Turpentine: Human health tier II assessment

29 June 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Turpentine oil	8006-64-2
Turpentine oil, resin	8052-14-0
Turpentine	9005-90-7

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**

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

This assessment contains a group of turpentines. Turpentines are multi-component substances extracted from various trees in the pine family (*Pinaceae* derivatives) and commonly contain alpha-pinene, beta-pinene, delta-3-carene and other terpenes.

In the European commission cosmetic ingredients database (CosIng) turpentine (CAS No. 8006-64-2, 9005-90-7, 8052-14-0) refers to "*Any of the volatile predominately terpenic fractions or distillates resulting from the solvent extraction of, gum collection from, or pulping of softwoods. Turpentine is a mixture of terpene hydrocarbons obtained from various species of Pinus"*. Depending on the source, the CAS No. 8006-64-2 refers to turpentine oil, 9005-90-7 to turpentine, and 8052-14-0 to turpentine oil resin (SciFinder) or to 'turpentine' without further specification (ChemID and Galleria Chemica). Separate exposure and hazard assessment of these turpentines is difficult due to the inconsistency and uncertainty in the use of the above CAS numbers. Therefore, these substances will be assessed together. The hazard profiles of these substances are expected to be similar.

It is important to note that the name turpentine is also used to identify white spirits or mineral turpentine. Mineral turpentine is a refined petroleum distillate with quite different properties to the pine-based turpentine, and which is not included in this report. Stoddard solvent (mineral turpentine) has been assessed under the IMAP program. For further information see **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1609**

Import, Manufacture and Use

Australian

Turpentine (CAS No. 9005-90-7) is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume of 1000–9999 tonnes (NICNAS, 2006).

Turpentine oil (CAS No. 8006-64-2) is available for purchase in Australia in hardware and office supply stores. It has reported domestic uses in automotive aftermarket products including car wash soaps, boat wash soaps, polishes, and rubbing compounds.

There is no use information for turpentine oil resin (CAS No. 8052-14-0).

International

The following international uses were identified through Galleria Chemica; the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier; Substances and Preparations in the Nordic countries (SPIN) database; United States (US) Department of Health National Toxicology Program (NTP); US Environmental Protection Agency (EPA) Chemical and Product Categories (CPCat); US Household Product database (HPD); the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary and Cosmetic Ingredients and Substances (CosIng) database.

The substances may have cosmetic uses as fragrances in:

- bath soaps and detergents;
- perfumes; and
- skin conditioners.

Turpentine (CAS No. 8006-64-2, 8052-14-0 and 9005-90-7) is listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011), indicating its use in three cosmetic products.

The substances may have domestic uses in:

- auto care products;
- paint thinners; and
- shoe care products.

The substances may have commercial uses in:

- solvents for paint, varnishes, lacquers, and rubber;
- water proofing;
- auto care products; and
- adhesives and sealants.

The use of turpentine as a solvent has decreased since less expensive petroleum-based solvents are now readily available.

The substances may have site-limited uses as intermediates in the synthesis of terpene-based fragrances.

The substances may have non-industrial uses in pesticides, flavouring agents and pharmaceuticals.

Restrictions

Australian

Turpentine oil is listed in the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, 2018) in Schedule 5.

TURPENTINE OIL except in preparations containing 25 per cent or less of turpentine oil.

Schedule 5 chemicals are described as '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.' Schedule 5 chemicals are labelled with 'Caution' (SUSMP, 2018).

International

The substances (CAS No. 8006-64-2, 9005-90-7, 8052-14-0) are subject to the EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Annex III: List of Substances which cosmetic products must not contain except subject to the restrictions laid down. Peroxide levels must be less than 10 mM. This limit applies to the substance and not to the finished cosmetic product (CosIng).

Pinacea derivatives are included in the International Fragrance Association (IFRA) Standards: Essential oils and isolates derived from the *Pinacea* family, should only be used when the level of peroxides is kept to the lowest practicable level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 10 mM peroxide.

Existing Worker Health and Safety Controls

Hazard Classification

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous, with the following hazard categories and hazard statements for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

- Acute toxicity – category 4; H332 (Harmful if inhaled)
- Acute toxicity – category 4; H312 (Harmful in contact with skin)
- Acute toxicity – category 4; H302 (Harmful if swallowed)
- Eye irritation – category 2; H319 (Causes serious eye irritation)
- Skin irritation – category 2; H315 (Causes skin irritation)
- Skin sensitisation – category 1; H317 (May cause an allergic skin reaction)
- Aspiration hazard – category 1; H304 (May be fatal if swallowed and enters airways)

The substances (CAS No. 9005-90-7 and 8052-14-0) are not listed on the HCIS (Safe Work Australia).

