



# Anthracene oil derivatives: Human health tier II assessment

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- Chemicals in this assessment
- Preface
- Grouping Rationale
- Import, Manufacture and Use
- Restrictions
- Existing Worker Health and Safety Controls
- Health Hazard Information
- Risk Characterisation
- NICNAS Recommendation
- References

## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
<b>Anthracene oil</b>	90640-80-5
<b>Anthracene oil, anthracene paste</b>	90640-81-6
<b>Anthracene oil, anthracene free</b>	90640-82-7

## Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to

human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: [www.nicnas.gov.au](http://www.nicnas.gov.au)

## Disclaimer

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## ACRONYMS & ABBREVIATIONS

## Grouping Rationale

The three chemicals assessed in this report belong to the group of anthracene oils. They are UVCB (unknown or variable composition, complex reaction products or biological materials) substances, consisting of a complex mixture of polycyclic aromatic hydrocarbons (PAHs) and heterocyclic compounds (ECHA, 2009). The ECHA (2009) targeted assessment report considered five chemicals under the group of anthracene oils. Only three of these chemicals are listed on AICS.

Anthracene oils are produced from distillation of coal tars, which are condensation products obtained by cooling of the gas evolved by carbonisation of coal (ECHA, 2009). Major constituents of these chemicals are polycyclic aromatic hydrocarbons with three to five fused aromatic rings. Minor constituents are three to four fused ring aromatic heterocycles with sulphur, nitrogen or oxygen heteroatoms (ECHA, 2009). The relative proportions of the constituents of anthracene oil are complex and variable, and dependent on the temperature used in the processes for the production of the tar. According to the International Agency for Research on Cancer (IARC, 1985), over 400 constituents have been identified in coal tars, and probably as many as 10,000 are actually present. The number of constituents present in most anthracene oils is estimated in the hundreds.

All three chemicals in this group contain anthracene (3-25 % in anthracene oil; 15-50 % in anthracene oil, anthracene paste and 1-6 % in anthracene oil, anthracene free), phenanthrene (10-35 % in anthracene oil; 5-30 % in anthracene oil, anthracene paste; and 10-30 % in anthracene oil, anthracene free) and carbazole (1-10 % in anthracene oil; 5-30 % in anthracene oil, anthracene paste; and 1-3 % in anthracene oil, anthracene free) as main components. Other main components present in some of these chemicals include: acenaphthene (0.2-16 % in anthracene oil; and 1-10 % in anthracene oil, anthracene free), fluoranthene (2-15 % in anthracene oil; and 5-15 % in anthracene oil, anthracene free), fluorene (1-16 % in anthracene oil; and 4-10 % in anthracene oil, anthracene free) and pyrene (1-10 % in anthracene oil; and 2-8 % in anthracene oil, anthracene free). Anthracene oil also contains dibenzofuran at 0.1-8 % (ECHA, 2009).

Depending on the composition, these chemicals can be solids or oily liquids (ECHA, 2009). Anthracene oils can contain benzo(a)pyrene at very low concentrations (< 0.05%). Benzo(a)pyrene causes fertility and developmental effects in addition to mutagenicity and carcinogenicity.

Toxicological data are available for UVCB substances containing mixtures of the component chemicals at varying concentrations. These mixtures are considered suitable analogues for the three chemicals included in this assessment report. Toxicological data on major chemical components (e.g. anthracene, phenanthrene) of the group members are also used to derive toxicity information for the group members.

## Import, Manufacture and Use

### Australian

No specific Australian use, import, or manufacture information has been identified.

### International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers, the European Commission (EC) International Uniform Chemical Information Database (IUCLID), Galleria Chemica, and Substances in Preparations in Nordic countries (SPIN) database.

Members of this group have the following reported commercial use including:

- as a component of coatings, paints, waterproofing materials and sealants (adhesives) for industrial spraying, roller or brush application, and treatment of articles by dipping or pouring; and
- a preservative to protect rail sleepers, electricity and telegraph poles against moisture, fungus and termites.

Members of this group have the following reported site-limited use including:

- as an industrial solvent;
- for formulating preparations;
- as an intermediate;
- as a raw material for producing several aromatic chemicals and UVCB substances;
- in aluminium, electro-steel, metallurgic, carbon and graphite industries;
- for the chemical reduction of iron in blast furnaces;
- manufacturing bulk, large scale chemicals (including petroleum products), other non-metallic mineral products, e.g. plasters, cement;
- as an absorbent for industrial gas cleaning (scrubber) or industrial solvent; and
- as fuel for industrial energy production.

