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NAPHTHALENE

CAS No: 91-20-3

EINECS No: 202-049-5

Summary Risk Assessment Report

2003 **Special Publication I.03.81**

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2003

United Kingdom

This document has been prepared by the UK rapporteur on behalf of the European Union. The scientific work on the environmental part was prepared by the Building Research Establishment Ltd (BRE), under contract to the rapporteur.

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Date of Last Literature Search:	**1996**
Review of report by MS Technical Experts finalised:	**2001**
Final report:	**2003**

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance naphthalene that has been prepared by the UK in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

1 European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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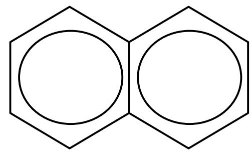
1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 91-20-3
EINECS Number: 202-049-5
IUPAC Name: naphthalene
Synonyms: antimite, naphthalin, naphthene, tar camphor
Molecular weight: 128.18
Molecular formula: $C_{10}H_8$
Structural formula:



1.2 PHYSICO-CHEMICAL PROPERTIES

Table 1.1 Summary of physico-chemical properties

Property	Value	Comments
Physical state at ntp	colourless brown solid	Physical characteristics of solid depends on manufacture
Melting point	80.0-80.3°C	Refers to pure compound – technical material (>95% pure) will have melting point circa 78-80°C
Boiling point	217.9-218°C	Refers to pure compound – technical material will have some variation
Density	1.175 at 25°C	Refers to pure compound – technical material will have some variation
Vapour (sublimation) pressure at 25°C	10.5 Pa	Vapour density is 4.42
Water solubility	0.03 g/l	Practically insoluble
Partition coefficient	3.40 (modified shake flask) 3.73 (modified chromatographic method)	Both values have been accurately measured but the rationale behind the methods is different
Flash point	79°C	Open cup National Fire Protection Association (USA)
	80-88 and 99°C	Closed cup, value of 99°C using method to DIN 51794
Autoignition	526 and 567°C 587°C (per Am. Pet. Inst.)	National Fire Protection Association (USA) gives 526°C
Explosive limits in air % by volume	l=0.9 h=5.9	
Flammability	Oxidising properties	
Explosive properties	Not an oxidising agent	Can be easily oxidised itself, burns readily in air. Violent reaction with CrO_3
Conversion factor	1 ppm = 5.24 mg/m^3	At 25°C and 101.3 kPa

1.3 CLASSIFICATION

The classification and labelling of naphthalene has been agreed at technical levels to be listed in Annex I to Directive 67/548/EEC following the adoption of the 29th Adaptation to Technical Progress, as follows:

Classification	Carc. Cat. 3; R40 Xn; R22 N; R50/53
Labelling	R: 22-40-50/53 S-(2-)36/37-(46-)60-61
R40 states:	Possible risk of irreversible effects Category 3 is for substances which cause concern for humans owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies but this is insufficient to place the substance in Category 2.
R22 states:	Harmful if swallowed
R50 states:	Very toxic to aquatic organisms.
R53 states	May cause long-term adverse effects in the aquatic environment.
S2 states:	Harmful if swallowed
S46 states:	If swallowed, seek medical advice immediately and show this container or label
S36/37 states:	Wear suitable protective clothing/gloves
S60 states:	This material and/or its container must be disposed of as hazardous waste
S61 states:	Avoid release to the environment. Refer to special instructions/safety data sheet

2 GENERAL INFORMATION ON EXPOSURE

There are two sources for the manufacture of naphthalene in the EU. These are coal tar (which accounts for the majority of the production) and petroleum. For the purposes of the assessment the total annual production of naphthalene in the EU has been taken to be 200,000 tonnes based on site-specific information. This figure includes a production tonnage of 20,000 tonnes per annum of "naphthalene oil" which is understood to be at least 90% pure. Lower grade naphthalene oil, containing about 60% naphthalene, has a separate CAS number and has not been considered in the assessment. Companies producing naphthalene are located in the UK, Belgium, France, Italy, Netherlands, Denmark, Germany, Austria and Spain. Production figures from individual producers ranged from 4,000 to 70,000 tonnes per annum.