Exposure Standards

Australian

Turpentine (wood) (CAS No. 8006-64-2) has an exposure standard of 557 mg/m^3 (100 ppm) time weighted average (TWA) (Safe Work Australia).

International

The following exposure standards are identified through Galleria Chemica:

Exposure limits for turpentine (including monoterpene constituents) between 112–560 mg/m^3 (20–100 ppm) TWA in different countries such as Canada, USA, Sweden and Spain and short-term exposure limit (STEL) exposure limits of 300–850 mg/m^3 (50–150 ppm) in Canada, USA, UK, Sweden and South Africa.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 20 ppm (112 mg/m^3) TWA 'to minimise the potential for upper respiratory tract irritation and long-term respiratory compromise'. Readers should refer to the relevant ACGIH documentation for substantiation for this value (ACGIH, 2011).

Health Hazard Information

Turpentine can be identified as any of the volatile predominantly terpenic fractions or distillates resulting from the solvent extraction of gum, or collection from, or pulping of softwoods (generally *Pinus*) (ChemIDPlus).

Turpentine is composed primarily of the terpene hydrocarbons: alpha-pinene, beta-pinene, delta-3-carene, and small amounts of other terpenes such limonene, camphene, and terpinolene (NTP, 2002). Aged turpentine may contain oxidised terpenes. The exact composition of turpentine varies depending on refining methods, age, location, and species of the softwood source (Scifinder). The chemical alpha-pinene is generally the most abundant component of turpentine (>50 %). The levels of beta-pinene vary greatly and are particularly low in turpentine from Greece, and Indonesia (1–3 %) and high in turpentine from New Zealand (40–60 %). Turpentine from India, Finland and Sweden tend to contain high levels of delta-3-carene (up to 70 %) while turpentine from southern European countries and USA generally contain low levels of delta-3-carene (Kasanen, 1999; NTP, 2002). The composition of the turpentines used in experimental studies is not always specified and unless otherwise stated, in this assessment the term turpentine is used to refer to unspecified turpentine.

The constituents of turpentine are susceptible to auto-oxidation leading to formation of hydroperoxide species. These oxidised species are thought to be responsible for the majority of sensitisation reactions to turpentine, acting as haptens.

The human health hazards of major components of turpentine, alpha-pinene, beta-pinene and delta-3-carene have been assessed under IMAP. The Tier II assessment reports for the alpha-pinene, beta-pinene and delta-3-carene are available at: **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=10275**, **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=12656** and **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=12653**.

These reports should be read in conjunction with this Tier II assessment.

Toxicokinetics

Turpentine is absorbed through the gastrointestinal and respiratory tracts and through skin. The majority of turpentine is eliminated through the urinary tract as glucuronidated terpene metabolites (NTP, 2002).

In a metabolic study, 8 male volunteers were exposed to 450 mg/m^3 (75 ppm) turpentine in an exposure chamber for 2 h during light physical exercise. Uptake of each inhaled alpha-pinene, beta-pinene, and delta-3-carene was approximately 65 %. Between 2–8 % of the uptake was detected in the expired air. Concentrations of alpha-pinene, beta-pinene, and delta-3-carene in the blood peaked 2 h after administration at 9.5, 10.25 and 2.5 µmol/L, respectively. The elimination was tri-phasic: the mean half-lives of the last phase (3.3–21.2 h) were 32, 25 and 42 h for alpha-pinene, beta-pinene and delta-3-carene, respectively (Filipsson, 1996).

In a metabolic study, male albino rabbits (6/group) received a single oral dose of 400–700 mg/kg bw of the turpentine constituents alpha-pinene, beta-pinene, or delta-3-carene. Over 3 days, more than 80 % of each chemical was recovered in the urine as glucuronic acid conjugates of hydroxylated terpene hydrocarbons. Metabolites detected were verbeneol (67 %) and myrtenol (14 %) for alpha-pinene, trans-10-pinanol (39 %), l-p-menthene-1,8-diol (30 %) and alpha-terpineol (5 %) for beta-pinene and m-mentha-4,6-dien-8-ol (72 %) for delta-3-carene (FFHPVC, 2006).

Acute Toxicity

Oral

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with hazard category 'Acute Toxicity Category 4' and hazard statement 'Harmful if swallowed' (H302) in the HCIS (Safe Work Australia). The available animal data suggest that the substances have low acute oral toxicity with experimental median lethal doses (LD50) >2000 mg/kg bw. However, in the absence of more comprehensive information, and human data indicating that lethality may occur from turpentine ingestions at comparatively low doses, there is insufficient evidence to recommend removal of the current HCIS classification. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to the other assessed substances (CAS No. 9005-90-7 and 8052-14-0) (refer to ***Recommendation*** section).