Coal tar and its distillates are used in some specialist paints (containing 0.5 % anthracene), damp proofing materials, waterproof membranes, coal tar epoxy paints and coal tar polyurethane sealers (EU, 2008).

In SPIN, only occupational use is indicated for two of the chemicals in this group. Apart from occupational use, consumer use (not specified) in Denmark is also indicated for anthracene oil, anthracene free (SPIN). The following general uses, which could be either commercial or consumer uses, are listed in SPIN:

- paints;
- varnishes;
- lacquers; and

- fillers.

## Restrictions

### Australian

No known specific restrictions have been identified for anthracene oils.

However, anthracene oils may be covered under the following two group listings in the Poisons Standard (SUSMP), depending on their precise composition:

- Schedule 7 (Dangerous Poison - Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply) -

**'Hydrocarbons Liquid Aromatic (including aromatic extract oils)**, any fraction of which boils above 350°C except: (a) when in solid polymers; (b) when containing 1 per cent or less of total polycyclic aromatic compounds as measured by IP 346; or (c) when having a Mutagenicity Index of zero as measured by ASTM E1687-95.'

- Schedule 5 (Caution - Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label) -

**'Hydrocarbons, Liquid**, including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), except: (a) toluene and xylene when included in Schedule 6; (b) benzene and liquid aromatic hydrocarbons when included in Schedule 7; (c) food grade and pharmaceutical grade white mineral oils; (d) in solid or semi-solid preparations; (e) in preparations containing 25 per cent or less of designated solvents; (f) in preparations packed in pressurised spray packs; (g) in adhesives packed in containers each containing 50 g or less of adhesive; (h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 mL or less; or (i) in other preparations when packed in containers with a capacity of 2 mL or less.'

PAHs are also on Schedule 4: Hazardous chemicals requiring health surveillance under National Code of Practice for the Control of Workplace Hazardous Chemicals (Galleria Chemica).

### International

- Council Directive 76/768/EC - Prohibited the use of anthracene oil in cosmetic products such as soaps, lotions, oils, shampoos and gels (EU, 2008).
- Council Directive 97/45/EC - Prohibited the use of coal tar in cosmetic products such as soaps, lotions, oils, shampoos and gels (EU, 2008).

## Existing Worker Health and Safety Controls

### Hazard Classification

The three chemicals in this group are classified as hazardous with the following risk phrase/s for human health (subject to benzo(a)pyrene and benzene concentrations above the specified levels as indicated by Notes M and J), in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Anthracene oil (CAS No. 90640-80-5)

Carc. Cat. 2; R45

(Note M: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005 % w/w benzo(a)pyrene (EINECS No. 200-028-5)).

Anthracene oil, anthracene paste and anthracene oil, anthracene-low (synonym for anthracene free)

Carc. Cat. 2; R45

Muta. Cat. 2; R46

(Note M: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005% w/w benzo(a)pyrene (EINECS No. 200-028-5); and Note J: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (EINECS No. 200-753-7)).

## Exposure Standards

### Australian

No specific exposure standards are available for the chemicals in this group.

### International

No specific exposure standards are identified for the chemicals in this group.

## Health Hazard Information

### Toxicokinetics

Polycyclic aromatic hydrocarbons (PAHs) can be absorbed through the respiratory tract, the gastrointestinal tract and the skin. Following absorption, PAHs are widely distributed throughout the body to all internal organs. During metabolism, the parent compounds are converted via intermediate epoxides to phenols, diols, and tetrols, which then conjugate with sulfate or glucuronic acids or with glutathione (IPCS, 1998).

### Acute Toxicity

#### Oral

No data are available for the chemicals in this group. Based on the data available for some of the main component chemicals and an analogue chemical, the chemicals of this group are considered to be of low acute oral toxicity.

The oral LD<sub>50</sub> for phenanthrene (CAS No. 85-1-8) is 16000 mg/kg bw in rats (EC, 2000).

The following oral LD<sub>50</sub> values are reported for the component chemicals in anthracene oil (ChemIDplus Advanced):

Anthracene (3–25 %) > 17,000 mg/kg bw in mice;

Fluoranthene (2–15 %) = 2000 mg/kg bw in rats; and

Pyrene (1–10 %) = 2700 mg/kg bw in rats.