Figures for the amount of naphthalene used within the EU vary. For the purposes of this assessment a value of approximately 140,000 tonnes per annum has been taken, with the remaining tonnage being exported. This value was derived from the most recent information available for the specific uses summarised in **Table 2.1**.

Table 2.1 Approximate tonnages of naphthalene assumed in the assessment

Process	Approximate annual continental tonnages used in assessment
Phthalic anhydride production	40,000
Manufacture of dyestuffs	46,000
Naphthalene sulphonic acid manufacture	24,000
Alkylated naphthalene solvent production	15,000
2-naphthol production	12,000
Pyrotechnics manufacture	15
Mothballs manufacture	1,000
Grinding wheels manufacture	350

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1.1 Environmental releases

The assessment considers the release of naphthalene to the environment from its production, its use as a chemical intermediate, the formulation and use of pyrotechnics, the formulation and use of mothballs and the production of grinding wheels. Releases of naphthalene to the environment also arise from indirect sources, particularly from vehicle emissions. Releases from these sources have been estimated and included in calculating PECs at the regional and continental levels. The vast majority (~99.5%) of emissions occur initially to air. Emissions from traffic are estimated to account for 87% of the total emissions to air.

3.1.1.2 Environmental fate

Naphthalene is readily volatilised from water. The half-life for volatilisation from water up to 1 m deep is approximately 7 hours. In the atmosphere, naphthalene reacts with hydroxyl radicals and has a half-life of approximately 1 day. It can also react with ozone and N_2O_5. It is expected to adsorb to soils and sediments to a moderate extent. The results of the only standardised screening test for inherent biodegradability suggest that naphthalene is not inherently biodegradable. However, numerous other ‘non-standard’ biodegradation tests suggest that it is easily degraded under aerobic and denitrifying conditions and it has therefore been considered to be inherently biodegradable in the risk assessment. Naphthalene is expected to show a moderate potential bioaccumulation but can be metabolised by a number of organisms. Bioconcentration factors for the whole body and for individual tissues range up to 427 and 1158 respectively.

3.1.1.3 Environmental concentrations

Water

Measured levels of naphthalene in unpolluted surface waters range up to 5 ng/l and in other areas levels up to a few µg/l have been found. Levels of naphthalene in uncontaminated groundwater range up to 0.03 µg/l. The highest level of naphthalene found in marine waters is 300 ng/l. Naphthalene levels in precipitation and drinking water range up to 370 ng/l although elevated levels have been found in drinking water samples from wells near a chemical waste dump in the US. Many measurements are available for contaminated sites where levels range up to 15.3 mg/l. Most of the high levels of naphthalene reflect general urban and industrial activity in which there is likely to be significant indirect production of naphthalene (traffic, combustion etc) rather than the production or use of naphthalene as a substance.

The regional and continental PECs in surface water were estimated to be 0.03 µg/l and 0.0025 µg/l respectively using the EUSES model. These values are consistent with measured values in surface water that is either unpolluted or little affected by industry or urbanisation. Local PECs derived from site-specific information for production and use as an intermediate range up to 0.31 µg/l. This value is consistent with measured levels in surface water associated with urban and industrial sources but is lower than the peak measured levels. Higher values have been calculated based on default emission factors given in the Technical

Guidance Document (TGD). The highest PEC for any process was 294 µg/l for the use of naphthalene in the manufacture of grinding wheels.

Sediment

Naphthalene has been widely detected in surface water sediments with maximum levels exceeding 100 µg/kg in many studies. Levels in sediments from estuarine and coastal sites were generally lower, although peak values again exceed 100 µg/kg. There are no widespread uses of naphthalene to account for its widespread occurrence and the high values were not associated with sites where naphthalene itself is produced or used. The majority of the high values (up to 7,720 mg/kg) found are related to contamination, for example by creosote, where naphthalene is a component in the mixture. The highest value reported for urban areas is 1.47mg/kg for suspended matter at a site near a sewage treatment plant. Other values for urban areas ranged up to 720 µg/kg and are likely to arise from combustion processes. Values of up to 520 µg/kg have been reported for motorway run-offs.

