ww after conversion to standard TGD soil)

dw = dry weight, ww = wet weight

Effects on terrestrial plants (Annex IIIA, point 3.4)

	Test substance	Endpoint/toxicity (mg/kg)
Acute toxicity to: lettuce (*L. sativa*)	PAH-contaminated soil	EC_{50} (5 d): 600 (dw) = 181 (ww) $NOEC_{seed\ germination}$ (5 d): 180 (dw) = 54 (ww) (Σ 9PAH)

tomato	PAH-mixture	$EC_{50growth\ inhibition}$ (20 d): 100 (dw) = 241 (ww) $NOEC_{growth\ inhibition}$ (20 d): 10 (dw) = 24 (ww) (Σ 4PAH/creosote)
red clover, ryegrass, mustard	phenanthrene, pyrene, fluorene, carbazole, dibenzofuran (tested ind.) fluoranthene	$EC_{50growth\ inhibition}$ (14 d): >1000 (dw) = 1100 (ww) $NOEC_{growth\ inhibition}$ (14 d): 10 (dw) = 11.1 (ww)
oat	anthracene	$NOEC_{growth\ inhibition}$ (14 d): 10 (dw) = 15 (ww) (in ww after conversion to standard TGD soil)

dw = dry weight, ww = wet weight

Effects on soil micro-organisms (Annex IIA, point 7.4)

	Test substance	Toxicity (mg/kg)
Nitrogen mineralization	creosote Grade B	NOEC (14 d): 316 (dw) = 373 (ww) NOEC (28 d): 1000 (dw) = 1180 (ww)
	1-/2-metylnaphthalene	NOEC (28 d): 100 (dw) = 80 (ww) (in ww after conversion to standard TGD soil)
Carbon mineralization	creosote Grade B	NOEC (28d): 1000 dw = 1180 ww (in ww after conversion to standard TGD soil)

dw = dry weight, ww = wet weight

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	> 3500 mg creosote/kg (rat)
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	No data
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	No data
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	No data

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Bioconcentration (Annex IIA, point 7.5)

	Creosote substance	BCF
Bioconcentration factor (BCF)	naphthalene 1-methyl-naphthalene 2-methyl-naphthalene phenanthrene anthracene fluoranthene fluorene pyrene	~70 – 1000 ~100 ~140 – 4300 ~1600 ~750 – 5000 ~380 ~540 ~50 – 70
For estimated BCFs based on log K_{ow}, see Doc II-A Table 4.1.3.1-2		
Depuration time (DT_{50})	naphthalenes anthracene fluoranthene	2 days (in oyster) 3 days (in oyster) 5 days (in oyster)
(DT_{95})	Most PAHs in creosote	2-5 days (in fish)
Level of metabolites (%) in organisms accounting for > 10 % of residues	No data	

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Summary of intended uses[4]

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	kg as/m^3 wood min max	water L/m^2 min max	g as/m^2 min max	
Wood rotting fungi	No data	creosote	Basidiomyctes: e.g. Lentinus Coniophora, Polystictus	Creosote EN 13991 Grade B and C	100 %	Pressure impregnation	1	none	40 – 150	--	--	
Please, note that the oil retention rates that have been applied for are 40-150 kg/m^3. RMS has nevertheless been informed during the evaluation process that in order to achieve full efficacy for marine applications, higher retention rates will be required. A full assessment regarding environmental risk characterisation, in the case of marine applications, has therefore to be performed at Member State level.												
Marine borers	No data	creosote	Crustaceae: Limnoria sp., Limnoria tripunctata, Limnoria lignorum / Teredo sp., e.g. Teredo utriculus, Teredo pedicullata	Creosote EN 13991 Grade B and C	100 %	Pressure impregnation	1	none	300 - 400	--	• - -	

(a) *e.g.* biting and suckling insects, fungi, molds;
(b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4);
(d) All abbreviations used must be explained
(e) g/kg or g/l;
(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

4 adapted from: EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
(Doc II-A, 1.4)	US EPA	1984b	Method 625 – Base/neutrals, acids. Methods for organic chemical analysis of municipal and industrial wastewater	Appendix A to Part 136, 40 CFR Part 136.1, US EPA (http://www.epa.gov/waterscience/methods/guide/methods.html)	--	Not appl.	Yes	No	public
(Doc II-A, 1.4)	US EPA	1996b	METHOD 8270C - SEMIVOLATILE ORGANIC COMPOUNDS BY GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS), Rev. 3, Dec. 1996, in: Test Methods for Evaluating Solid Waste	SW-846, Off. of Solid Waste, Washington, D.C. [www.epa.gov/sw-846/pdfs/8720c.pdf]	--	Not appl.	Yes	No	public
(DOC-IIA, 4.2.1.2)	Hooftman RN, Evers-de Ruiter A	1992d	Early life stage tests *with Brachydanio rerio* and several polycyclic aromatic hydrocarbons (Draft OECD Guideline)	TNO/NL	TNO Report IMW-R 92/210, 07 Oct. 1992	yes	no	Yes(i)	Creosote Council Europe
2	CEN (European Committee for Standardization)	2003	Derivatives of coal pyrolysis - Coal tar based oils: creosotes - Specifications and test methods.	CEN	EN 13991, Aug. 2003	--	yes	No	public
A2	RÜTGERS Chemicals AG	2005a	Characterisation of Creosote Grade B and C by gas chromatography: Description of the method, Not GLP, Not Published	RUETGERS Chemicals AG	--	no	no	Y(ii)	Creosote Council Europe

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
A2 A2.7.1/03	RÜTGERS Chemicals AG	2008a	Extended GC-analysis of creosote Not GLP, Not Published	RUETGERS Chemicals AG	--	no	no	Y(ii)	Creosote Council Europe
2.10.1/01	Bookbinder MG	2001	Assessment of potential creosote inhalation and dermal exposure associated with pressure-treatment of wood with creosote,	American Agricultural Services, Inc., Cary, NC, USA	AA990308, 30 January 2001	yes	no	Yes(i)	US Creosote Council III, Inc.
2.10.1/02	Borak J, Sirianni G, Cohen H, Chemerynski S, Jongeneelen F	2002	Biological versus ambient exposure monitoring of creosote facility workers.	J. Occup. Environ. Med., 44, 310-319,	--	no	yes	No	public
2.10.1/02	Jongeneelen FJ, Anzion RBM, Henderson PT	1987	Determination of hydroxylated metabolites of polycyclic aromatic hydrocarbons in urine.	J. Chromatogr., 413, 227-232		no	yes	no	public
2.10.1/03	Elovaara E, Heikkilä P, Pyy L, Mutanenen P, Riihimäki V	1995	Significance of dermal and respiratory uptake in creosote workers: exposure to polycyclic hydrocarbons and urinary excretion of 1-hydroxypyrene.	Occup. Environ. Med., 52, 196-203	--	no	yes	No	public
2.10.1/03	Heikkilä P	2001	Respiratory and dermal exposure to creosote.	University of Kuopio/Finland, Kuopio Univ. Publ. C	Doctoral dissertation	no	yes	No	public
2.10.1/03	Heikkilä PR, Hämeilä M, Pyy L, Raunu, P	1987	Exposure to creosote in the impregnation and handling of impregnated wood	Scand. J. Work Environ. Health, 13, 431-437		no	yes	No	public
2.10.1/03	Jongeneelen FJ, Anzion RBM, Henderson PT	1987	Determination of hydroxylated metabolites of polycyclic aromatic hydrocarbons in urine.	J. Chromatogr., 413, 227-232		no	yes	no	public
2.10.2/01	Havermans JBGA, Homan WJ, Boostra MJ	1993	The shower test method: A leaching test for assessing preservative losses from treated timber under simulated open storage conditions. TNO, Maarsen, Delft/NL	2nd Inter. Symposium on Wood Preservation (Cannes, 08/09 Feb. 1993)	IRG working paper 93-50001	no	yes	No	TNO, Maarsen, Delft/NL
2.10.2/01	Van der Zee ME and Homan WJ	2001	Uitloging van 16 EPA-PAK uit met Imprägnieröl GX verduurzaamd vuren paler met behulp van de doucheproefmethode)	SHR Hout Research/NL	Report 1.242, 26 June 2001	no	no	Yes(i)	Van Swaay Hout

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
2.10.2/01	Van der Zee ME and Homan WJ	2001	Leaching of EPA-16 PAHs from pine posts preserved with Imprägnieröl GX, determined using the Shower Test Method. (English translation)	SHR Hout Research/NL	Report 1.242, 26 June 2001	no	no	Yes(i)	Van Swaay Hout
2.10.2/02	Van Dongen R	1987	Uitloogkarakteristieken van verduurzaamed hout in de opslagfase, Part 1 + 2.	Project: 600736617, Hout Institute, TNO/Delft	Report HI 87.1178, 04 Dec. 1987	no	no	Yes(i)	VROM = Ministerie van Vo kshuisves ting Ruimtelijke Ordening en Milieubeheer
2.10.2/02	Van Dongen R	1987	Leaching characteristics of preserved wood in the storage phase., Part 1 + 2. (English translation)	Project: 600736617, Hout Institute, TNO/Delft	Report HI 87.1178, 04 Dec. 1987	no	no	Yes(i)	VROM = Ministerie van Vo kshuisves ting Ruimtelijke Ordening en Milieubeheer
2.10.2/02	Van Dongen R	1989	Auswaschverhalten von Impraegnieroel (Creosote) aus impraegnierten Kiefern- und Fichtenrundhoelzern während der Lagerung.	TNO, Delft	Summary report in German	no	no	Yes(i)	VROM =Ministerie van Vo kshuisves ting Ruimtelijke Ordening en Milieubeheer
2.10.2/03	Oldeman GJW and Havermans JBGA	1989	Uitlogen verduurzaamd hout na de opslagfase.	Wood Inst. TNO	HI 89.1026	no	no	Yes(i)	VROM = Ministerie van Volkshuisvest ing Ruimtelijke Ordening en Milieubeheer
2.10.2/03	Oldeman GJW and Havermans JBGA	1989	Leaching of preserved wood following the storage phase (English translation)	Wood Inst. TNO	HI 89.1026	no	no	Yes(i)	VROM = Ministerie van Volkshuisvest ing Ruimtelijke Ordening en Milieubeheer