An analogue substance (creosote, CAS No. 8001-58-9: a complex combination of monocyclic aromatic hydrocarbons, polycyclic aromatic hydrocarbons, tar acids and tar bases, obtained by the distillation of coal tars produced by the high-temperature

destructive distillation of bituminous coal to form coke) is of low acute oral toxicity. The LD50 is 3500 and 4000 mg/kg bw in male and female rats, respectively (REACH).

## Dermal

No data are available for the chemicals in this group. Based on the data available for a component chemical and an analogue chemical, the chemicals in this group are considered to be of low acute dermal toxicity.

A dermal LD50 of 3180 mg/kg bw for rabbits is reported for the component chemical, fluoranthene (ChemIDplus Advanced).

An analogue substance (creosote, CAS No. 8001-58-9) is of low acute dermal toxicity (LD50 > 2000 mg/kg bw in rats). No local effects were reported at the sites of application to the skin (REACH).

## Inhalation

No data are identified for the chemicals in this group or suitable analogues. Based on the limited data available (i.e. LC50 for pyrene), the chemicals in this group should be classified for acute inhalation toxicity, subject to their pyrene concentration.

No data are available for the three main component chemicals: anthracene, phenanthrene or carbazole.

An inhalation LC50 of 170 mg/m<sup>3</sup> for rats is reported for a component chemical, pyrene (ChemIDplus Advanced). Pyrene could be present at 1–10 % concentration in anthracene oil; and 2–8 % in anthracene oil, anthracene free. Considering the LC50 for pyrene (classifiable as 'Very toxic by inhalation' according to the Approved Criteria) and its possible maximum concentrations in anthracene oil; and anthracene oil, anthracene free; the chemicals of this group are considered to be toxic by inhalation, subject to the concentration of pyrene in the substance.

## Corrosion / Irritation

### Respiratory Irritation

No data are available for the chemicals in this group or any analogues. The limited information available is not sufficient to make a conclusion on respiratory irritation.

It is reported that anthracene fumes at 4.7 mg/m<sup>3</sup> can cause mild irritation to the respiratory tract (IPCS, 1998).

### Skin Irritation

No data are available for the chemicals of this group. Based on the information available for component chemicals and an analogue, the chemicals of this group are considered to be skin irritants. Based on the irritation scores available for the analogue chemical, a hazard classification for skin irritation is warranted.

Phenanthrene was slightly irritating to rabbit skin (EC, 2000).

In a skin irritation study (OECD TG 404) with an analogue test material (creosote, CAS No. 8001-58-9), the average erythema and oedema scores (24, 48 and 72 h) in New Zealand White rabbits were 2.2 and 3.1 respectively. The test material was a skin irritant (REACH).

Anthracene fumes at 4.7 mg/m<sup>3</sup> can cause mild skin irritation in mice (IPCS, 1998).

### Eye Irritation

Based on the limited information available, the chemicals in this group are not considered to be eye irritants.

Anthracene vapours caused mild eye irritation (IPCS, 1998).

Phenanthrene was not irritating to rabbit eyes (EC, 2000).

In an eye irritation study with three New Zealand White rabbits (OECD TG 405), the analogue test material (creosote, CAS No. 8001-58-9) caused very slight chemosis (score of one in one animal only) and slight (score 1) to moderate (score 2) redness of the conjunctivae between one and 48 h after exposure. The test material was not irritating to the eyes (REACH).

## Observation in humans

Skin disorders related to irritation and sensitisation are relatively common among workers exposed to coal tar-containing products (EU, 2008).

## Sensitisation

### Skin Sensitisation

No data are available for the chemicals in this group. Based on the information available for an analogue chemical and some component chemicals, the chemicals in this group are considered to be skin sensitisers.

A guinea pig maximisation test (OECD TG 406) for an analogue chemical (creosote, CAS No. 8001-58-9) is available. Guinea pigs were induced by intradermal and epicutaneous administration of the analogue chemical and challenged (epicutaneous, occlusive) with the same chemical. There was a brownish discolouration at the site of application and dryness of the skin after 48 h. Positive skin reactions were reported in 17/19 animals after 24 h (average Draize score = 1.2) and 6/19 animals after 48 h (average Draize score = 0.4). Under the conditions of the test, the analogue chemical was reported to be a skin sensitiser (REACH).

IPCS (1998) reported that the component chemicals anthracene and benzo(a)pyrene having potential for phototoxicity; anthracene as a sensitiser; and benzo(a)pyrene causing skin hypersensitisation (details not available). Phenanthrene was reported as not inducing contact sensitivity.