The regional and continental concentrations of naphthalene in sediment were estimated to be 1.0 µg/l and 0.075 µg/l respectively using the EUSES model. The highest PEC for sediment calculated using site-specific information for production and use of naphthalene is 8.7 µg/kg. Higher values have been calculated based on default emission factors given in the TGD. The highest value was 8232 µg/l for the use of naphthalene in the manufacture of grinding wheels.

Soil

The available data indicate that, in uncontaminated soils, mean naphthalene levels are around 10-20 µg/kg. Much higher levels have been found on contaminated sites, the highest found being 400 mg/kg. The vast majority of these sites are contaminated with naphthalene indirectly, for example on gasworks sites or hazardous waste dumps. No values are available for locations close to the production and use sites of naphthalene itself.

The regional and continental PECs for soil calculated using the EUSES model, 0.296 µg/kg and 0.023 µg/kg respectively for agricultural soil. The highest local PEC calculated for production and use of naphthalene as an intermediate based on site-specific data was 1.7 µg/kg. However, a value of 50 µg/kg was calculated for releases from a site where naphthalene is used as an intermediate based on default data. The local PEC calculated for the use of naphthalene in the manufacture of grinding wheels was 4,600 µg/l.

Air

In remote and urban sites levels of naphthalene in the atmosphere ranged up to 11.2 µg/m^3 but at source dominated locations levels up to 415 µg/m^3 were found. PECs calculated for the regional and continental environments are consistent with measured levels found in remote and some urban areas. PECs calculated for the local environment are similar to the high concentrations measured at urban and site dominated locations. The highest calculated PEC derived from site-specific data for naphthalene production and use was 0.9 µg/m^3; the highest generic calculated value was 1.9 µg/m^3 for grinding wheels production.

3.2 EFFECTS ASSESSMENT

3.2.1 Aquatic compartment (incl. sediment)

There are a lot of data available on naphthalene toxicity to a wide range of fish and invertebrate species. All of the organisms tested appear to show similar sensitivity in the short term tests with results generally lying in the range 1-10 mg/l. Longer-term studies give similar LC_{50}s to the short-term tests. The lowest NOEC reported in the literature is 0.12 mg/l. The available data cover two trophic levels and, as all organisms appear to have similar sensitivity in the short-term tests, these can be considered to cover the most sensitive species. Hence a factor of 50 is applied to the lowest value (0.12 mg/l) to give a PNEC of 2.4 µg/l. Toxic effects on nitrifying micro-organisms are observed at naphthalene concentrations of 29 mg/l (IC_{50} for *Nitrosomonas*). Using an assessment factor of 10 leads to a PNEC for microorganisms of 2.9 mg/l.

In the absence of data on the toxic effects on sediment dwelling organisms the value for $PNEC_{sediment}$ has been calculated from the PNEC for water using the equilibrium partitioning method as given in the TGD. This gives a $PNEC_{sediment}$ of 67.2 µg/kg for freshwater.

3.2.2 Terrestrial compartment

Results of toxicity testing for terrestrial organisms are limited. The PNEC for the terrestrial compartment has therefore been calculated from the PNEC for water using the equilibrium partitioning method in the TGD giving a value for the PNEC for soil of 53.3 µg/kg.

3.2.3 Atmosphere

There are no data for the effects of naphthalene on organisms exposed through the atmosphere, but the results of the human health assessment of inhalation toxicity will be considered in the risk characterisation. Naphthalene absorbs strongly in the solar UV region and is not expected to contribute to global warming. The atmospheric lifetime is thought to be approximately 1 day based on measurements of reactions with hydroxyl radicals. It will not contribute significantly to stratospheric ozone depletion. It may contribute to the formation of tropospheric ozone. It is not likely to contribute to acidification in the atmosphere.

3.3 RISK CHARACTERISATION

Realistic worst-case PEC/PNEC ratios are summarised in **Table 3.1**. A ratio greater than 1 indicates a cause for concern.