In an oral acute toxicity study similar to the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 401, Wistar rats (10/dose; sex not reported) were administered 2752, 3440, 4300 or 5375 mg/kg bw of turpentine oil (CAS No. 8006-64-2) containing 59 % alpha-pinene, 24 % beta-pinene, 5 %, dipentene, 2 % each of beta-phellandrene, alpha-terpineol, and linalool, 1 % each methyl chavicol, cis-anethole and trans-anethole. Mortalities occurred at all doses with a calculated median lethal dose of (LD50) of 3956 mg/kg bw (FFHPVC, 2006; REACHa).

In a non-guideline oral acute toxicity study, Sprague Dawley (SD) rats were administered 1260, 1580, 2000, 2510, 3160 or 3980 mg/kg bw of turpentine oil (CAS No. 8006-64-2) via the oral route and observed for 14 days. Mortalities were observed at all dose levels. An LD50 of 2600 mg/kg bw was reported (FFHPVC, 2006).

In a limit test, 10 male Wistar rats received a single dose of 5000 mg/kg bw of turpentine oil (same composition as the study above). At this dose, six mortalities occurred and an LD50 of <5000 mg/kg bw was reported (FFHPVC, 2006).

An LD50 of 5760 mg/kg bw for turpentine (CAS No. 8006-64-2) in rats has been reported. No further study details are available (MAK, 2012).

The following oral LD50 values have been reported for the major components of turpentine in rats:

- alpha-pinene (CAS No. not specified): 2100–3700 mg/kg bw (FFHPVC, 2006; MAK, 2012).
- alpha-pinene multiconstituent (containing alpha-pinene stereoisomers CAS No. 7785-70-8 and 7785-26-4): higher than 300 mg/kg bw but lower than 2000 mg/kg bw (NICNASa).
- beta-pinene (CAS No. not specified): 4700 and >5000 mg/kg bw (NICNASc).

No data are available for turpentines referred to as CAS No. 9005-90-7 or 8052-14-0.

Dermal

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with the hazard category 'Acute Toxicity Category 4' and hazard statement 'Harmful in contact with skin' (H312) in the HCIS (Safe Work Australia). The available data suggest that this substance has low acute dermal toxicity with experimental LD50 > 2000 mg/kg bw. However, in the absence of more comprehensive information, there is insufficient evidence to recommend removal of the current HCIS classification. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to other assessed substances (CAS No. 9005-90-7 and 8052-14-0) (refer to ***Recommendation*** section).

In a dermal study, New Zealand White (NZW) rabbits (10/dose; sex not reported) turpentine oil (CAS No. 8006-64-2) was applied to clipped abraded abdominal skin at 2000 mg/kg bw for 24 h. Rabbits were monitored for seven days. All animals survived the study and there was no evidence of treatment-related toxicity. An LD50 of >2000 mg/kg bw was reported. No further data are available (REACHa).

Low acute dermal toxicity has also been reported for the major constituents of turpentine.

In an OECD TG 402 study in SD rats, a dermal LD50 of >2000 mg/kg bw was reported for alpha-pinene multiconstituent (CAS No. 7785-70-8 and 7785-26-4) (NICNASa).

In a limit test, 10 NZW rabbits received a single application of 5000 mg/kg bw beta-pinene (CAS No. 127-91-3) on clipped abraded abdominal skin for 24 h. No mortalities occurred during the seven days of observation. An LD50 of >5000 mg/kg bw was reported (NICNASc; REACHa).

No data are available for turpentine referred to as CAS No. 9005-90-7 or 8052-14-0.

Inhalation

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with hazard category 'Acute Toxicity Category 4' and hazard statement 'Harmful if inhaled' (H332) in the HCIS (Safe Work Australia). The available median lethal concentration (LC50) of 13.7 mg/L supports this classification. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to other assessed substances (CAS No. 9005-90-7 and 8052-14-0) (refer to ***Recommendation*** section).

Reported signs of toxicity include salivation, weakness, incoordination, bloody nasal discharge, paraplegia, ataxia, tremor, convulsions, respiratory distress, coma, and mortality due to sudden apnoea (NTP, 2002).

In a study similar to OECD TG 403, rats (10–19/dose; strain not specified) were exposed to turpentine vapour (CAS No. 8006-64-2) at 12600–15700, 15800–19800, 19900–25000 or 25100–31500 mg/m^3 for 1, 2, 4, or 6 h. A dose-related increase in respiratory distress was reported. However, no pulmonary lesions were observed at necropsy. The LC50 for the different time-points ranged between 12000–20000 mg/m^3 (12–20 mg/L) and the LC50 for 4 h was 13700 mg/m^3 (13.7 mg/L) (FFHPVC, 2006).