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
2.10.2/03	Van Dongen R	1987	Uitloogkarakteristieken van verduurzaamed hout in de opslagfase, Part 1 + 2.	Project: 600736617, Hout Institute, TNO/Delft	Report HI 87.1178, 04 Dec. 1987	no	no	Yes(i)	VROM = Ministerie van Vo kshuisves ting Ruimtelijke Ordening en Milieubeheer
2.10.2/03	Van Dongen R	1987	Leaching characteristics of preserved wood in the storage phase., Part 1 + 2. (English translation)	Project: 600736617, Hout Institute, TNO/Delft	Report HI 87.1178, 04 Dec. 1987	no	no	Yes(i)	VROM = Ministerie van Vo kshuisves ting Ruimtelijke Ordening en Milieubeheer
2.10.2/04	Homan WJ and Beckers EPJ	1994	Ontwikkeling van een meetmethode voor de vaststelling van de relatieve luchtemissie van gecreosoteerd hout.	Stichting Hout Research (SHR)	Report 93.023, 22 Nov. 1994	no	no	No	VROM/NL
2.10.2/04	Homan WJ and Beckers EPJ	1994	Developing a method for measuring relative air emissions from creosoted timber.) (English translation)	Stichting Hout Research (SHR)	Report 93.023, 22 Nov. 1994	no	no	No	VROM/NL
2.10.2/05	Bestari KTJ, Robinson RD, Solomon KR, Steele TS, Day KE, Sibley PK	1998b	Distribution and composition of polycyclic aromatic hydrocarbons within experimental microcosms treated with creosote-impregnated Douglas fir pilings.	Environ. Toxicol. Chem., 17(12), 2369-2377		no	yes	No	public
2.10.2/06	Ingram LL, McGinnis GD, Gjovik LR and Roberson G	1982	Migration of Creosote and its Components from Treated Piling Sections in a Marine Environment.	J. American Wood-Preservers' Association (AWPA), 1982, 1 - 8		no	yes	No	public
2.10.2/07	Berbee RMP	1989	Onderzoek naar uitloging in oppervlaktewater van PAK en koper, chroom, arseen uit impregneerd hout.	RWS RIZA/NL	Nota-Nr: 89.049	no	no	Yes(i)	RIZA, CINDU, Markerink´s Houtbedrijf

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
2.10.2/07	Berbee RMP	1989	STUDY INTO THE LEACHING OF PAHS AND COPPER, CHROMIUM, ARSENIC TO SURFACE WATER FROM IMPREGNATED WOOD (English translation)	RWS RIZA,NL	Nota-Nr: 89.049	no	no	Yes(i)	RIZA, CINDU, Markerink´s Houtbedrijf
2.10.2/08	Esser PM; Suitela WLD	1993	Emissiebepalingen in 45 jaar oude gecreosoteerde grenen palen, afkomstig van een oeverbeschoeiing in den Lemstervaart	TNO Bouw/Delft	TNO Report 93-CHT-R0940	no	no	Yes(i)	Waterschap Noordoost-polder and R jkswatersta at (RWS), NL
2.10.2/08	Esser PM; Suitela WLD	1993	Emissions from 45-year-old creosoted pine piles taken from canalbank shoring on the Lemstervaart (North-East Polder) (English translation),	TNO Bouw/Delft	TNO Report 93-CHT-R0940,	no	no	Yes(i)	Waterschap Noordoost-polder and R jkswatersta at (RWS), NL
2.10.2/09	Brooks KM	2000	Assessment of the Environmental Effects Associated With Wooden Bridges Preserved With Creosote, Pentachlorophenol, or Chromated Copper Arsenate	United States Department of Agriculture, Forest Service, Forest Products Laboratory, Madison	Research Paper FPL-RP-58 September 2000	no	no	No	US Department of Agriculture, WI/USA
2.10.2/10	Goyette D and Brooks KM	1998	Creosote Evaluation: Phase II - Sooke Basin Study - Baseline to 535 days post construction 1995-1996.	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR98-04, Dec. 1998	no	yes	No	Environment Canada
2.10.2/10	Goyette D and Brooks KM	2001	Continuation of the Sooke Basin Creosote Evaluation Study (Goyette and Brooks, 1998). Year Four - Day 1360 and Day 1540	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR00-03, 12 May 2001	no	yes	No	Environment Canada

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
2.10.2/11	Brooks KM	2004a	Environmental Response to Creosote Treated Wood Structures in Puget Sound, Washington, Report sponsored by Creosote Council II, USA, 20 Jan. 2004	Aquatic Environmental Sciences, Port Townsend, Washington		no	no	Yes(i)	US Creosote Council III, Inc.
2.10.2/12	Electric Power Research Institute (EPRI)	1997	Pole Preservatives in Soils Adjacent to In-Service Utility Poles in the United States	EPRI Projects 2879 and 9024, ESEERCO Project EP92-37, EPRI Distribution Center, Pleasant Hill, CA, USA	Final Report TR-108598	no	no	Yes(i)	US Creosote Council III, Inc.
2.10.2/13	Brooks KM	2002a	Final Report: Evaluation of Polycyclic Aromatic Hydrocarbon Migration from Railway Ties into Ballast and Adjacent Wetlands	Midwest Generation Corporate EH&S Group, Chicago		no	no	No	Midwest Generation Corp. EH&S Group, USA
2.10.2/13	Brooks KM	2004b	Polycyclic aromatic hydrocarbon migration from creosote-treated railway ties into ballast and adjacent wetlands	Madison, WI: U.S. Department of Agriculture, Forest Service, Forest Products Laboratory	Res. Pap. FPL-RP-617	no	no	No	US Department of Agriculture, WI/USA
3	CEN (European Committee for Standardization)	2003	Derivatives of coal pyrolysis - Coal tar based oils: creosotes - Specifications and test methods	CEN	EN13991, Aug. 2003	no	no	no	public
3	RÜTGERS Chemicals AG	2008b	Analysis of three Creosote samples according to EN 13991 Not GLP, Not Published	RÜTGERS Chemicals AG	--	no	no	Y (ii)	Creosote Council Europe
3.2	BUA (Beratergremium für umweltrelevante Stoffe, GDCh)	1990	Methylnaphthaline	VCH, Weinheim	BUA-Stoffbericht No. 47, March 1990	no	yes	no	public
3.2	RUETGERS Chemicals AG	2004a	Internal report on the determination of the vapour pressure curves of Grade B and C in comparison	RUETGERS Chemicals AG		no	no	Yes(ii)	Creosote Council Europe
3.2.1	ATSDR (Agency for Toxic Substances and Disease Registry)	1995	Toxicological Profile for Polycyclic Aromatic Hydrocarbons (Update).	U.S. DHHS (http://www.atsdr.cdc.gov/toxprofiles/)		no	yes	No	public

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
3.2.1	ECB (European Chemicals Bureau)	2003	Risk Assessment Report NAPHTHALENE CAS No: 91-20-3, EINECS No: 202-049-5, European Union, 2003 [naphthalenereport020]	European Union, 2003 [naphthalenereport020]	Vol 33	no	yes	no	public
3.2.1	WHO (World Health Organization)	1998	Selected non-heterocyclic polycyclic aromatic hydrocarbons. Environmental Health Criteria, 202, Not GLP, Published	Environmental Health Criteria, 202,	---	no	no	no	public
3.2.1	Mackay D, Shiu WY	1981	A critical review of Henry´s Law Constants for chemicals of environmental interest	J. Phys. Chem. Ref. Data, 193, p. 1188, American Chemical Society		no	yes	No	public
3.5/01	Inst. Fresenius	2002a	Study on the toxicity towards algae of creosote		Study-No. IF-101/38792-00	yes	no	Yes(ii)	Creosote Council Europe
3.5/01	LAUS GmbH	2004	Determination of the water solubility of creosote ,	LAUS GmbH, Neustadt/ Germany	Final Report No. AB0480401 G910, 24 Sep. 2004	yes	no	Yes(ii)	Creosote Council Europe
3.5/01	Steinhaeuser KG, Kunz C, Amann W, Schößer I	1989	Chemische Zusammensetzung und Leuchtbakterientoxizitaet wässriger Auszuege von Mineraloelprodukten und Teererzeugnissen.	Vom Wasser, 72, 93-108		no	yes	no	public
3.5/01	Steinhaeuser KG, Kunz C, Amann W, Schößer I	1989	Chemical Composition and Toxicity on Luminescent Bacteria of Water Soluble Fractions of Petroleum and Coal Tar Products (English translation)	Vom Wasser, 72, 93-108		no	yes	no	public
3.5/02	Inst. Fresenius	2002a	Study on the toxicity towards algae of creosote		Study-No. IF-101/38792-00	yes	no	Yes(ii)	Creosote Council Europe
3.5/03	SINTEF	2006	Chemical analysis of Water Accommodated Fraction (WAF) from three different Creosote samples.	SINTEF Materials and Chemistry, Trondheim/ Norway	Report No. STF80MK F0619614, July 2006	no	no	Yes(ii)	Creosote Council Europe