Table 3.1 Summary of PECs and PEC/PNEC ratios

Release source	Surface water		Sediment		Soil		Air
	PEC (μg/l)	PEC/ PNEC	PEC (μg/kg)	PEC/ PNEC	PEC (μg/kg)	PEC/ PNEC	PEC (μg/m³)
Production (worst case)	0.310	0.13	8.7	0.13	1.7	0.032	0.64
Use as intermediate (site specific)	0.04	0.017	1.1	0.016	1.0	0.019	0.9
use as intermediate	0.042	0.018	1.2	0.018	50	0.94	1.1
Pyrotechnics manufacture	2.35	0.98	66	0.98	36	0.68	0.15
Mothballs manufacture	0.03	0.013	0.83	0.013	1.0	0.019	0.9
Grinding wheels manufacture	294	123	8,232	123	4,600	86	1.9
Regional	0.03	0.013	0.83	0.012	0.3	0.006	0.14

3.3.1 Aquatic compartment (incl. sediment)

The PECs calculated from site-specific data for sites where naphthalene is produced and used as an intermediate indicate that it is unlikely to cause adverse effects in the aqueous compartment as a result of these uses. The highest ratios for such sites (where specific information is available) are 0.13 for both sediment and water. Default emission factors have been used for releases from pyrotechnics formulation and mothball formulation; the highest PEC/PNEC ratio values are 0.98 for both water and sediment, again indicating no concern. Calculations using data from a real site indicate that the use of naphthalene in the manufacture of grinding wheels may cause adverse effects in water and sediment. The PECs calculated for the regional and continental environments suggest that adverse effects on the aquatic compartment will not occur.

The PEC/PNEC ratios for microorganisms suggest that naphthalene is unlikely to cause adverse effects in a treatment plant as a result of production or use as an intermediate, or use in pyrotechnics or mothballs. Use in grinding wheel production may lead to adverse effects.

The very high levels of naphthalene found in waters and sediments at contaminated sites may be expected to cause adverse effects on aquatic organisms with PEC/PNEC ratios for water and sediment ranging up to 5,875 and 124,000 respectively for such sites. These sites are not contaminated through the production or use of naphthalene itself, but through other activities. PEC/PNEC ratios for urban sites range up to 23.6 for sediment and 0.93 for water.

3.3.2 Terrestrial compartment

Based on the available toxicity data for terrestrial organisms, naphthalene is not expected to cause adverse effects in the terrestrial compartment as a result of its production, use as an intermediate, use in pyrotechnics or in mothballs. The PEC/PNEC ratio for use in the production of grinding wheels indicates possible effects on the terrestrial compartment.

Naphthalene has been found at very high levels in soil as a result of indirect naphthalene contamination, for example on gasworks sites or hazardous waste dumps. At these levels it may cause adverse effects as indicated by PEC/PNEC ratios of up to 7.1.

3.3.3 Atmosphere

Levels of naphthalene in the atmosphere as a result of production and direct use are expected to be low. Higher levels have been measured in close proximity to a range of activities which are indirect sources of the substance. The major source of naphthalene in the atmosphere is vehicle exhausts. The human health assessment for inhalation exposure concluded that there was a sufficient margin of safety between the calculated levels of naphthalene in air at local sites and the effect levels. This is considered to also be protective of organisms in the environment. Naphthalene is not thought to contribute to global warming, stratospheric ozone depletion or acidification. It has a photochemical ozone creation potential of 35, and may be a minor contributor to low-level ozone.

3.3.4 Conclusions

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion is based on site-specific data from one plant using naphthalene in the manufacture of grinding wheels. The calculations indicate that the use of naphthalene in this process is likely to cause adverse effects in water and sediment, to microorganisms in the wastewater treatment plant and in the soil compartment. Information from another plant using naphthalene in the manufacture of grinding wheels has indicated that there should be no adverse effects arising from its use at this location.

It is recognised that for both sediment and soil the PNEC used is derived from the surface water PNEC using the equilibrium partitioning method, and so in both of these cases the PNEC could be revised through toxicity testing. However, risks have only been identified for one site using naphthalene for this purpose. This site is developing plans to reduce releases to water, air and sludge so the rapporteur does not think it necessary to require such testing to be carried out. The planned risk management strategy will be based on the above conclusions to ensure that emissions to water (and hence sediment) and sludge are limited.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

This conclusion applies to release of naphthalene to the aquatic (including sediment) and terrestrial compartments from naphthalene production and its use as an intermediate, in pyrotechnics and in mothballs. There is also no risk to microorganisms from production or any of these uses.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

Occupational exposure to naphthalene potentially occurs in the following scenarios:

- manufacture of naphthalene,
- manufacture of phthalic anhydride,
- blending and use of creosote,
- manufacture of moth balls,
- manufacture of grinding wheels,
- manufacture and use of coal tar paints/ membranes,
- during the professional use of consumer products such as creosote products, damp-proofing and coal tar soaps and shampoos.