In a non-guideline study, SD rats (4/sex/dose) and albino guinea pigs (2/sex/dose) were exposed to turpentine vapour (CAS No. 8006-64-2) at 2400, 4800, 9500, 19000 or 38000 mg/m^3 for 6 h. In addition, Swiss mice (4/sex/dose) were exposed to 2200, 4500, 9000, 18000 or 36000 mg/m^3 of turpentine vapour. Animals were observed for fourteen days following the exposure period. The reported LC50 values were 13500 mg/m^3 for rats and guinea pigs and 9000 mg/m^3 for mice (FFHPVC, 2006).

No data are available for turpentine referred to as CAS No. 9005-90-7 or 8052-14-0.

Observation in humans

Reported oral lethal doses for turpentine in humans range between 15–180 mL and the average single lethal oral dose has been estimated to be approximately 2 mL/kg bw (MAK, 2012). Symptoms of intoxication include: central nervous system (CNS)depression; renal damage; spasms; coma; headache; dizziness nausea; weakness; burning sensation in the mouth, throat and stomach, thirst; vomiting and diarrhoea (NTP, 2002; MAK, 2012).

Inhalation of turpentine may also cause headache, dizziness, nausea and unconsciousness (NTP, 2002).

Turpentine oil (CAS No. 8006-64-2) is currently classified as hazardous with hazard category 'Aspiration hazard category 1' and hazard statement 'May be fatal if swallowed and enters airways' (H304) in the HCIS (Safe Work Australia). Aspiration of turpentine may cause chemical pneumonitis, accumulation of fluid in the lungs, breathing difficulties and cyanosis (ACGIH, 2011; MAK, 2012).

Corrosion / Irritation

Respiratory Irritation

Studies in mice suggest that turpentine is a sensory irritant. Sensory irritation is the result of the chemical stimulating the trigeminal nerve endings in the cornea and nasal mucosa, which evokes a stinging or burning sensation in the eyes and upper respiratory tract (nose and throat). This is a receptor mediated mode of action and occurs at relatively low concentrations. Sensory irritation is different to eye and skin irritation used for hazard classification and also different from the irritation leading to

cytotoxicity. This latter example is a result of physical damage to the cells, whereas sensory irritation is a nerve response (NICNASd). While there is clear evidence of irritation, sensory irritation is not considered to be specific target organ toxicity (STOT) under GHS.

The concentration that causes a 50 % respiratory rate decrease (RD50) was determined using a mouse bioassay measuring a decrease in breathing rate due to stimulation of the trigeminal nerve endings in the nasal mucosa. In the study, 36 Oncin France 1 (OF1) mice were exposed to turpentine (53 % delta-3-carene, 15 % beta-pinene, 14 % alpha-pinene and 2 % limonene) in a glass tube attached to an exposure chamber (head only exposure). Concentration in the chamber was regulated by airflow to the chamber and the actual concentration in the chamber was continuously monitored by infrared spectroscopy. Control mice (n=8) were exposed to room air only. The maximum response generally occurred after 30 min. At higher concentrations, body movements slowed down and at exposures above 1400 ppm (7.8 mg/L) slight sedation or drowsiness was observed. Recovery was rapid and no macroscopic effects were seen 1 h or 7 days after the end of the exposure. An RD50 of 1173 ppm (6.5 mg/L) was reported (Kasanen, 1999).

Skin Irritation

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with hazard category 'Skin irritation category 2' and hazard statement ‘Causes skin irritation’ (H315) in the HCIS (Safe Work Australia). The available data support this classification. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to other assessed substances (CAS No. 9005-90-7 and 8052-14-0).

The major component of turpentine, alpha-pinene was considered a dermal irritant in an in vitro EpiSkin model (similar to OECD TG 439) (using reconstructed epidermis from normal human keratinocytes) (NICNASa).

In an acute toxicity study in 10 NZW rabbits (refer to ***Acute toxicity: Dermal***), slight (8/10) and moderate (1/10) erythema was observed 24 h after application of the substance. Slight (4/10) and moderate (1/10) oedema was also observed. No signs of erythema or oedema were present after 3 and 5 days, respectively.

Eye Irritation

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with hazard category ‘Eye irritation – category 2’ and hazard statement ‘Causes serious eye irritation’ (H319) in the HCIS (Safe Work Australia). The available in vitro, animal and human data (refer to ***Observation in humans***) suggest that turpentine is mild to moderate eye irritant. However, in the absence of more comprehensive information, there is insufficient evidence to recommend removal of the current HCIS classification. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to other assessed substances (CAS No. 9005-90-7 and 8052-14-0).

No experimental in vivo or in vitro data are available for turpentine. However, the following studies are available for the major constituents of turpentine.