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
3.5/04	ATSDR (Agency for Toxic Substances and Disease Registry)	1995	Toxicological Profile for Polycyclic Aromatic Hydrocarbons (Update).	U.S. DHHS (http://www.atsdr.cdc.gov/toxprofiles/)		no	yes	no	public
3.5/04	Miller MM, Was k P, Huang G-L, Shiu W-Y, and Mackay D	1985	Relationships between octanol-water partition coefficient and aqueous solubility	Environ. Sci. Technol., 19, 522-529		no	yes	no	public
3.5/04	WHO (World Health Organization)	1998	Selected non-heterocyclic polycyclic aromatic hydrocarbons. Environmental Health Criteria, 202,	Intern. Programme on Chemical Safety (IPCS), WHO/ Geneva	Environmental Health Criteria, 202	no	yes	no	public
3.9/01	Sparacino CM	1999a	Product chemistry - North American composite test material CTM creosote P1/P13, Res. Triangle Inst., (US study)	Res. Triangle Inst.	Report No. 70C-6939-001, 29 Jan. 1999	yes	no	Yes(i)	US Creosote Council III, Inc.
3.9/01	Sparacino CM	1999b	Product chemistry - North American composite test material CTM creosote P2, Res. Triangle Inst, (US study)	Res. Triangle Inst.	Report No. 70C-6939-001, 29 Jan. 1999	yes	no	Yes(i)	US Creosote Council III, Inc.
3.9/02	ATSDR (Agency for Toxic Substances and Disease Registry)	1995	Toxicological Profile for Polycyclic Aromatic Hydrocarbons (Update).	U.S. DHHS (http://www.atsdr.cdc.gov/toxprofiles/)		no	yes	no	public
3.9/02	ECB (European Chemicals Bureau)	2003	Risk Assessment Report NAPHTHALENE CAS No: 91-20-3, EINECS No: 202-049-5	European Union, 2003 [naphthalenereport020]	Vol. 33	no	yes	no	public
3.9/02	Miller MM, Was k P, Huang G-L, Shiu W-Y, and Mackay D	1985	Relationships between octanol-water partition coefficient and aqueous solubility	Environ. Sci. Technol., 19, 522-529		no	yes	no	public
3.9/02	WHO (World Health Organization)	1998	Selected non-heterocyclic polycyclic aromatic hydrocarbons. Environmental Health Criteria, 202,	Intern. Programme on Chemical Safety (IPCS), WHO/ Geneva	Environmental Health Criteria, 202	no	yes	no	public

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
4.1	DIN (Deutsches Institut für Normung)	2004	Testing of mineral oil hydrocarbons, similar liquids and solvents for paints and varnishes – Analysis by gas chromatography – General working principles (German)	Deutsches Institut für Normung	DIN 51405, Jan. 2004	no	yes	No	public
4.1/01	CEN (European Committee for Standardization)	1995a	Wood preservatives - Creosotes and creosoted timber - Methods of sampling and analysis - Part 4: Determination of the water-extractable phenols content of creosote	European Committee for Standardization	EN 1014-4, July 1995	no	yes	no	public
4.1/02	CEN (European Committee for Standardization)	1997b	Wood preservatives: Creosote and creosoted timber - Methods of sampling and analysis. Part 3: Determination of the benzo[a]pyrene content of creosote	European Committee for Standardization	EN 1014-3, Aug. 1997	no	yes	no	public
4.1/03	RUETGERS Chemicals AG	2005a	Characterisation of Creosote Grade B and C by gas chromatography: Description of the method,	RUETGERS Chemicals AG	Report M. Levering, 12 Jan. 2005	no	No	Yes(ii)	Creosote Council Europe
4.1/04	RUETGERS Chemicals AG	2005b	Extended GC-analysis of creosote	RUETGERS Chemicals AG	Report M. Levering, 05 Dec. 2005	No	No	Yes(ii)	Creosote Council Europe
4.1/05	RÜTGERS Chemicals AG	2008a	Extended GC-analysis of creosote Not GLP, Not Published	RÜTGERS Chemicals AG	--	no	no	Yes(ii)	Creosote Council Europe
4.2/01	CEN (European Committee for Standardization)	1995b	Wood preservatives - Creosotes and creosoted timber - Methods of sampling and analysis - Part 2: Procedure for obtaining a sample of creosote from creosoted timber for subsequent analysis	European Committee for Standardization	EN 1014-2, Nov. 1995	no	yes	no	public
4.2/02	US EPA (US Environmental Protection Agency)	1984a	Methods for organic chemical analysis of municipal and industrial wastewater. Method 610 - Polynuclear aromatic hydrocarbons.A to Part 136, 40 CFR Part 136	US EPA (http://www.epa.gov/waterscience/methods/guide/methods.html)	Appendix A to Part 136, 40 CFR Part 136.1	no	yes	No	public

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
4.2/03	DIN (Deutsches Institut für Normung)	1995	Substance group analysis (group F) – Determination of six polycyclic aromatic hydrocarbons (PAHs) in water by means of high performance liquid chromatography (HPLC) using fluorescence detection	DIN (Deutsches Institut für Normung)	DIN 38407-8, Oct. 1995	no	yes	No	public
4.2/04	Hartn k T, Norli HR, Eggen T, Breedveld GD	2006	Bioassay-directed identification of toxic organic compounds in creosote-contaminated groundwater	Chemosphere, 66, 435-443, 2006		No	yes	No	public
4.2/05	SINTEF	2006	Chemical analysis of Water Accommodated Fraction (WAF) from three different Creosote samples, 14 July 2006	SINTEF Materials and Chemistry, Trondheim/ Norway	Report No. STF80MK F06196	Yes	No	Yes(ii)	Creosote Council Europe
4.2/06	SINTEF	2006	Chemical analysis of Water Accommodated Fraction (WAF) from three different Creosote samples, 14 July 2006	SINTEF Materials and Chemistry, Trondheim/ Norway	Report No. STF80MK F06196	Yes	No	Yes(ii)	Creosote Council Europe
4.2/07	SINTEF	2006	Chemical analysis of Water Accommodated Fraction (WAF) from three different Creosote samples, 14 July 2006	SINTEF Materials and Chemistry, Trondheim/ Norway	Report No. STF80MK F06196	Yes	No	Yes(ii)	Creosote Council Europe
4.2/07b	RÜTGERS Chemicals GmbH	2007a	GC-Analysis WAF (Water Accommodated Fraction) of Creosote	RÜTGERS Chemicals GmbH	Report M. Levering, 30 June 2007	No	No	Yes(ii)	RÜTGERS Chemical GmbH
4.2/08	Borak J, Sirianni G, Cohen H, Chemerynski S, Jongeneelen F	2002	Biological versus ambient exposure monitoring of creosote facility workers.	J. Occup. Environ. Med., 44, 310-319,	--	no	yes	No	public
4.2/08	Jongeneelen, FJ, Anzion RBM, Henderson PT	1987	Determination of hydroxylated metabolites of polycyclic aromatic hydrocarbons in urine.	J. Chromatogr., 413, 227-232	--	No	Yes	No	public
4.2/08	Van Rooij JGM, De Roos JHC, Bodelier-Bade MM, and Jongeneelen FJ	1993	Absorption of polycyclic aromatic hydrocarbons through human skin: differences between anatomical sites and individuals	J. Toxicol. Environ. Health, 38, 355-368	--	No	Yes	No	public
4.2/09	Van Rooij JGM, Vinke E, De Lange J, Bruijnzeel PL, Bodelier-Bade MM, Noordhoek J, Jongeneelen FJ	1995	Dermal Absorption of Polycyclic Aromatic Hydrocarbons in the Blood-Perfused Pig Ear.	J. Appl. Toxicol., 15, 193-200	--	No	Yes	No	public

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4.2/10	Grimmer G, Brune H, Dettbarn G, Heinrich U, Jacob J, Mohtashamipur E, Norpoth K, Pott F, Wenzel-Hartung R	1988	Urinary and faecal excretion of chrysene and chrysene metabolites by rats after oral, intraperitoneal, intratracheal or intrapulmonary application.	Arch. Toxicol., 62, 401-405	--	no	yes	No	public
4.2/10	Grimmer G, Brune H, Dettbarn G, Jacob J, Mohtashamipur E, Norpoth K, Pott F, Wenzel-Hartung R	1990	Urinary and fecal excretion of phenanthrene and phenanthrols by rats following oral, intraperitoneal, or intrapulmonary application.	Polycyclic Aromat. Compd, 2, 39-47	--	no	yes	No	public
4.2/10	Jacob J, Brune H, Dettbarn G, Grimmer G, Heinrich U, Mohtashamipur E, Norpoth K, Pott F, Wenzel-Hartung R	1989	Urinary and faecal excretion of pyrene and hydroxypyrene by rats after oral, intraperitoneal, intratracheal or intrapulmonary application.	Cancer Lett., 46, 15-20	--	no	yes	No	public
4.2/10	Jacob J, Grimmer G	1987	Capillary gaschromatographical analysis of mass spectrometric identification of polycyclic aromatic hydrocarbons metabolites from biological materials	Rev. Anal. Chem., 9, 49-89	--	No	Yes	No	public
4.2/11	Grimmer G; Jacob J; Naujack KW	1997	Atmospheric emission of polycyclic aromatic hydrocarbons in sampling areas of the German environmental specimen bank. Method for the precise measurement of gaseous and particulate-associated polycyclic aromatic hydrocarbons in the sub-nanogram range using deuterated internal standards	Chemosphere, 34, 2213-2226		no	yes	No	public
4.2/12	Bookbinder MG	2001	Assessment of potential creosote inhalation and dermal exposure associated with pressure-treatment of wood with creosote,,	American Agricultural Services, Inc., Cary, NC, USA	US study: No. AA990308, 30 January 2001	yes	No	Yes(i)	US Creosote Council III, Inc.
4.2/13	Heikkilä P	2001	Respiratory and dermal exposure to creosote.	University of Kuopio/Finland, Kuopio Univ. Publ. C	Doctoral dissertation	no	yes	No	public