The industries with the highest occupational inhalation exposures to naphthalene are mothball manufacture, manufacture of grinding wheels and creosote use, particularly bulk impregnation. Blending of creosote and packaging into containers for do-it-yourself use do not result in high exposures as these involve semi-enclosed plant with short duration exposure during specific tasks. Manufacture and use in chemical synthesis also use semi-enclosed plant with exposure during tasks such as sampling and maintenance.

Occupational exposure to both particulate and vapour during mothball manufacture is estimated to range from 5 to 20 mg/m^3 (8-hour TWA). Exposure (8-hour TWA) during the manufacture of grinding wheels is estimated to be up to 3.1 $mg \cdot m^{-3}$ for operations with LEV and up to 20 $mg \cdot m^{-3}$ without LEV, for combined particulate and vapour exposure. A reasonable worst-case occupational exposure to naphthalene for operators exposed during creosote use (bulk impregnation) is about 26 $mg \cdot m^{-3}$ (8-hour TWA).

In relation to dermal exposure, the most prominent exposures are likely to be during mothball manufacture and creosote use. During mothball manufacture workers may be directly handling naphthalene. Exposure was predicted to be 0.1 to 1 $mg \cdot cm^{-2}.day^{-1}$. However, workers use scoops to transfer materials and wear gloves to reduce exposure. Exposure is therefore likely to be at the bottom of the range. The same range is predicted for workers handling creosote, although this will be reduced to 0.025 to 0.25 $mg \cdot cm^{-2}.day^{-1}$ as the maximum concentration of naphthalene is 25%. Due to the unpleasant nature of creosote on the skin including possible irritation it is assumed that workers will wear gloves for most tasks. Dermal exposure at the bottom of the range is therefore likely.

4.1.1.2 Consumer exposure

The potential consumer exposures to naphthalene can be split into continuous daily exposure and one-off infrequent exposure. Continuous exposure results from the use of moth repellents, damp proofing (following laying), and soaps and shampoos. Together, these exposures could produce a daily total of 54.3 mg. Although concurrent exposure to these exposures is unlikely, a reasonable worst-case scenario should include them all.

A consumer could also be exposed infrequently to naphthalene from the use of creosote. An exposure from this use would be 29.6 mg. The laying of a damp proof course could add an extra 108 mg of naphthalene exposure on that particular day.

4.1.1.3 Humans exposed via the environment

The daily intake for humans via the environment based upon typical human consumption and inhalation rates at the regional level is $6.55 \cdot 10^{-5}$ $mg \cdot kg^{-1} \cdot day^{-1}$ and the highest local exposure (manufacture of grinding wheels) is 0.25 $mg \cdot kg^{-1} \cdot day^{-1}$.

4.1.2 Effects assessment

The limited information available in humans indicates that naphthalene is readily absorbed by all exposure routes. Animal data shows that almost complete and rapid absorption occurs following ingestion. In humans, naphthalene is metabolised to naphthol and naphthoquinone. *In vitro* studies in human liver microsomes and human lung preparations indicate that epoxide hydrolase is involved in the metabolic pathway by which naphthalene is metabolised to naphthalene 1,2-dihydrodiol. The urine is the main route of rapid excretion.

There is no information on the effects of naphthalene following acute inhalation or dermal exposure in humans. Acute oral exposure to naphthalene causes haemolytic anaemia, which may be fatal. Rodents are not suitable animal models for the acutely toxic effects of haemolytic anaemia. Naphthalene does not have significant skin or eye irritation potential. There are no concerns for skin or respiratory sensitisation.