The chemical alpha-pinene was not considered to cause severe eye damage in an OECD TG 492 in vitro Reconstructed Human Cornea-like Epithelium (RhCE) study (NICNASa).

In an OECD TG 405 eye irritation study, 0.1 mL of undiluted beta-pinene or delta-3-carene was applied to one eye of NZW rabbits (3/chemical) while the other eye served as the control. The eyes were examined for irritation scores at 1 h and 1, 2, 3, 4, 7 and 8 days after application. For beta-pinene, moderate redness of the conjunctivae was observed 1 h after the treatment. The average scores at 24, 48 and 72 h after exposure for the 3 rabbits were 0, 0, 0 for the cornea; 0, 0, 0 for the iris; 1, 1, 2 for the conjunctivae and 1.3, 1, 1 for chemosis (NICNASc). Similar results were obtained for delta-3-carene. The average scores at 24, 48 and 72 h after exposure for the 3 rabbits were 0, 0, 0 for the cornea; 0, 0, 0 for the iris; 2, 1.33, 1.33 for the conjunctivae and 2, 1.33, 1 for chemosis. After 8 days the irritation (from both chemicals) had completely resolved (NICNASb).

Observation in humans

In patch tests in 30 patients that were not allergic to turpentine, freshly distilled turpentine constituents (non-oxidised alpha-pinene, beta-pinene, delta-3-carene and limonene) were irritating to the skin at high concentrations (70–80 %) but not at lower

concentrations (20–35 %). However, oxidised turpentine constituents (>2 % hydroperoxide) caused irritation in almost all patients (MAK, 2012).

Eye, nose and throat irritation was reported in an inhalation study, where 8 male volunteers were exposed to turpentine at 81 ppm (450 mg/m^3) for 2 h (ACGIH, 2011).

Exposure to 75 ppm (420 mg/m^3) of turpentine vapour for 3–5 min resulted in throat and nose irritation in several volunteers while exposure to 175 ppm (975mg/ m^3) for the same time was considered intolerable for most volunteers. In general, the highest concentration that could be tolerated for 8 h was 100 ppm (556 mg/m^3) (NTP, 2002).

Sensitisation

Skin Sensitisation

Turpentine oil (CAS No. 8006-64-2) is classified as hazardous with hazard category 'Skin sensitisation – category 1' and hazard statement 'May cause an allergic skin reaction (H317) in the HCIS (Safe Work Australia). The available animal and human data (refer to ***Observations in humans***) as well as in silico alerts support this classification. Hydroperoxide species originating from auto-oxidation are thought to be the major contributors. Due to uncertainty and inconsistency in the use of CAS numbers, the classification should also apply to other assessed substances (CAS No. 9005-90-7 and 8052-14-0).

In a guinea pig maximisation test (GPMT) conducted similarly to OECD TG 406, 25 female albino guinea pigs received a 5 % (v/v) intradermal injection and a 25 % (v/v) topical application of turpentine (induction). Two weeks after the induction, 20 % (v/v) of turpentine in petrolatum was applied to the flank of the guinea pigs for 24 h under occlusion (challenge). The challenge site was evaluated 24 h after removal of the occlusion patch. Reaction to the challenge was reported in 16 out of 25 animals suggesting that turpentine is a sensitiser (REACHa).

Animal data are also available for the constituents of turpentine.

In a local lymph node assay (LLNA) performed in accordance with OECD TG 429, using beta-pinene the reported concentration of beta-pinene producing a three-fold increase in lymphocyte proliferation (EC3) was 29 % indicating weak sensitisation potential (NICNASc).

The turpentine constituent delta-3-carene was tested in a cumulative contact enhancement test in female Dunkin Hartley guinea pigs. Reaction to delta-3-carene was reported in 15 out of 22 animals. Therefore, the chemical was considered positive for sensitisation (NICNASb).

A chemical preparation of delta-3-carene containing 5 % hydroperoxides was also reported as skin sensitiser in domestic pigs. Limited study details are available (NICNASb).

The chemical alpha-pinene was negative for skin sensitisation in non-guideline studies including a local lymph node assay (LLNA), a popliteal lymph node assay (PLNA) in mice and a GPMT in guinea pigs (NICNASa).

Hydroperoxide species originating from autooxidation of turpentine constituents are thought to be major contributors to sensitisation reactions. This is supported by (Q)SAR data described below.

No structural alerts for skin sensitisation were present for turpentine constituents alpha-pinene, beta-pinene or delta-3-carene using OECD QSAR Toolbox v3.4. However, when auto-oxidation was simulated, mechanistic alerts, including alerts for protein binding via nucleophilic additions and free radical formation were present for the metabolites of all three constituents.