## Repeated Dose Toxicity

### Oral

No data are available for the chemicals in this group or suitable analogues. Based on the data available for some main component chemicals, the chemicals in this group are not considered to cause serious damage to health through repeated oral exposure.

The following information/studies are available for main component chemicals:

- The tolerable daily intake (TDI) of phenanthrene is reported as 0.04 mg/kg bw/d (REACH).
- In a 90 days study, mice (CD-1 BR) received anthracene by oral gavage doses of 0, 250, 500, or 1000 mg/kg bw/d. No treatment related effects were reported. The no observed effect level (NOEL) is reported as 1000 mg/kg bw/d (IPCS, 1998).
- In a 13 weeks oral study, mice (CD-1) received fluorene at 0, 125, 250, or 500 mg/kg bw/d. A NOAEL of 125 mg/kg bw/d is reported based on haematological effects (decreased haemoglobin concentration) and increased liver, spleen and kidney weights observed at or above 250 mg/kg bw/d. Increased salivation and hypoactivity were observed in all treated males (IPCS, 1998).

- Mice (CD-1) received 0, 125, 250, or 500 mg/kg bw/d fluoranthene by gavage for 13 weeks. Treated mice showed dose dependent nephropathy, increased salivation, and increased liver enzyme activities. These effects were not considered either significant or adverse at 125 mg/kg bw/d. On the basis of the increased alanine aminotransferase activity, effects in the kidney and liver, and clinical and haematological changes at higher doses, a NOAEL of 125 mg/kg bw/d was established (IPCS, 1998).
- In a 13 weeks study, mice (CD-1) received 0, 75, 125, or 250 mg/kg bw/d pyrene in corn oil by gavage. A NOAEL of 75 mg/kg bw/d is reported based on nephropathy and decreased kidney weights at higher dose groups (IPCS, 1998).

## Dermal

No data are available for the chemicals in this group, the main component chemicals or suitable analogues.

## Inhalation

No data are available for the chemicals in this group or main component chemicals. Based on the limited data available, the degree of repeat dose inhalation toxicity is unknown.

A 90 days inhalation study (OECD TG 413) in rats (CrI:CD® BR VAF/PLUS) is available for a distilled coal tar complex hydrocarbon mixture containing 12.2 % phenanthrene, 2.2 % anthracene, 6.8 % fluoranthene, 6 % pyrene and other components. The mean nominal concentrations used for whole body exposure in rats were 22, 128 or 221 mg/m<sup>3</sup> (equal to mean aerosol concentrations of 5.4, 49, 106 mg/m<sup>3</sup>). Heart lesions were found in one male at 128 mg/m<sup>3</sup> which died during the study, and in one male and one female in the 221 mg/m<sup>3</sup> group (diffuse myocardial degeneration affecting mainly the right side of the heart). These two animals in the high dose group also had diffuse centrilobular fibrosis within the liver. Relative liver weights were significantly increased in the mid and high dose group animals (> 20 % and > 25 %, respectively). All treated animals had small black pigment granules within alveolar macrophages. The no observed adverse effect concentration (NOAEC) was reported as 22 mg/m<sup>3</sup> (5.4 mg/m<sup>3</sup> mean aerosol concentration), based on decreased bodyweight gain (> 10 %), increased liver weight (≥ 20 %) and increased follicular cell hyperthrophy at higher doses (REACH).

The tolerable air concentration (TCI) for phenanthrene is reported as 0.2 mg/m<sup>3</sup> (REACH).

## Genotoxicity

Two chemicals in this group (CAS No. 90640-81-6 and 90640-82-7) are currently classified as Category 2 mutagens with the risk phrase 'May cause heritable genetic damage' (T; R46) in HSIS (Safe Work Australia). This classification is subject to the benzene concentration in the substance (Note J: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (EINECS No. 200-753-7)). Limited in vitro and/or in vivo genotoxicity data are available for anthracene oil, component chemicals or analogue chemicals. Based on the data available, this hazard classification is supported for all three chemicals, but only subject to meeting the specified benzene concentration.

Anthracene oil produced negative results in a bacterial reverse mutation test (Ames test) with *Salmonella typhimurium* strains TA 98, TA 1535, TA 1537, TA 102 with or without metabolic activation. In another Ames test, *S. typhimurium* Strain TA 100 was positive with metabolic activation; the result was reproducible at cytotoxic concentrations (cytotoxic at ≥ 200 µg/plate with metabolic activation). No mutagenic activity was observed in any test at non-cytotoxic concentrations (REACH).