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4.2/13	Heikkilä PR, Hämeilä M, Pyy L, Raunu, P	1987	Exposure to creosote in the impregnation and handling of impregnated wood	Scand. J. Work Environ. Health, 13, 431-437		no	yes	No	public
4.2/14	Heikkilä P	2001	Respiratory and dermal exposure to creosote.	University of Kuopio/Finland, Kuopio Univ. Publ. C	Doctoral dissertation	no	yes	No	public
4.2/14	Heikkilä PR, Hämeilä M, Pyy L, Raunu, P	1987	Exposure to creosote in the impregnation and handling of impregnated wood	Scand. J. Work Environ. Health, 13, 431-437		no	yes	No	public
4.2/15	Bookbinder MG	2001	Assessment of potential creosote inhalation and dermal exposure associated with pressure-treatment of wood with creosote,,	American Agricultural Services, Inc., Cary, NC, USA	US study: No. AA990308, 30 January 2001	yes	No	Yes(i)	US Creosote Council III, Inc.
4.2/16	Meador JP, Casillas E, Sloan CA, Varanasi U	1995	Comparative bioaccumulation of polycyclic aromatic hydrocarbons from sediment by two infaunal invertebrates	Mar. Ecol. Progr. Ser.,123, 107-124		no	yes	No	public
4.2/17	US EPA (US Environmental Protection Agency)	1996c	Method 3540, SOXHLET EXTRACTION, in: Test Methods for Evaluating Solid Waste	SW-846, Rev. 3, Dec. 1996, Off. of Solid Waste, Wash., D.C. [www.epa.gov/sw-846/pdfs/3540b.pdf]	--	Not appl.	Yes	No	public
4.3/01	ATSDR (Agency for Toxic Substances and Disease Registry)	1995	Toxicological Profile for Polycyclic Aromatic Hydrocarbons (Update).	U.S. DHHS (http://www.atsdr.cdc.gov/toxprofiles/)		no	yes	No	public
A5/B5	Boon C	2006	Efficacy of creosote. Note to Levering, M. (RÜTGERS Chemicals AG), 06 July 2006	Vereniging van Houtimpregneerbedr jven in Nederland	--	No	No	No	Creosote Council Europe
A5/B5	CEN (European Committee for Standardization)	2006	Durability of wood and wood-based products - Performance of preventive wood preservatives as determined by biological tests - Part 1: Specification according to use class	CEN	EN 599-1 (Revision Draft	no	yes	No	public

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5	CEN (European Committee for Standardization)	1994	Durability of wood and wood–based products: Natural durability of solid wood – Part 2: Guide to natural durability and treatability of selected wood species of importance in Europe	CEN	EN 350-2, May 1994	no	yes	No	public
5	CEN (European Committee for Standardization)	1996a	Durability of wood and wood–based products: Performance of preventive wood preservatives as determined by biological tests - Part 1: Specification according to hazard	CEN	EN 599-1, May 1996	no	yes	No	public
5	Kohler M, Künninger T, Schmid P, Gujer E, Crockett R, Wolfenberger M	2000	Inventory and emission factors of creosote, polycyclic aromatic hydrocarbons (PAH), and phenols from railroad ties treated with creosote	Environ. Sci. Technol., 34, 4766-4772		no	yes	no	public
5	Kollmann F	1955	Technologie des Holzes und der Holzwerkstoffe	Springer-Verlag, Berlin, Heidelberg		no	yes	no	public
5	Pitman AJ, Sawyer GS, Daniel G	1995	The attack of naturally durable and creosote treated timbers by *Limnoria tripunctatum* Menzies. 26th Annual Meeting, Helsinki 11-16 June 1995,	IRG Secretariat, Stockholm		no	No	No	public
5.3	CEN (European Committee for Standardization	1997a	Wood preservatives: Accelerated ageing of treated wood prior to biological testing - Leaching procedur	CEN	EN 84, Jan. 1997	no	yes	No	public
5.3	CEN (European Committee for Standardization)	1996b	Wood preservatives: Test method for determining the protective effectiveness against wood destroying basidiomycetes - Determination of the toxic value	CEN	EN 113, Sep. 1996	no	yes	No	public
5.3	CEN (European Committee for Standardization)	2001a	Wood preservatives: Determination of the effectiveness against soft rotting micro-fungi and other soil inhabiting microorganisms	CEN	ENV 807, May 2001	no	yes	No	public
5.3	CEN (European Committee for Standardization)	2005	Wood preservatives: Determination of the toxic value against larvae of *Hylotrupes bajulus* (Linnaeus) (Laboratory method).	CEN	EN 47, March 2005	no	yes	No	public

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5.3	DIN (Deutsches Institut für Normung)	1972	Bestimmung der vorbeugenden Wirkung von Holzschutzmitteln: Prüfung mit holzzerstörenden Basidiomyceten nach dem Klötzchen-Verfahren in Kolleschalen	DIN	DIN 52176, Sep. 1972	No	yes	No	public
B.5	DIN (Deutsches Institut für Normung)	1972	Bestimmung der vorbeugenden Wirkung von Holzschutzmitteln: Prüfung mit holzzerstörenden Basidiomyceten nach dem Klötzchen-Verfahren in Kolleschalen	DIN	DIN 52176, Sep. 1972	No	yes	No	public
B5	CEN (European Committee for Standardization	1997a	Wood preservatives: Accelerated ageing of treated wood prior to biological testing - Leaching procedure	CEN	EN 84, Jan. 1997	no	yes	No	public
B5	CEN (European Committee for Standardization)	1988	Wood preservatives: Accelerated ageing of treated wood prior to biological testing - Evaporative ageing procedure	CEN	EN 73, Nov. 1988	no	yes	No	public
B5	CEN (European Committee for Standardization)	1992	Wood preservatives: Determination of the protective effectiveness against marine borers	CEN	EN 275, Sep. 1992	no	yes	No	public
B5	CEN (European Committee for Standardization)	1994	Durability of wood and wood–based products: Natural durability of solid wood – Part 2: Guide to natural durability and treatability of selected wood species of importance in Europe	CEN	EN 350-2, May 1994	no	yes	No	public
B5	CEN (European Committee for Standardization)	1996a	Durability of wood and wood–based products: Performance of preventive wood preservatives as determined by biological tests - Part 1: Specification according to hazard	CEN	EN 599-1, May 1996	no	yes	No	public
B5	CEN (European Committee for Standardization)	1996b	Wood preservatives: Test method for determining the protective effectiveness against wood destroying basidiomycetes - Determination of the toxic value	CEN	EN 113, Sep. 1996	no	yes	No	public
B5	CEN (European Committee for Standardization)	2001a	Wood preservatives: Determination of the effectiveness against soft rotting micro-fungi and other soil inhabiting microorganisms	CEN	ENV 807, May 2001	no	yes	No	public

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B5	Kohler M, Künninger T, Schmid P, Gujer E, Crockett R, Wolfenberger M	2000	Inventory and emission factors of creosote, polycyclic aromatic hydrocarbons (PAH), and phenols from railroad ties treated with creosote	Environ. Sci. Technol., 34, 4766-4772		no	yes	no	public
B5	Kollmann F	1955	Efficacy test against termites excerpt (p. 91) from: Technologie des Holzes und der Holzwerkstoffe. Springer-Verlag, Berlin, Heidelberg 1955 (Engl. Translation)	Springer-Verlag, Berlin, Heidelberg		no	yes	no	public
B5	Kollmann F	1955	Technologie des Holzes und der Holzwerkstoffe	Springer-Verlag, Berlin, Heidelberg		no	yes	no	public
B5	Pitman AJ, Sawyer GS, Daniel G	1995	The attack of naturally durable and creosote treated timbers by *Limnoria tripunctatum* Menzies. 26th Annual Meeting, Helsinki 11-16 June 1995,	IRG Secretariat, Stockholm		no	No	No	public
B5.10	CEN (European Committee for Standardization)	2001a	Wood preservatives: Determination of the effectiveness against soft rotting micro-fungi and other soil inhabiting micro-organisms.	CEN	ENV 807, May 2001	no	No	No	public
B5.10/01	Boenigk W, Behr H, Komora F	1996	Verbesserte Umweltverträglichkeit teerstämmiger Holzschutzmittel	. Holz-Zentralblatt 23 (21 Feb. 1996), p. 357/364		no	yes	No	public
B5.10/01	Boenigk W, Behr H, Komora F	1996	Better environmental compatability of tar-based wood preservatives(English translation)	Holz-Zentralblatt 23 (21 Feb. 1996), p. 357/364		no	yes	No	public
B5.10/01	Komora F	1999	Teeröle für den chemischen Holzschutz unverzichtbar (Part 2)	Holz-Zentralblatt 85 (16 July 1999), p. 1210		no	yes	yes	public
B5.10/01	Komora F	1999	Tar oils are indispensible for chemical wood preservation (English translation)	Holz-Zentralblatt 85 (16 July 1999), p. 1210		no	yes	No	public
B5.10/02	Wälchli O	1983	Biologische Wirksamkeit von Steinkohlenteeröl	. Holz als Roh- u. Werkstoff 41, 465-469		no	yes	No	public

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B5.10/02	Wälchli O	1983	Biological Effectiveness of Coal-tar Creosote (English translation)	Holz als Roh- u. Werkstoff 41, 465-469		no	yes	No	public
B5.10/03	Willeitner H	1975	Fungizide Wirkung verschieden gewaschener Steinkohlenteeröle	Holz als Roh- u. Werkstoff 33, 66-70		no	yes	No	public
B5.10/03	Willeitner H	1975	Fungicidal effect of differently washed creosotes (English translation)	Holz als Roh- u. Werkstoff 33, 66-70		no	yes	No	public
B5.10/04	Becker G	1950	Der Wert von Steinkohlenteer-Bestandteilen für den Holzschutz.	Bitumen, Teere, Asphalte, Peche, 1, 93-101		no	yes	no	public
B5.10/04	Becker G	1950	The value of creosote components for wood preservation (English translation)	Bitumen, Teere, Asphalte, Peche, 1, 93-101		no	yes	no	public
B5.10/04	Kollmann F	1955	Efficacy test against termites excerpt (p. 91) from: Technologie des Holzes und der Holzwerkstoffe. Springer-Verlag, Berlin, Heidelberg 1955 (Engl. Translation)	Springer-Verlag, Berlin, Heidelberg		no	yes	no	public
B5.10/05	NWPC (Nordic Wood Preservation Council)	1993	Marint feltforsøk - resultat etter 10 og 11 år (Marine field test – results after 10 and 11 years),),	NWPC (Nordic Wood Preservation Council)	NTR Informasjon Nr. 29/93, 1993	no	No	yes(ii)	Nordisk Trebeskyttelsesråd (NWPC)
6.1.1	IBR Forschungs GmbH	1987	Akute orale Toxizität an Ratten mit 103.206.	IBR	Projekt No. 1-4-425-87, July 1987	yes	no	Yes(i)	Creosote Council Europe
6.1.1	IBR Forschungs GmbH	1987	Acute Oral Toxicity in Rats with 103.206 (English translation)	IBR	Project No. 1-4-425-87, July 1987	yes	no	yes(i)	Creosote Council Europe
6.1.2	CIT (Centre International de Toxicologie)	1993d	Toxicité aigue par voie dermique chez le rat - Creosote SNCF	CIT (Centre International de Toxicologie)	Report No. 11128 TAR, 01 Dec. 1993	yes	no	Yes(i)	Creosote Council Europe
6.1.3	Hilaski RJ	1993	Acute Inhalation Toxicity Evaluation on North American Creosote Composite P1/P13 in Rats	International Research and Development Corp., Mattawan, Michigan, USA	Study No. 671-005, 10 Nov 1993	yes	no	Yes(i)	US Creosote Council III, Inc.