Skin sensitisation predictions were produced using OASIS–TIMES 2.27.19. Predictions for alpha-pinene and beta-pinene were in domain while those for delta-3-carene were out of domain (90 % in domain). All predictions were negative for unmetabolised chemicals. Several auto-oxidised metabolites of the turpentine constituents were predicted to be weak sensitisers, which were supported by mechanistic alerts for hydroperoxide free radical decomposition and nucleophilic addition to ketones.

Observation in humans

Turpentine is considered to be a chemical of concern in the European Commission Scientific Committee on Consumer Safety (SCCS) opinion on fragrance materials with >1000 reported dermatitis cases published (SCCS, 2012).

Numerous studies of the contact allergy to turpentine were undertaken between 1940 and 1990. There is a large variability (1.3–22.3 %) in the number of positive reactions to turpentine in patients with contact dermatitis. This variability is thought to depend on the variable composition (particularly delta-3-carene content) and variability in exposure to turpentine throughout different decades (MAK, 1996; SCCS, 2012).

In a Kligman maximisation test, 25 healthy male volunteers received 5 dermal applications of turpentine (50 %, v/v; CAS No not specified) in petrolatum for 48 h under occlusion followed by a challenge dose of 20 % turpentine in petrolatum under occlusion for 48 h. The challenge site was observed immediately after removal of the patch and again 48 h later; obvious erythema was considered a positive response. Under these test conditions, 18/25 volunteers displayed a reaction to the substance and turpentine was therefore considered a strong sensitiser (REACHb).

Turpentine allergy in pottery workers increased in the 6 months following a change from Portuguese to Indonesian turpentine. In a patch-test study in 24 dermatitis patients working in the local pottery industry, 14 patients reacted positively to Indonesian turpentine (85 % alpha-pinene, >15 % delta-3-carene) and 3 to Portuguese turpentine (78 % alpha-pinene, <0.7 % delta-3-carene). When individual turpentine constituents were tested, 8 patients displayed a reaction to alpha-pinene, 4 to delta-3-carene and 2 to oxidised turpentine. All substances were tested at 10 % in petrolatum. The complete compositions of the turpentines and individual constituents were not reported. Therefore, other unidentified components may also have contributed to the reactions (Lear et al., 1996).

Repeated Dose Toxicity

Oral

No data are available for the assessed substances or the main constituents.

Dermal

No data are available for the assessed substances or the main constituents.

Inhalation

Based on the available animal data for the turpentine constituent alpha-pinene and human data for turpentine (refer to ***Observations in Humans***), turpentine may cause adverse health effects following repeated inhalation exposure, warranting hazard classification (refer to ***Recommendation*** section).

In a repeated dose inhalation study conducted similarly to OECD TG 413, Fischer rats (F344) and B6C3F1 mice (10/sex/dose) were exposed to 25, 50, 100, 200 or 400 ppm (139–2225 mg/m^3) of alpha-pinene in an inhalation chamber for 6 h/day, 5 days/week for 14 weeks.

In rats, increased mortality and reduced bodyweight gain was noted in females at 400ppm. Males exposed to alpha-pinene vapour showed a statistically significant decrease in cauda epididymal sperm numbers. The sperm numbers were reduced by approximately 20 % following exposure to 200 and 400 ppm of alpha-pinene. There were no supporting histopathological findings due to inappropriate fixation. The testicular sperm numbers and cauda epididymal sperm motility were unchanged. No evidence of changes in weight or histology of other male and female reproductive organs was reported. Reported no observed adverse effect concentration (NOEAC) for male rats was 100 ppm for males based on effects on sperm count and 200 ppm for females, based on mortality and reduced rate of weight gain (NTP, 2016; NICNASa).

All mice survived until the end of the study and no changes in body weights were observed. Minimal to moderate hyperplasia in the transitional epithelium of the urinary bladder was observed in mice exposed to 100 ppm and above. In male mice, the reduction in caudal sperm numbers was dose-dependent with a 25, 33, and 40 % decrease after exposure to 100, 200 and 400 ppm alpha-pinene, respectively. Similarly to rats, all other sperm parameters remained unchanged and histopathological data were not available. Reported NOAECs for males and females were 50 ppm based on reduced sperm numbers and epithelial changes in males and urinary bladder epithelial changes in females (NTP, 2016; NICNASa).

Observation in humans

Chronic effects in workers exposed to turpentine have been reported. However, often co-exposure to sawdust or other chemicals are confounding factors.

A group of 5 shoe-polish factory workers that worked in inadequately ventilated rooms suffered from dizziness and a feeling of intoxication, which subsided when the workplace was aired. The workers urine contained increased levels of glucuronic acid and they suffered from bladder inflammation. The shoe-polish contained 65–70 % turpentine or alpha-pinene, 7 % white spirit, 23–24 % paraffin and waxes, 0.8 % of each of nigrosine and induline colourants, 0.4 % diphenylamine and 0.3 % perfume. The concentration of turpentine that elicited the response is unknown. However, when the terpene (turpentine constituents) concentrations in air were 100–300 mg/m^3 (well-ventilated area), the workers had no symptoms (MAK, 2012).