There is limited information on the effects of repeated exposure to naphthalene in humans. A principal effect is haemolytic anaemia. Animal studies reveal species differences in response to naphthalene. Haemolytic anaemia was noted in a dog following oral dosing of 220 mg/kg/day for 7 days but not in rodents even with high/prolonged exposures. Although cataract formation has been seen in rats and rabbits (but not mice) following repeated oral exposure, the lack of reliable reports of cataracts in humans despite the widespread use of naphthalene and high dose accidental exposure, suggests that this is unlikely to be a significant health effect in humans. Following repeated inhalation exposure in animals, the main effect is damage to the respiratory tract. Limited signs of nasal olfactory inflammation were reported in a 28-day rat inhalation study at 5 $mg \cdot m^{-3}$. More marked changes in the olfactory epithelium were noted in a 90-day rat inhalation study at the lowest exposure level of 10 $mg \cdot m^{-3}$. These nasal effects became more marked with increasing levels of naphthalene exposure. In a 104-week carcinogenicity study in mice, signs of nasal, olfactory and pulmonary inflammation were noted at 50 $mg \cdot m^{-3}$, the lowest exposure concentration used. A NOAEL could not be identified for local respiratory effects from these studies.

The balance of evidence indicates that naphthalene is not genotoxic. In relation to carcinogenicity, no conclusions can be drawn from the limited information available in humans. The carcinogenic potential of naphthalene has been well investigated in animals. In rats, an increased incidence of respiratory epithelial adenomas and olfactory epithelial neuroblastomas (a very rare tumour type) was observed even with the lowest exposure concentration of 10 ppm. In another study, female mice showed an increased incidence of a benign tumour (alveolar/bronchiolar adenomas), to which this species is prone, following inhalation exposure to naphthalene. Given the negative *in vivo* genotoxicity profile, the tumours are considered to arise via a non-genotoxic mechanism and consideration must therefore be given to other potential mechanisms underlying the carcinogenic response.

Rat nasal tumours develop only at the sites where non-neoplastic inflammatory changes also occur (such as atrophy, hyperplasia and metaplasia). Thus, it is considered that the development of the nasal tumours in the rat is a consequence of chronic tissue injury, for which an identifiable threshold of effect will exist, although currently not identified. Although there is some uncertainty about the relevance of the rat nasal effects to human health, it is not possible to dismiss the findings as being irrelevant for humans. In contrast, the available data indicates that the mouse is more susceptible to the pulmonary toxicity of naphthalene than other species, and the development of mouse lung adenomas is not considered to be of relevance to human health.

In relation to fertility, there is no information available in humans and there are no animal studies specifically investigating such effects. However there are no indications from repeated exposure studies for an effect of naphthalene on the reproductive organs. With respect to developmental toxicity, data from animal studies indicates that naphthalene does not produce adverse effects on the developing offspring except at dose levels that are also toxic to the dam. Overall, there is no concern for adverse effects on reproduction.

4.1.3 Risk characterisation

The endpoints for which there are concerns are haemolytic anaemia, local effects on the respiratory tract following repeated inhalation exposure and carcinogenicity. There are no concerns for irritation, sensitisation, mutagenicity or for effects on reproduction.

In relation to haemolytic anaemia, the available data do not allow the identification of a NOAEL nor the dose-response characteristics for this endpoint. In the absence of such information, it is considered that any significant body burden (values in the mg/kg range) arising from inhalation and/or dermal exposure gives rise to concern.

Workers

There are concerns for haemolytic anaemia, for local effects on the respiratory tract following repeated inhalation exposure, and for carcinogenicity for all occupational scenarios, except the professional use of coal tar soaps and shampoos.

Consumers

In relation to haemolytic anaemia, exposure of infants to textiles (clothing/bedding) that have been stored for long periods with naphthalene moth repellent raises significant concern. However, there are concerns for this endpoint for all consumer exposure scenarios.

In relation to local effects on the respiratory tract following repeated inhalation exposure, and carcinogenicity, there are concerns for exposure from the use of mothballs and for exposures arising after damp-proof laying. There are no concerns for such effects for scenarios which involve single infrequent exposure, nor for scenarios with negligible inhalation exposure i.e. creosote application, damp-proof laying and the use of coal tar soaps and shampoos.