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6.1.4	CIT (Centre International de Toxicologie)	1993a	Irritation cutanée aigue chez le lapin - Creosote SNCF	CIT (Centre International de Toxicologie)	Report No. 11029 TAL, 01 Dec. 1993	yes	no	Yes(i)	Creosote Council Europe
6.1.4	CIT (Centre International de Toxicologie)	1993b	Irritation oculaire aigue chez le lapin- Creosote SNCF	CIT (Centre International de Toxicologie)	Report No. 11030 TAL, 01 Dec. 1993	yes	no	yes(i)	Creosote Council Europe
6.1.5	CIT (Centre International de Toxicologie)	1993c	Test de sensibilisation cutanée chez le cobaye - Creosote SNCF (sponsored by Elf Atochem)	CIT (Centre International de Toxicologie)	Report No. 11031 TSG, 01 Dec. 1993	yes	no	yes(i)	Creosote Council Europe
6.1.5	Hilaski RJ	1995a	Dermal Sensitization Study (Buehler) on North American Creosote P1/P13 CTM in the A bino Guinea Pig	International Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-026, 5 June 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.2/01	Van Rooij JGM, Vinke E, De Lange J, Bruijnzeel PL, Bodelier-Bade MM, Noordhoek J, Jongeneelen FJ	1995	Dermal Absorption of Polycyclic Aromatic Hydrocarbons in the Blood-Perfused Pig Ear	J. Appl. Toxicol., 15, 193-200		no	yes	No	public
6.2/02	Van Rooij JGM, De Roos JHC, Bodelier-Bade MM, and Jongeneelen FJ	1993	Absorption of polycyclic aromatic hydrocarbons through human skin: Differences between anatomical sites and individuals	J. Toxicol. Environ. Health, 38, 355-368		no	yes	No	public
6.2/03	Moody R, Nadeau B, Chu I	1995	In vitro and in vivo dermal absorption of benzo(a)pyrene in rat, guinea pig, human and tissue-cultured skin	J. Dermatol. Sci., 9, 48-58		no	yes	No	public
6.2/04	Sartorelli P, Cenni A, Matteucci G, *et al*.	1999	Dermal exposure assessment of polycyclic aromatic hydrocarbons: In vitro percutaneous penetration from lubricating oil	Int. Arch. Occup. Environ. Health, 72, 528-532		no	yes	No	public
6.2/05	Withey JR, Law FCP, Endrenyi L	1993	Percutaneous uptake, distribution, and excretion of pyrene in rats	J. Toxicol. Environ. Health, 40, 601-612		no	yes	No	public

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6.2/06	Sanders CL, Skinner C, and Gelman RA	1986	Percutaneous absorption of $^{7,10-14}$C-benzo(a)pyrene and $^{7,12-14}$C-dimethylbenz(a)- anthracene in mice	J. Environ. Pathol. Toxicol. Oncol., 7, 25-34		no	yes	No	public
6.2/07	Dankovic DA, Wright CW, Zangar RC, Springer DL	1989	Complex mixture effects on the dermal absorption of benzo(a)pyrene and other polycyclic aromatic hydrocarbons from mouse skin	J. Appl. Toxicol., 9, 239-244		no	yes	No	public
6.2/08	Chang LH, Young L	1943	The metabolism of acenaphthene in the rat	. J. Biol. Chem., 151, 87-91		no	yes	No	public
6.2/09	Grimmer G; Brune H; Dettbarn G; Jacob J; Mohtashamipur E; Norpoth K; Pott F; Wenzel-Hartung R	1991	Urinary and fecal excretion of phenanthrene and phenanthrols by rats following oral, intraperitoneal, or intrapulmonary application	Polycyclic Aromat. Compd, 2, 39-47		no	yes	No	public
6.2/09	Jacob J; Schmoldt A; Grimmer G	1982a	Influence of monooxygenase inducers on the metabolic profile of phenanthrene in rat liver microsomes	Toxicology, 25, 333-343		no	yes	No	public
6.2/10	Polcaro C, Nicoletti I, Ossicini L, Caponecchi G	1988	Chromatographic and cytogenetic analysis of in vivo metabolites of fluoranthene	J. Chromatogr., 448, 127-133		no	yes	No	public
6.2/11	Day, BW; Sahali Y; Hutchins, DA; Wildschutte M; Pastorelli R; Nguyen TT; Naylor S; Skipper PL; Wishnok JS; Tannenbaum SR	1992	Fluoranthene metabolism: Human and rat liver microsomes display different stereoselective formation of the trans-2,3-dihydrodiol	Chem. Res. Toxicol., 5, 779-786		no	yes	No	public
6.2/12	Jacob J, Brune H, Dettbarn G, Grimmer G, Heinrich U, Mohtashamipur E, Norpoth K, Pott F, Wenzel-Hartung R	1989	Urinary and fecal excretion of pyrene and hydroxypyrene by rats after oral, intraperitoneal, intratracheal or intrapulmonary application	Cancer Lett., 46, 15-20		no	yes	No	public
6.2/12	Jacob J, Grimmer G, Raab G, Schmoldt A	1982b	The metabolism of pyrene by rat liver microsomes and the influence of various mono-oxygenase inducers	Xenobiotica, 12, 45-53		no	yes	No	public

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6.4.2	Hilaski RJ	1995c	North American P1/P13 Creosote 90-Day Subchronic Dermal Toxicity Study in Rats,	Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-013, 13 April 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.4.2	Hilaski RJ	1995e	North American P2 Creosote 90-Day Subchronic Dermal Toxicity Study in Rats,	Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-014, 14 April 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.4.3	Hilaski RJ	1995b	North American P1/P13 Creosote Thirteen Week Subchronic Inhalation Toxicity Study in Rats	International Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-016, 28 March 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.4.3	Hilaski RJ	1995d	North American P2 Creosote CTM: Thirteen Week Subchronic Inhalation Toxicity Study in Rats	International Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-018, 14 April 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.6.1/01	Weill N	1990	Creosote spéciale 14130 - Salmonella typhimurium/mammalian microsome plate incorporation assay (Ames test)	Hazelton	Report No. 001376E, 15. Feb. 1990	yes	no	Yes(i)	Creosote Council Europe
6.6.1/02	CIT (Centre International de Toxicologie)	1993e	Test de mutation reverse sur bacteries Salmonella typhimurium - Creosote SNCF	CIT	Report No. 11032 MMO, 28 Dec. 1993	yes	no	Yes(i)	Creosote Council Europe
6.6.2	Weill N	1991a	Creosote spéciale 14130 - Test to evaluate the induction of chromosome aberrations in human lymphocytes	Hazelton	Report No. 101312, 11 June 1991	yes	no	Yes(i)	Creosote Council Europe
6.6.3	Brightwell J	2002	Creosote - Mutation in L5178TK+/- Mouse Lymphoma Cells (Fluctuation Method),		Final Report No. 9464, Roma, 18 Oct. 2002	yes	no	Yes(ii)	Creosote Council Europe
6.6.4	Weill N	1991b	Creosote spéciale 14130 - Micronucleus test in the mouse	Hazelton	Report No. 005420E, 05. June 1991	yes	no	Yes(i)	Creosote Council Europe

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6.6.6	Mitchell AD	1996a	Rat Dominant Lethal Testing of Creosote P1/P13	Genesys Research, Inc., Durham, North Carolina, USA	Study No. 94038, 8 February 1996	yes	no	Yes(i)	US Creosote Council III, Inc.
6.7	Fraunhofer Institute of Toxicology and Aerosol Research	1997	Dermal Carcinogenicity Study of Two Coal Tar Products (CTP) by Chronic Epicutaneous Application in Male CD-1 Mice (78 Weeks)	Fraunhofer Institute of Toxicology and Aerosol Research	Final Report, Hanover, June 1997	yes	no	Yes(i)	Creosote Council Europe
6.8.1/01	York R	1995a	Developmental Toxicity in Rats - AWPA Creosote P1/P13 CTM	International Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-020, 10 March 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.8.1/02	York R	1995c	Developmental Toxicity in Rats North American P2 Creosote CTM	International Research and Development Corp., Mattawan, Michigan, USA	Report No. 671-022, 10 March 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.8.2	York R	1995b	North American Creosote P1/P13 Two-Generation Reproduction/Fertility in Rats	International Research and Development Corp., Mattawan, Michigan, USA	Study No. 672-006, 13 March 1995	yes	no	Yes(i)	US Creosote Council III, Inc.
6.12	Sapphire Group, Inc	2004	Cancer risk assessment for creosote wood treating workers., (submitted to Antimicrobials Division Office of Pesticide Programs and Toxic Substances (OPPTS), U.S. Environmental Protection Agency Washington, D.C. by Creosote Council III/USA)	The Sapphire Group, Inc., Cleveland, Ohio and Bethesda, Maryland	March 2004	no	no	Yes(i)	US Creosote Council III, Inc.
7.1 – 7.3	Herbes SE, Southworth GR, Shaeffer DL, Griest, WH, Maskarinec, MP	1980	Critical pathways of polycyclic aromatic hydrocarbons in aquatic environments	The Scientific Basis of Toxicity Assessment (Witschi H., ed.), p. 113-128, Elsevier, North-Holland Biomedical Press		no	yes	No	public