With in vitro assays using various *S. typhimurium* strains and other cell lines, benzo(a)pyrene (a component reported to be present at < 0.05 % in anthracene oil) produced positive results. Fluoranthene produced positive results in the majority of assays using *S. typhimurium* strains (IPCS, 1998). Anthracene, phenanthrene and pyrene produced mixed results (positive or negative) and fluorene was negative in all *S. typhimurium* and *Escherichia coli* assays with or without metabolic activation (IPCS, 1998).

An analogue chemical (creosote, CAS No. 8001-58-9) was tested using an in vitro mammalian cell gene mutation test with mouse lymphoma L5178Y cells, with or without metabolic activation (OECD TG 476) at 2.5–100 µg/mL and exposure times up to 24 hours. The cell death was 100 % at 100 µg/mL (cytotoxic concentration). The test substance showed a weak positive mutagenic activity in the presence of metabolic activation (REACH).



In a sister chromatid exchange (SCE) assay, male Chinese hamsters received phenanthrene intraperitoneally for 24 hours. There were no chromosome aberrations at 100 mg/kg bw and no induction of micronuclei at 500 mg/kg bw. Positive results for the SCE were reported at the highest dose of 100 mg/kg bw (EC, 2000). In another SCE assay, male and female Chinese hamsters received two doses (48 hours apart) of phenanthrene intraperitoneally at 450 mg/kg bw. The SCE at metaphase was  $5.5 \pm 0.7$  for the test group compared with  $3.9 \pm 0.9$  for the control group (details not available) (EC, 2000).

A chromosome aberration test in Chinese hamsters with phenanthrene (2 x 1500 mg/kg bw, route of administration not available) showed no chromosome aberration in bone marrow cells (EC, 2000).

IPCS (1998) reported that one of the main component chemicals, fluoranthene, and a minor component chemical, benzo(a)pyrene was genotoxic, while the component chemicals anthracene and fluorene were non genotoxic.

## Carcinogenicity

All three chemicals in this group are currently classified as Category 2 carcinogens with the risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia). This classification is subject to the benzo(a)pyrene and/or benzene concentration in the substance (Note M: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005 % w/w benzo(a)pyrene; and/or Note J: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene). The data available support this classification.

The IARC (1985) states that, there is sufficient evidence for carcinogenicity in experimental animals from coal tars, creosotes, creosote oils and anthracene oils and there is limited evidence that coal tar derived creosotes are carcinogenic in humans. Taken together, the IARC concluded that, creosotes derived from coal tars are probably carcinogenic in humans.

No mammary tumours were observed in Sprague Dawley rats, 60 days after a single oral gavage dose of phenanthrene at 200 mg/rat. Swiss Webster mice that received three intraperitoneal injections of phenanthrene at doses of 0.035, 0.0712 or 0.142 mg/animal showed pulmonary adenomas (17 % compared with 15 % in the control group). Details of these studies are not available (EC, 2000). A rat study has shown questionable carcinogenic potential for phenanthrene (IPCS, 1998).

A number of individual PAHs have shown carcinogenicity in experimental animals (producing tumours at the site of contact and distantly), indicating that they are potentially carcinogenic to humans. Mixtures containing PAHs have also shown an increased incidence of cancer in exposed human populations (IPCS, 1998).

IPCS (1998) reported that one of the main component chemicals, fluoranthene and a minor component chemical, benzo(a)pyrene are carcinogenic. It also stated that the component chemicals anthracene and fluorene, are non-carcinogenic.

## Reproductive and Developmental Toxicity

No data are available for the chemicals in this group. Based on the information available for an analogue chemical, the chemicals in this group are not considered to cause reproductive or developmental toxicity.

A two generations reproductive toxicity study (OECD TG 416) in rats (strain: SD Crl:CD) is available for distilled coal tar, a complex hydrocarbon mixture containing 12.2 % phenanthrene, 2.2 % anthracene, 6.8 % fluoranthene, 6 % pyrene and others components including benzo(a)pyrene at 0.5 %. There were decreased fertility and pregnancy indices in the F1 female parental rats at all dose levels (25, 75, 150 mg/kg bw/d), and a significant dose related reduction in the number of live F1 offspring at doses  $\geq 75$  mg/kg bw/d. A dose related decrease in growth of the F1 offspring was reported starting at 25 mg/kg bw/d. Although the NOAEL is reported as 25 mg/kg bw/d (REACH), reproductive effects were indicated at all dose levels.