Humans exposed via the environment

For regional exposure, the estimated total daily intake of naphthalene is very low. Given this, there are no concerns for haemolytic anaemia. Similarly, in relation to local effects on the respiratory tract and carcinogenicity, these very low exposures do not cause concern. Exposure in the locality of grinding wheel plants is estimated to result in a much higher daily intake (0.25 mg/kg/day) and is potentially of concern. Since environmental concerns have been identified for this use, it is anticipated that exposures will be reduced as a result of risk reduction measures. Measured exposure data for this scenario should be obtained following risk reduction and used to reconsider the risk to humans via local environmental exposure.

Combined exposure

The potential body burden arising from combined occupational, consumer and indirect environmental exposure gives rise to concerns for haemolytic anaemia. There are also concerns for repeated inhalation toxicity and carcinogenicity for combined exposure and the same conclusions as for workers and consumers apply.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

There are no significant risks from physicochemical properties.

5 RESULTS

5.1 ENVIRONMENT

The environmental risk characterisation considers naphthalene production, its use as an intermediate and its use in the production of mothballs, pyrotechnics and grinding wheels. Local concentrations are estimated for these areas. Calculations for production, use as an intermediate and in grinding wheel production are based on specific information from the relevant industries; those for other uses use default estimates of emissions. In addition, estimates have been made for the amount of naphthalene released from indirect sources for use in the regional and continental modelling. Vehicle exhausts account for 87% of releases.

The PEC/PNEC ratios for water (including sediment), soil and microorganisms in wastewater treatment plants are < 1 for production and all uses except grinding wheel production.

Overall conclusions

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion is based on site-specific data from one plant using naphthalene in the manufacture of grinding wheels. The calculations indicate that the use of naphthalene in this process is likely to cause adverse effects in water and sediment, to microorganisms in the wastewater treatment plant and in the soil compartment. Information from another plant using naphthalene in the manufacture of grinding wheels has indicated that there should be no adverse effects arising from its use at this location.

It is recognised that for both sediment and soil the PNEC used is derived from the surface water PNEC using the equilibrium partitioning method, and so in both of these cases the PNEC could be revised through toxicity testing. However, risks have only been identified for one site using naphthalene for this purpose. This site is developing plans to reduce releases to water, air and sludge so the rapporteur does not think it necessary to require such testing to be carried out. The planned risk management strategy will be based on the above conclusions to ensure that emissions to water (and hence sediment) and sludge are limited.

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

This conclusion applies to release of naphthalene to the aquatic (including sediment) and terrestrial compartments from naphthalene production and use as an intermediate, in pyrotechnics and in mothballs. There is also no risk to microorganisms in wastewater treatment plants from production or any of these uses.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

5.2.1.1 Workers

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion applies to all occupational exposure scenarios except the professional use of coal tar soaps and shampoos, because of concerns for haemolytic anaemia, local effects on the respiratory tract following repeated inhalation exposure and carcinogenicity.

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

This applies to the professional use of coal tar soaps and shampoo.

5.2.1.2 Consumers

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

There are concerns for haemolytic anaemia for all consumer exposure scenarios. In relation to local effects on the respiratory tract following repeated inhalation exposure, and carcinogenicity, all scenarios for which there is the potential for repeated inhalation exposure to naphthalene are considered to give rise to concern. Thus, conclusion (iii) applies to the consumer use of mothballs and to exposures arising after damp-proof laying.

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

There are no concerns for local effects on the respiratory tract, or carcinogenicity, for single, infrequent exposures, nor for exposure scenarios that result in negligible inhalation exposure i.e. creosote application, damp-proof laying and the use of coal tar soaps and shampoos.

5.2.1.3 Humans exposed via the environment

Conclusion (i) There is need for further information and/or testing.

Further information on exposures in the locality of grinding wheel plants should be obtained following environmental risk reduction activity for this scenario and the data used to reconsider the risk to humans for haemolytic anaemia via local environmental exposure.

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

The estimated daily intake of naphthalene arising from regional sources are very low and do not give rise to concern for any health effects. For exposures at a local level, there are no concerns for effects on the respiratory tract or for carcinogenicity.

5.2.1.4 Combined exposure

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

The combined exposure from occupational, consumer and indirect exposures via the environment are give rise to concerns for haemolytic anaemia. There are also concerns for repeated inhalation toxicity and carcinogenicity.

5.2.2 Human health (risks from physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

There are no significant risks from physicochemical properties.