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7.1.1.1.2	Herbes SE, Southworth GR, Shaeffer DL, Griest, WH, Maskarinec, MP	1980	Critical pathways of polycyclic aromatic hydrocarbons in aquatic environments	The Scientific Basis of Toxicity Assessment (Witschi H., ed.), p. 113-128, Elsevier, North-Holland Biomedical Press		no	yes	No	public
7.1.1.1.2	WHO (World Health Organization)	1998	Selected non-heterocyclic polycyclic aromatic hydrocarbons,	Intern. Programme on Chemical Safety (IPCS), Geneva	Environmental Health Criteria, 202	no	yes	No	public
7.1.1.1.2/01	Zepp RG, Schlotzhauer PF	1979	Photoreactivity of selected aromatic hydrocarbons in water	Polynuclear Aromatic Hydrocarbons (Jones,PW, Leber P, eds.), 141-158, Ann Arbor Sci. Publ./MI		no	yes	No	public
7.1.1.1.2/02	Lehto KM, Lemmetyinen H, Puhakka J	2000	Biodegradation of photoirradiated polycyclic aromatic hydrocarbon constituents of creosote oil	Environ. Technol., 21, 901-907		no	yes	No	public
7.1.1.1.2/03	Diarra B, Venien F, Le Guayader A, Venien J, Cormier M	1984	Oxydation photoinduite et biodegradation de naphtalenes dans l´eau de mer	Environ. Technol. Lett., 7, 319-332		no	yes	No	public
7.1.1.2	Brooks KM	1995	Computer Model and Assessment of the Potential Environmental Risks Associated With Creosote Treated Wood Products Used in Aquatic Environments		Literature Review April 1995, revised June 1997	no	no	yes(i)	Western Wood Preservers Institute
7.1.1.2.2	Tabak HH, Quave SA, Mashni CI, Barth EF	1981	Biodegradability studies with organic priority pollutant compounds.	J. Water Poll. Control Fed., 53(10), 1504-1518		no	yes	No	public
7.1.1.2.3/01	Männisto MK, Melin ES, Puhakka JA, Ferguson JF	1996	Biodegradation of PAH mixtures by marine sediment enrichment	Polycyclic Arom. Compd., 11, 27-34		no	yes	No	public

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7.1.1.2.3/02	Lee RF; Gardner WS; Anderson JW; Blaylock JW Barwell-Clarke J	1978	Fate of polycyclic aromatic hydrocarbons in controlled ecosystem enclosures	Environ. Sci. Technol., 12, 832-838		no	yes	No	public
7.1.2.2.2/01	Coates, JD; Woodward J; Allen J Philp P; Lovley D	1997	Anaerobic degradation of polycyclic aromatic hydrocarbons and a kanes in petroleum-contaminated marine harbor sediments	Appl. Environ. Microbiol., 63, 3589-3593		no	yes	No	public
7.1.2.2.2/02	Mihelcic JR, Luthy RG	1988a	Degradation of Polycyclic Aromatic Compounds Under Various Redox Conditions in Soil-Water Systems	Appl. Environ. Microbiol., 54, 1182-1187		no	yes	No	public
7.1.2.2.2/02	Mihelcic JR, Luthy RG	1988b	Microbial Degradation of Acenaphthene and Naphthalene under Denitrification Conditions in Soil-Water Systems	Appl. Environ. Microbiol., 54, 1188-1198		no	yes	No	public
7.1.2.2.2/03	McNally DL, Mihelcic JR, Lueking DR	1999	Biodegradation of Mixtures of Polycyclic Aromatic Hydrocarbons under Aerobic and Nitrate-Reducing Conditions	Chemosphere, 38, 1313-1321		no	yes	No	public
7.1.2.2.2/03	McNally DL, Mihelcic JR, Lueking DR	1998	Biodegradation of three- and four-ring polycyclic aromatic hydrocarbons underaerobic and denitrifying conditions	Environ. Sci. Technol., 32, 2633-2639		no	yes	No	public
7.1.2.2.2/04	Johnson K, Ghosh S	1988	Feasability of anaerobic biodegradation of PAHs in dredged river sediments	Water Sci. Technol., 38, 41-48		no	yes	No	public
7.1.2.2/ 01	Bestari KTJ, Robinson RD, Solomon KR, Steele TS, Day KE, Sibley PK	1998a	Distribution and composition of polycyclic aromatic hydrocarbons within experimental microcosms treated with liquid creosote	Environ. Toxicol. Chem., 17(12), 2359-2368		no	yes	No	public
7.1.2.2/ 02	Cerniglia CE; Heitkamp MA	1989	Microbial degradation of polycyclic aromatic hydrocarbons (PAH) in the aquatic environment	Metabol. Polycyclic Aromat. Hydrocarbons Aquat. Environ. (Varanashi U, ed.), 41-68, CRC		no	yes	No	public

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7.1.2.2/ 02	Heitkamp MA; Cerniglia CE	1987	The effects of chemical structure and exposure on the microbial degradation of polycyclic aromatic hydrocarbons in freshwater and estuarine ecosystems	Environ. Toxicol. Chem., 6, 535-546		no	yes	No	public
7.1.3	Burden AN and Curl MG	2002	Creosote - Soil Adsorption Coefficients (Koc)	TSGE, Knaresborough, North Yorkshire/UK	Report No. 13-2-4, 18 Dec. 2002	no	no	YesI(ii)	Creosote Council Europe
7.1.3	Dzombak DA and Luthy RG	1984	Estimating adsorption of polycyclic aromatic hydrocarbons on soils	Soil Sci., 137, 292-308		no	yes	No	public
7.1.4	Meador JP, Casillas E, Sloan CA, Varanasi U	1995	Comparative bioaccumulation of polycyclic aromatic hydrocarbons from sediment by two infaunal invertebrates	Mar. Ecol. Progr. Ser.,123, 107-124		no	yes	No	public
7.2.1/01	Park KS, Sims RC, Dupont RR, Doucette WJ, Matthews JE	1990	Fate of PAH compounds in two soil types: influence of volatilization, abiotic loss and biological activity	Environ. Toxicol. Chem., 9, 187-195		no	yes	No	public
7.2.1/02	Coover MP, Sims RC	1987	The effect of temperature on polycyclic aromatic hydrocarbon persistence in an unacclimated agricultural soil.	Hazardous Waste & Hazardous Materials, 4, 69-82	--	no	yes	No	public
7.2.1/02	Keck J, Sims RC, Coover M, Park K, Symons B	1989	Evidence for cooxidation of polynuclear aromatic hydrocarbons in soil.	Wat. Res., 23, 1467-1476	--	no	yes	No	public
7.2.3	Grenney WJ, Caupp CL, Sims RC	1987	A mathematical model for the fate of hazardous substances in soil: Model description and experimental results	Hazardous Waste & Hazardous Materials, 4, 223-239		no	yes	No	public
7.3.1	Arey J and Atkinson R	2003	Photochemical reactions of PAHs in the atmosphere	PAHs - An Ecotoxicological Perspective / Ecological and Environmental Toxicology Series (Douben PET, ed.), p. 47 – 64, John Wiley & Sons		no	yes	No	public

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7.3.1	Phousongphouang PT, Arey J	2002	Rate constants for the gas-phase reactions of a series of alkylnaphthalenes with the OH radical	Environ. Sci. Technol., 36, 1947-1952		no	yes	No	public
7.3.1	WHO (World Health Organization)	1998	Selected non-heterocyclic polycyclic aromatic hydrocarbons.,), ,	WHO, Intern. Programme on Chemical Safety(IPCS), Geneva	Environmental Health Criteria, 202	no	yes	No	public
7.4.1.1/ 01	SEPC (Société d´Élevage Pisciole Controlé)	1993a	Test to evaluate acute toxicity (96 hours) in freshwater fish (*Brachydanio rerio*) using a static method.Unpublished results	SEPC (Société d´Élevage Pisciole Controlé)	Report No. D154, 08 Nov. 1993	yes	no	Yes(i)	Creosote Council Europe
7.4.1.1/ 02	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	Ecotox. Environ. Safety, 21, 57-67		no	yes	No	public
7.4.1.1/ 02	Yoshida T	1985	Report on fish acute toxicity of creosote, coaltar and coal tar pitch	Chemical Biotesting Center of Chemicals Inspection, Japan, Sep. 1985		no	no	Yes(i)	Creosote Council Europe
7.4.1.1/ 03	Borthwick PW, Patrick JM	1982	Use of aquatic toxicology and quantitative chemistry to estimate environmental deactivation of marine-grade creosote in seawater	Environ. Toxicol. Chem., 1, 281-288		no	yes	No	public
7.4.1.1/ 04	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	Ecotox. Environ. Safety, 21, 57-67		no	yes	No	public
7.4.1.1/ 04	Yoshida T	1985	Report on fish acute toxicity of creosote, coaltar and coal tar pitch	Chemical Biotesting Center of Chemicals Inspection, Japan, Sep. 1985		no	no	Yes(i)	Creosote Council Europe
7.4.1.2/01	SEPC (Société d´Élevage Pisciole Controlé)	1993b	Test to evaluate acute toxicity (48 hours) in daphnia: *Daphnia magna*, (sponsored by Elf Atochem)	SEPC (Société d´Élevage Pisciole Controlé)	Report No. D152 08 Nov. 1993	yes	no	Yes(i)	Creosote Council Europe