Respiratory symptoms have been reported in 48 sawmill workers exposed to 100–550 mg/m^3 mix of alpha-pinene and delta-3-carene in a ratio of 3:1 or 2:1 (MAK, 2012).

Respiratory symptoms including coughing, chronic bronchitis and irritation in the throat were reported from employees exposed to fumes containing above 125 mg/m^3 terpenes when sawing wood. At higher concentrations (up to 300 mg/m^3) the employees also reported tiredness, headaches and nausea (MAK, 2012).

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, turpentine is not considered to be genotoxic.

In vitro

Several in vitro assays were conducted using turpentine oil (REACHa). These included:

- Negative in vitro point mutation studies in *Salmonella typhimurium* strains TA98, TA100, TA1535, or TA1537 at concentrations up to 500 µg/plate, with or without metabolic activation.
- Negative gene mutation study in the thymidine kinase (tk) locus in L5178Y mouse lymphoma cells treated with DMT at 5–70 µL/mL with metabolic activation and 5–60 µL/mL without metabolic activation.
- Negative chromosome aberration study in human lymphocytes exposed to 0.17 µL/mL for 22 h with and without metabolic activation.

The turpentine constituents alpha-pinene, beta-pinene and delta-3-carene were considered negative for in vitro gene mutation (NICNASa; NICNASb; NICNASc).

In vivo

The major turpentine constituent, alpha-pinene, was negative in an OECD TG 474 mammalian erythrocyte micronucleus test (NICNASa).

Carcinogenicity

Data from long-term animal carcinogenicity studies are not available.

Several studies examining the ability of turpentine to initiate or promote tumour formation have been undertaken.

Undiluted turpentine was shown to have a mild tumour promoting effect in mice after initiation with 7,12-dimethylbenz[a]-anthracene (DMBA). Application of undiluted turpentine without initiation with DMBA did not lead to tumour formation. Diluted turpentine at 20–50 % concentrations in acetone or mineral oil did not promote tumour formation in mice (MAK, 2012).

In a study in NZW rabbits, turpentine (50 % in acetone) pre-treatment increased the susceptibility to develop virion-induced skin papillomas (MAK, 2012).

In another study investigating the effects of turpentine-induced inflammation on transplantable melanoma cells, turpentine induced an inflammatory response but failed to promote melanoma development. The transplantable melanoma K1735 cells were injected into ears of syngeneic C3H/HeN(MTV-) mice, followed by treatment with turpentine (10 µL) twice a week for 3 weeks (NTP, 2002).

Observations in humans

Two epidemiological studies have assessed the association between occupational exposure to turpentine or terpenes, and cancer outcomes. A study in Finnish woodworkers found a weak association between exposure to terpenes (primarily alpha-pinene and delta-3-carene) lasting longer than 1 month, and the incidence of respiratory cancers. Another study found an association between paternal exposure to turpentine and the incidence of neuroblastoma in their offspring (NTP, 2016; NICNASa).

Reproductive and Developmental Toxicity

Based on data from the turpentine constituent alpha-pinene, turpentine may affect sperm numbers in male rats and mice. Maternal exposure to turpentine at high doses may produce developmental toxicity. However, the effects are not sufficient to warrant hazard classification.

In a repeated dose inhalation toxicity study (refer to ***Repeated dose toxicity*** section), male rats and mice exposed to alpha-pinene vapour showed a statistically significant decrease in cauda epididymal sperm numbers (NICNASa). There were no supporting histopathological findings due to inappropriate fixation. The testicular sperm numbers and cauda epididymal sperm motility were unchanged. No evidence of changes in weight or histology of either male or female reproductive organs including the clitoris, ovaries, uterus, preputial gland, seminal vesicles and testes were reported.

In a developmental toxicity study, 5 pregnant SD rats were exposed to turpentine (saturated vapour) twice daily for 10 min on gestation days (GD) 17–21. High mortality (60 %) and evidence of severe nervous system disorder and dyspnoea were reported for pups exposed in utero. After approximately 5 min of exposure the dams displayed signs of incoordination, ataxia, hyperpnoea, and salivation (MAK, 2012). No further study details are available.