The analogue mixture used in the above study was also used in a prenatal developmental toxicity study (OECD TG 414). In this study, rats (strain: SD, Crl:CD) were treated from gestation days (GD) 6–15, at doses of 25, 50 or 175 mg/kg bw/d. There were no mortalities. Weak maternal toxicity was observed at the highest dose (increased hair loss, body weight loss during GD 6-9, inhibition of body weight gain throughout gestation and decreased food consumption). At the highest dose, increased incidence of post-implantation loss and a reduced number of live foetuses were observed. There were no maternal or developmental toxicity effects at 25 or 50 mg/kg bw/d. Foetal malformations were reported in litters at all dose levels, but most of the malformations were reported to be fairly common in rats; the eye malformations observed were within the historical control range. The NOAEL for maternal toxicity is reported as 50 mg/kg bw/d and teratogenicity 175 mg/kg bw/d (REACH).

The benzo(a)pyrene concentration in the analogue test material used in the two studies above is more than 10 times higher than that reported in anthracene oils. Therefore, the reproductive or developmental effects reported in these studies could be due to the high benzo(a)pyrene level, and may not be relevant for anthracene oils with < 0.05 % benzo(a)pyrene concentration.

Benzo(a)pyrene is reported to cause adverse effects on female fertility, reproduction, and postnatal development. A no-observed-effect level (NOEL) of 150 mg/kg bw/d was established for benzo(a)pyrene in a mouse study based on fertility effects (sperm in lumen of testes and size of litters) and embryotoxicity (malformations) (IPCS, 1998).

## **Risk Characterisation**

### **Critical Health Effects**

The main critical effects to human health are inhalation toxicity, skin irritation and potential for skin sensitisation from short term exposure; and carcinogenicity and genotoxicity from long term exposure, depending on the precise chemical composition of the anthracene oils.

### **Public Risk Characterisation**

No known domestic/consumer uses in Australia are identified for the chemicals of this group. There is information that anthracene oil, anthracene free has consumer uses in Denmark (SPIN). Considering the health effects, there may be a concern if these chemicals are used in domestic products. If these chemicals are proposed for consumer use in Australia, the relevance of the existing SUSMP entries to the precise chemical formulation should be taken into account. If new information on consumer uses and the precise identity of the chemical in use becomes available, NICNAS may recommend risk management for public safety.

### **Occupational Risk Characterisation**

Given the critical health effects, the risk to workers from these chemical is considered high if adequate control measures to minimise occupational exposure to these chemicals are not implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business, or an employee at a workplace, has adequate information to determine appropriate controls.

## **NICNAS Recommendation**

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

## **Regulatory Control**

### **Public Health**

Considering the available information to indicate low public exposure from these chemicals, no regulatory controls are recommended.

### **Work Health and Safety**

The chemicals are recommended for classification and labelling under the current approved criteria and adopted Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

\*\* R23—This classification need not apply if it can be shown that the anthracene oil contains less than 8 % pyrene; R20 classification applies for anthracene oils containing > 1 % pyrene.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Toxic by inhalation (T; R23)	Fatal if inhaled - Cat. 2 (H330)
Irritation / Corrosivity	Irritating to skin (Xi; R38)	Causes skin irritation - Cat. 2 (H315)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)
Genotoxicity	Muta. Cat 2 - May cause heritable genetic damage (T; R46)*	May cause genetic defects - Cat. 1B (H340)
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)*	May cause cancer - Cat. 1B (H350)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

\* Existing Hazard Classification. No change recommended to this classification

## Advice for industry

### Control measures

Control measures to minimise the risk from dermal and inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

### ***Obligations under workplace health and safety legislation***

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of these chemicals has not been undertaken as part of this assessment.

## **References**

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## Chemical Identities

Chemical Name in the Inventory and Synonyms	<b>Anthracene oil</b> Light coal tar distillate Middle coal tar distillate
CAS Number	90640-80-5
Structural Formula	<b>No Structural Diagram Available</b>
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Anthracene oil, anthracene paste</b>
CAS Number	90640-81-6
Structural Formula	<b>No Structural Diagram Available</b>

Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Anthracene oil, anthracene free</b> Anthracene oil, anthracene low
CAS Number	90640-82-7
Structural Formula	<b>No Structural Diagram Available</b>
Molecular Formula	Unspecified
Molecular Weight	

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