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7.4.1.2/02	Borthwick PW, Patrick JM	1982	Use of aquatic toxicology and quantitative chemistry to estimate environmental deactivation of marine-grade creosote in seawater.	Environ. Toxicol. Chem., 1, 281-288		no	yes	No	public
7.4.1.2/03	Borthwick PW, Patrick JM	1982	Use of aquatic toxicology and quantitative chemistry to estimate environmental deactivation of marine-grade creosote in seawater	Environ. Toxicol. Chem., 1, 281-288		no	yes	No	public
7.4.1.2/04	Borthwick PW, Patrick JM	1982	Use of aquatic toxicology and quantitative chemistry to estimate environmental deactivation of marine-grade creosote in seawater.	Environ. Toxicol. Chem., 1, 281-288		no	yes	No	public
7.4.1.2/05	Borthwick PW, Patrick JM	1982	Use of aquatic toxicology and quantitative chemistry to estimate environmental deactivation of marine-grade creosote in seawater.	Environ. Toxicol. Chem., 1, 281-288		no	yes	No	public
7.4.1.3	Inst. Fresenius	2002a	Study on the toxicity towards algae of creosote	Inst. Fresenius	Final report Study-No. IF-101/38792-00, March 2002	yes	no	Yes(i)	Creosote Council Europe
7.4.1.4/01	Inst. Fresenius	2002b	Study on the acute toxicity towards bacteria of creosote	Inst. Fresenius	Final report, Study-No. 1189, 16 April 2002	yes	no	yes(i)	Creosote Council Europe
7.4.1.4/02	Hudak JP, Fuhrman, JA	1988	Effects of four organic pollutants on the growth of natural marine bacterioplankton populations.	Mar. Ecol.: Progr. Ser., 47, 185-194	--	No	no	No	public
7.4.2/01	Roubal WT, Stranahan SI, and Malins DC	1978	The accumulation of low molecular weight aromatic hydrocarbon of crude oil by Coho salmon (*Oncorhynchus kisutch*) and starry flounder (*Platichthys stellatus*)	Arch. Environ. Contam. Toxicol., 7, 237-244		no	yes	No	public

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7.4.2/02	Finger SE, Little EF, Henry MG, Fairchild JF, Boyle TP	1985	Comparison of laboratory and field assessment of fluorene -PART I: Effects of fluorene on survival,. growth, reproduction, and behaviour of aquatic organisms in laboratory tests	Validation and Predictability of Laboratory Methods for Assessing the Fate and Effects of Contaminants in Aquatic Ecosystems (Boyle TP, ed.)	ASTM STP 865, 120-133, Am. Soc. of Testing and Materials, Philadelphia	no	yes	no	public
7.4.2/03	Hall AT and Oris JT	1991	Anthracene reduces reproductive potential and is maternally transferred during long-term exposure in fathead minnows	Aquatic Toxicol., 19, 249-264		no	yes	No	public
7.4.2/04	Gerhart E, Carlson R	1978	Hepatic mixed-function oxidase activity in rainbow trout exposed to several polycyclic aromatic compounds	Environ. Res., 17, 284-295		no	yes	No	public
7.4.2/05	Hooftman RN, Evers-de Ruiter A	1992a	The toxicity and uptake of fluoranthene in *Brachydanio rerio* in an early life stage tests (Draft OECD Guideline)	TNO/NL	TNO Report IMW-R 92/207, 06. Oct. 1992	yes	no	Yes(i)	Creosote Council Europe
7.4.3.2/01	Hooftman RN, Henzen L and Roza P	1993	The toxicity of a polycyclic aromatic mixture in an early stage toxicity test carried out in an intermittent flow-through system	TNO/NL	TNO Report IMW-R 93/253 (1993)	yes	no	Yes(i)	Creosote Council Europe
7.4.3.2/02	Finger SE, Little EF, Henry MG, Fairchild JF, Boyle TP	1985	Comparison of laboratory and field assessment of fluorene -PART I: Effects of fluorene on survival,. growth, reproduction, and behaviour of aquatic organisms in laboratory tests.	Validation and Predictability of Laboratory Methods for Assessing the Fate and Effects of Contaminants in Aquatic Ecosystems (Boyle TP, ed.)	ASTM STP 865, 120-133, Am. Soc. of Testing and Materials, Philadelphia	no	yes	No	public
7.4.3.2/03	Hooftman RN, Evers-de Ruiter A	1991a	The influence of phenanthrene on the early life stages of *Brachydanio rerio* (semi-static test) (Draft OECD Guideline)	TNO/NL	TNO Report R 91/059, 24 Oct. 1991	yes	no	Yes(i)	Creosote Council Europe

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7.4.3.2/03	Hooftman RN, Evers-de Ruiter A	1992b	Investigations into the aquatic toxicity of phenanthrene (Cover report for reproduction tests with the water flea *Daphnia magna* and an Early Life Stage (ELS) test with the zebra fish *Brachydanio rerio*)	TNO/NL	TNO Report R 92/290, 19. Oct. 1992	yes	no	Yes(i)	Creosote Council Europe
7.4.3.2/04	Hooftman RN, Evers-de Ruiter A	1992a	The toxicity and uptake of fluoranthene *in Brachydanio rerio* in an early life stage tests (Draft OECD Guideline)	TNO/NL	TNO Report IMW-R 92/207, 06. Oct1992	yes	no	Yes(i)	Creosote Council Europe
7.4.3.2/05	Hall AT and Oris JT	1991	Anthracene reduces reproductive potential and is maternally transferred during long-term exposure in fathead minnows	Aquatic Toxicol., 19, 249-264		no	yes	No	public
7.4.3.2/06	Hooftman RN, Evers-de Ruiter A	1992c	The toxicity and uptake of benzo[k]fluoranthene using *Brachydanio rerio* in an early life stage tests (Draft OECD Guideline)	TNO/NL	TNO Report IMW-R 92/218, 06. Oct. 1992	yes	no	Yes(i)	Creosote Council Europe
7.4.3.2/07	Vines CA, Robbins T, Griffin FJ, Cherr GN	2000	The effects of diffusible creosote-derived compounds on development in Pacific herring (*Clupea pallasi*)	Aquatic Toxicol., 51, 225-239		no	yes	No	public
7.4.3.3.2/01	Goyette D and Brooks KM	1998	Creosote Evaluation: Phase II - Sooke Basin Study - Baseline to 535 days post construction 1995-1996	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR98-04, Dec. 1998	no	yes	No	Environment Canada
7.4.3.3.2/01	Goyette D and Brooks KM	2001	Continuation of the Sooke Basin Creosote Evaluation Study (Goyette and Brooks, 1998). Year Four - Day 1360 and Day 1540	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR00-03, 12 May 2001	no	yes	No	Environment Canada

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7.4.3.3.2/02	Lee RF; Gardner WS; Anderson JW; Blaylock JW Barwell-Clarke J	1978	Fate of polycyclic aromatic hydrocarbons in controlled ecosystem enclosures	Environ. Sci. Technol., 12, 832-838		no	yes	No	public
7.4.3.3.2/03	Meador JP, Casillas E, Sloan CA, Varanasi U	1995	Comparative bioaccumulation of polycyclic aromatic hydrocarbons from sediment by two infaunal invertebrates	Mar. Ecol. Progr. Ser.,123, 107-124		no	yes	No	public
7.4.3.4/01	Finger SE, Little EF, Henry MG, Fairchild JF, Boyle TP	1985	Comparison of laboratory and field assessment of fluorene -PART I: Effects of fluorene on survival,. growth, reproduction, and behaviour of aquatic organisms in laboratory tests	Validation and Predictability of Laboratory Methods for Assessing the Fate and Effects of Contaminants in Aquatic Ecosystems (Boyle TP, ed.),	ASTM STP 865, 120-133, Am. Soc. of Testing and Materials, Philadelphia	no	yes	No	public
7.4.3.4/02	Hooftman RN	1991b	The influence of phenanthrene on reproduction of *Daphnia magna* (intermittent flow-through system) (OECD Guideline No. 202)	TNO/NL	TNO Report R 91/058, 24 Oct. 1991	yes	no	Yes(i)	Creosote Council Europe
7.4.3.4/03	Holst LL and Giesy JP	1985	Chronic effects of the photoenhanced toxicity of anthracene on *Daphnia magna* reproduction	Environ. Toxicol. Chem., 8, 933-942		no	yes	No	public
7.4.3.4/04	Geiger JG and Buikema AL	1982	Hydrocarbons depress growth and reproduction of *Daphnia pulex* (Cladocera)	Can. J. Fish. Aquatic Sci., 39(6), 830-836		no	yes	No	public
7.4.3.4/05	Geiger JG and Buikema AL	1982	Hydrocarbons depress growth and reproduction of *Daphnia pulex* (Cladocera)	Can. J. Fish. Aquatic Sci., 39(6), 830-836		no	yes	No	public
7.4.3.4/06	Geiger JG and Buikema AL	1982	Hydrocarbons depress growth and reproduction of *Daphnia pulex* (Cladocera)	Can. J. Fish. Aquatic Sci., 39(6), 830-836		no	yes	No	public