In a US Food and Drug Administration (FDA) sponsored study, the reproductive toxicity of an essential oil containing alpha-pinene (20–25 %), beta-pinene (15–18 %) and sabinene (38–42 %) was evaluated in CD-1 mice, Wistar rats and golden hamsters. Pregnant Wistar rats (22–23/dose) received 0, 3, 2, 56 or 260 mg/kg bw/day of the test material in corn oil on GD6 and through to GD15 by oral gavage. No effects were observed on implantation, maternal survival or any measured foetal parameter. Similar results were reported for pregnant golden hamsters receiving up to 600 mg/kg bw/day and in pregnant mice receiving up to 560 mg/kg bw/day of the test substance (FFHPVC, 2006).

Other Health Effects

Neurotoxicity

Turpentine can induce salivation, weakness, incoordination, paraplegia, ataxia, tremor, convulsions, respiratory distress and coma in animals and central nervous system depression, spasms, coma, headache, dizziness, nausea and weakness in humans (refer to ***Acute toxicity*** and ***Reproductive and Developmental Toxicity*** sections for more details). Therefore, hazard classification is warranted (refer to ***Recommendation*** section).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects of skin sensitisation and irritation, sensory irritation in the upper respiratory tract and systemic acute (particularly CNS depression) and long-term effects from inhalation of turpentine.

Turpentine could also have the potential to cause chemical pneumonitis if aspirated depending on the viscosity as introduced.

Public Risk Characterisation

Based on the Australian and international uses identified, the substances may be used in cosmetic and domestic products in Australia. The general public could be exposed to the chemical when using cosmetics or domestic products containing turpentine.

In Europe, the substances are restricted in cosmetics and can only be used if the peroxide levels are below 10mM (CosIng). The substances are readily available, and are expected to be widely distributed for use as raw fragrance materials. However, the distribution of the chemicals for fragrance purposes is expected to be largely controlled by members of IFRA. Implementation of the restriction of these chemicals under the IFRA Standard is expected to sufficiently address the public risks associated with chemical exposure through fragrances (e.g. concentration limits of peroxide levels in the product of 10mM) (IFRA, 2015). Turpentine is an essential oil which is expected to be widely available in commerce, limiting the applicability of the IFRA standard. However, for essential oils, use concentrations are expected to be limited by the strong odours. Domestic products such a shoe polishes, may contain higher levels but exposure is expected to be less frequent. In Australia, products containing more than 25 % of turpentine must be labelled with 'Caution' (SUSMP, 2018).

Consumer products containing turpentine can oxidise over time. Therefore, products that contain relatively high concentrations but are used infrequently and have long shelf-lives could contain oxidation products that pose a sensitisation hazard to sensitive individuals. This oxidation potential in consumer products can be reduced by incorporating an anti-oxidant and by avoiding use of aged products.

Provided that normal precautions are taken to avoid prolonged skin contact, the risk to the public posed by domestic products containing turpentine is not considered to be unreasonable at concentrations below 25 %. At higher concentrations, potential harm is reduced by using warnings and safety directions on the label. Concentrations in cosmetic products are expected to be low (<0.6 %) due to their use as fragrances (The Goodscents Company).

Occupational Risk Characterisation

Given the critical local and systemic health effects, the substances could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, oral, ocular and inhalation exposure are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to ***Recommendation*** section).

Sensory irritation and respiratory symptoms in humans following exposure is reported at airborne concentrations below the current workplace exposure standard TWA of 100 ppm. Lower exposure standards to minimise the potential for these effects have been established overseas. Therefore, a review of the current exposure standard may be beneficial to mitigate the risk of adverse effects. Airborne concentrations of the chemical should be kept as low as reasonably practicable to minimise risk.

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended 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.

It is recommended that Safe Work Australia consider whether current controls adequately minimise the risk to workers. A Tier III assessment may be necessary to provide further information about whether the current exposure controls are adequate to protect workers.

Regulatory Control

Public Health

Products containing the substances should be labelled in accordance with state and territory legislation (SUSMP, 2018).

Work Health and Safety

The substances are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) May be fatal if swallowed and enters airways - Aspi. Cat. 1 (H304) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1 (H317)
Repeat Dose Toxicity	Not Applicable	Causes damage to organs through prolonged or repeated exposure through inhalation - Cat. 1 (H372)
Other Health Effects	Not Applicable	May cause drowsiness or dizziness - Specific target organ tox, single exp Cat. 3 (H336)

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

[b] 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 consumers

Products containing the substances should be used according to the instructions on the label.

Advice for industry

Control measures to minimise the risk from oral, dermal, ocular 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 chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- 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 help meet 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 chemicals 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.

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Last Update 29 June 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Turpentine oil** sulfate turpentine terpentine spirits turpentine, steam distilled turpentine
CAS Number	8006-64-2
Structural Formula	

	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Turpentine oil, resin**
CAS Number	8052-14-0
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Turpentine** gum turpentine TERP turpentine (oil)

	turpentine gum pine resin
CAS Number	9005-90-7
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	Unspecified

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