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7.4.3.5/01	Goyette D and Brooks KM	1998	Creosote Evaluation: Phase II - Sooke Basin Study - Baseline to 535 days post construction 1995-1996	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR98-04, Dec. 1998	no	yes	No	Environment Canada
7.4.3.5/01	Goyette D and Brooks KM	2001	Continuation of the Sooke Basin Creosote Evaluation Study (Goyette and Brooks, 1998). Year Four - Day 1360 and Day 1540.	Environment Canada, 224 West Esplanade, North Vancouver, British Columbia, Canada V7M 3H7	Regional Program Report PR00-03, 12 May 2001	no	yes	No	Environment Canada
7.4.3.5/02	Brooks KM	2004a	Environmental Response to Creosote Treated Wood Structures in Puget Sound, Washington	Aquatic Environmental Sciences, Port Townsend, Washington	Report 20 Jan. 2004	no	no	Yes(i)	US Creosote Council III, Inc.
7.4.3.5/03	Brooks KM	2000	Assessment of the Environmental Effects Associated With Wooden Bridges Preserved With Creosote, Pentachlorophenol, or Chromated Copper Arsenate.	United States Department of Agriculture, Forest Service, Forest Products Laboratory, Madison, Wisconsin	Research Paper FPL-RP-587, September 2000	no	no	No	US Department of Agriculture, WI/USA
7.4.3.5/04	Tagatz ME, GR Plaia, CH Deans and EM Lores	1983	Toxicity of Creosote-Contaminated Sediment to Field and Laboratory Colonized Estuarine Benthic Communities	Environ. Toxicol. Chem., 2, 441-450		no	yes	No	public
7.5.1.1/01	Scheerbaum D	2007a	Creosote Grade B – Soil microorganisms: carbon transformation test. DR.U.NOACK-LABORATOR EN, Sarstedt/Germany	--	Study No. TBC115081 24 July 2007	Yes	No	Yes(ii)	Creosote Council Europe
7.5.1.1/02	Scheerbaum D	2007b	Creosote Grade B – Soil microorganisms: nitrogen transformation test. DR.U.NOACK-LABORATOR EN, Sarstedt/Germany	--	Study No. TBN115081 24 July 2007	Yes	No	Yes(ii)	Creosote Council Europe

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7.5.1.1/03	BioChem GmbH	1992c	1-/2-Methylnaphthalin 98%: Auswirkungen auf die Aktivität der Bodenmikroflora gemäß BBA-Richtlinie VI, 1-1	BioChem GmbH	Test report 911049009, 28. Aug. 1992	yes	no	Yes(i)	Creosote Council Europe
7.5.1.1/03	BioChem GmbH	1992c	1-/2-Methylnaphthalene 98%: Effect on the Activity of Soil Microflora in accordance with BBA Guideline VI, 1-1 (English translation)	BioChem GmbH	Test report 911049009 28. Aug. 1992	yes	no	Yes(i)	Creosote Council Europe
7.5.1.2/01	BioChem GmbH	1992a	1-/2-Methylnaphthalin 98% - Prüfung auf Toxizität Regenwurm - *Eisenia foetida* (LC50-Test) gemäß OECD-Richtlinie 207, (sponsored by RUETGERSWERKE AG/Germany)	BioChem GmbH	Test report 921049001, 22 April 1992	yes	no	Yes(i)	Creosote Council Europe
7.5.1.2/02	BioChem GmbH	1992a	1-/2-Methylnaphthalene 98% - Test for Toxicity Earthworm – *Eisenia foetidia* (LC 50 Test) in accordance with OECD Guideline 207 (English translation)	BioChem GmbH	Test report 921049001 (22 April 1992)	yes	no	Yes(i)	Creosote Council Europe
7.5.1.2/02	Neuhauser EF, Durkin PR, Malecki MR, Anatra M	1986	Comparative toxcity of ten organic chemicals to four earthworm species	Comp. Biochem. Physiol., 83C, 197-200		no	yes	No	public
7.5.1.2/03	Bowmer CT, Roza P, Henzen L, Degeling C	1993	The development of chronic toxicological tests for PAH contaminated soils using the earthworm *Eisenia foetida* and the springtail *Folsomia candida*	TNO Environment, Energy and Process Innovation	TNO-report R92/387, 05 Oct. 1993	yes	no	Yes(i)	Creosote Council Europe
7.5.1.2/04	Hund K, Traunspurger W	1994	Ecotox-evaluation strategy for soil bioremediation exemplified for a PAH-contaminated site	Chemosphere, 29, 371-390	--	No	Yes	No	public
7.5.1.3/01	Baud-Grasset F, Baud-Grasset S, Safferman SI	1993	Evaluation of the bioremediation of a contaminated soil with phytotoxicity tests	Chemosphere, 26, 1365-1374	--	No	Yes	No	public
7.5.1.3/02	Hulzebos EM, Adema DMM, Dirven-van Breemen EM, Henzen L, van Dis WA, Herbold HA, Hoekstra JA, Baerselman R, van Gestel CAM	1999	Phytotoxicity studies with Lactuca sativa in soil and nutrient solution	Environ. Toxicol. Chem., 12, 1079-1094	--	No	Yes	No	public

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7.5.1.3/03	Maliszewska-Kordybach B, Smreczak B	2000	Ecotoxicological activity of soils polluted with polycyclic aromatic hydrocarbons (PAHs) - effects on plants	Environ. Technol., 21, 1099-1110	--	No	Yes	No	public
7.5.1.3/04	Sverdrup LE, Krogh PH, Nielsen T, Kjcr C, Stenersen J	2003	Toxicity of eight polycyclic aromatic compounds to red clover (Trifolium pratense), ryegrass (Lolium perenne), and mustard (Sinapsis a ba).	Chemosphere, 53, 993-1003	--	No	Yes	No	public
7.5.1.3/05	Mitchell RL, Burchett MD, Pulkownik A, McCluskey L	1988	Effects of environmentally hazardous chemicals on the emergence and early growth of selected Australian plants	Plant Soil, 112, 195-199	--	No	Yes	No	public
7.5.1.3/06	Fiskesjö G	1985	The allium test as a standard in environmental monitoring	Hereditas, 102, 99 - 112		no	yes	No	public
7.5.1.3/06	Sundström G, Larsson A, Tarkpea M	1986	Creosote	Hutzinger O (ed.) Environmental Chemistry; Volume 3 Part D: Anthropogenic Compounds. Berlin, Springer Verlag, 159 - 205		no	yes	No	public
7.5.2.1/01	Bruhnke C	2007	Creosote Grade B - Inhibition of Reproduction of Collembola (Folsomia candida). DR.U.NOACK-LABORATORIEN, Sarstedt/Germany	--	Study No. ICR115081, 28 June 2007	Yes	No	Yes(ii)	Creosote Council Europe
7.5.2.1/02	Droge STJ, Paumen,ML, Bleeker EAJ, Kraak MHS, van Gestel CAM	2006	Chronic toxicity of polycyclic aromatic compounds to springtail Folsomia candida and the enchytraeid Enchytraes crypticus	Environ. Toxicol. Chem., 25, 2423-2431	--	No data	Yes	No	public
7.5.2.1/03	Sverdrup LE, Jensen J, Kelley AE, Krogh PH, Stenersen J	2002c	Effects of eight polycyclic aromatic compounds on the survival and reproduction of Enchytraeus crypticus (Oligochaeta, clitellata)	Environ. Toxicol. Chem., 21, 109-114	--	No data	Yes	No	public
7.5.2.1/04	BioChem GmbH	1992b	Prüfung der Wirkung von 1-/2-Methylnaphthalin auf Reproduktion von Collembolen (NOEC-Test) gemäß BBA-Verfahrensvorschlag BBA-CP 411, 10/91	Biochem GmbH	Test report 921049020, 14 Dec.1992	yes	no	Yes(i)	Creosote Council Europe

Section No.	Authors	Year	Title	Source	Report No.	GLP/GEP (yes/no)	Published (yes/no)	Data Protection Claimed (Yes(i)/Yes(ii)/No)	Owner
7.5.2.1/04	BioChem GmbH	1992b	Test on the Effect of 1-/2-Methylnaphthalene on the Reproduction of Collembol (NOEC Test) in accordance with BBA Procedural Recommendations BBA-CP 411, 10/91 (English translation)	BioChem GmbH	Test report 921049020, 14 Dec.1992	yes	no	Yes(i)	Creosote Council Europe
7.5.2.1/05	Bowmer CT, Roza P, Henzen L, Degeling C	1993	The development of chronic toxicological tests for PAH contaminated soils using the earthworm *Eisenia foetida* and the springtail *Folsomia candida*	TNO Environment, Energy and Process Innovation	TNO-report R92/387, 05 Oct. 1993	yes	no	Yes(i)	Creosote Council Europe
7.5.2.1/06	Bowmer CT, Roza P, Henzen L, Degeling C	1993	The development of chronic toxicological tests for PAH contaminated soils using the earthworm *Eisenia foetida* and the springtail *Folsomia candida*	TNO Environment, Energy and Process Innovation	TNO-report R92/387, 05 Oct. 1993	yes	no	Yes(i)	Creosote Council Europe
7.5.5/01	Bowmer CT, Roza P, Henzen L, Degeling C	1993	The development of chronic toxicological tests for PAH contaminated soils using the earthworm *Eisenia foetida* and the springtail *Folsomia candida*	TNO Environment, Energy and Process Innovation	TNO-report R92/387, 05 Oct. 1993	yes	no	Yes(i)	Creosote Council Europe
7.5.5/02	Bowmer CT, Roza P, Henzen L, Degeling C	1993	The development of chronic toxicological tests for PAH contaminated soils using the earthworm *Eisenia foetida* and the springtail *Folsomia candida*	TNO Environment, Energy and Process Innovation	TNO-report R92/387, 05 Oct. 1993	yes	no	Yes(i)	Creosote Council Europe
7.5.5/03	Allard AS, Malmberg, M, Neilson AH, Remberger, M	2005	Accumulation of polycyclic aromatic hydrocarbons from creosote-contaminated soil in selected plants and the oligochaete worm Enchytraeus crypticus.	J. Environ. Sci. Health A Tox. Hazard Subst., 40, 2057-2072	--	No	Yes	No	public
B7.5	CCE (Creosote Council Europe)	2005	Dissipation of Aromatic Compounds in Environmental Compartments - Calculation Based on the Fugacity Model Level I	Creosote Council Europe	09 March 2005	no	no	Yes(ii)	Creosote Council Europe