Ligroine: Human health tier II assessment

24 April 2015

CAS Number: 8032-32-4

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

Chemical Identity

Synonyms	Benzoline Mineral spirits Painters naphtha Petroleum ether
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight (g/mol)	N/A
Appearance and Odour (where available)	Clear to yellowish liquid with pleasant, aromatic odour.
SMILES	C(C)CCCCCC

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers;
- the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR);
- Galleria Chemica;
- the Substances and Preparations in Nordic countries (SPIN) database;
- the European Commission Cosmetic Ingredients and Substances (CosIng) database;
- the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and,
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic uses as a:

- solvent in cleansing products (cold creams, cleansing lotions, liquids and pads), eye make-up preparations, mascara; and
- component that regulates viscosity and pigment suspension in cosmetic formulation types.

The chemical has reported domestic use as a solvent in paints, coatings and adhesives.

The chemical has reported commercial use as a component of professional cleaning/washing agents, corrosion inhibitors, and degreasers.

The chemical has reported site-limited use as an intermediate in closed processes.

Restrictions

Australian

The chemical is listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 5 (SUSMP, 2015).

Schedule 5:

'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 grams 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.'

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, 2015).

International

The chemical is listed on the EU Cosmetics Regulation 1223/2009 Annex II: List of substances prohibited in cosmetic products, if the chemical contains >0.1% benzene (CosIng).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Carc. Cat. 2; R45—'May cause cancer'
- Muta. Cat. 2; R46—'May cause heritable genetic damage'
- Xn; R65—'May cause lung damage if swallowed'

These classifications are subject to notes H, P & E:

'**Note H**: The classification and label shown for this substance applies to the dangerous property(ies) indicated by the Risk Phrase(s) in combination with the category(ies) of danger shown. The manufacturers, distributors and importers of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of Section 7 of Annex VI of directive 67/548/EEC.'

'**Note P**: 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). When the substance is classified as a carcinogen or mutagen, Note E shall also apply. When the substance is not classified as a carcinogen or mutagen, at least the Safety Phrases (2-)23-24-62 shall apply. This note applies only to certain complex oil-derived substances in Annex I.'

'**Note E**: For substances ascribed Note E, the Risk Phrases R20, R21, R22, R23, R24, R25, R26, R27, R28 R39, R68 (harmful), R48 and R65 and all combinations of these Risk Phrases should be preceded by the word 'also'.'

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 300–1400 mg/m^3 (300 ppm) time weighted average (TWA) and 1800 mg/m^3 (375–400 ppm) short-term exposure limit (STEL) in different countries such as the USA (Hawaii, Vermont), Canada (Alberta) and Latvia.

Health Hazard Information

The chemical is described as: 'A complex combination of hydrocarbons obtained by the fractional distillation of petroleum. This fraction boils in the range of approximately 60°C to 110°C (140°F to 230°F)' (SciFinder). This chemical has the following reported hydrocarbon components and their relative compositions: linear and branched alkanes (~55 %), cycloalkanes (~32 %), aromatics (~12 %; which includes benzene at 0.1 %) (OECD, 2010).

The aromatic components of the chemical, in general, are more toxic than the aliphatic components. Benzene (CAS No. 71-43-2) (NICNAS, 2001) has the highest toxicity of these components and also serves as a marker for the aromatic content of these unknown or variable composition, complex reaction products or biological materials (UVCBs).

Since there is limited hazard information specific to the chemical, the hazards of reference chemicals with known PONA (paraffinic, olefinic, naphthenic, and aromatic) hydrocarbon content (US EPA, 2011) will be relevant in assessing the chemical, where appropriate. The reference chemicals used as markers were 'light alkylate naphtha' (CAS No. 64741-66-8), 'light catalytic cracked naphtha' (CAS No. 64741-55-5), 'heavy straight run naphtha' (CAS No. 64741-41-9), and 'full range catalytic reformed naphtha' (CAS No. 68955-35-1), respectively, for the paraffinic, olefinic, naphthenic, and aromatic hydrocarbon content of the 'low boiling point naphthas' (US EPA, 2011; Government of Canada, 2014; NICNAS).

Acute Toxicity

Oral

No data are available for this chemical. The reference chemicals identified by the CAS Nos. 64741-55-5 (olefinic), 64741-66-8 (paraffinic), and 68955-35-1 (aromatic), have low acute oral toxicity based on results from animal tests with median lethal doses (LD50s) in Sprague Dawley (SD) rats reported to be >2000 mg/kg bw (Government of Canada, 2011; US EPA, 2011).

No mortalities nor behavioural changes were observed in female SD rats after a single intraperitoneal (i.p.) injection of analytical grade petroleum ether (reported boiling point: 40–60 °C) at doses of up to 2000 mg/kg bw (Parasuraman et al., 2014).

Dermal

No data are available for this chemical. The reference chemicals have low acute dermal toxicity based on results from animal tests with LD50s in New Zealand White rabbits for the chemicals identified by the CAS Nos. 64741-55-5 (olefinic) and 68955-35-1 (aromatic) reported to be >2000 mg/kg bw (Government of Canada, 2011; US EPA, 2011). No mortalities occurred at any doses for any of the reference chemicals specified above.

Inhalation

The chemical is classified as hazardous with the risk phrase 'May cause lung damage if swallowed' (Xn; R65) in the HSIS (Safe Work Australia).

In an experiment equivalent or similar to the OECD Test Guideline (TG) 403, male Wistar rats were exposed to the chemical at a single four-hour concentration of 4.4, 9.8 or 26 mg/L via inhalation. No deaths occurred in the 4.4 and 9.8 mg/L groups but they did show evidence of bronchial effects and extraneous lesions in organs other than the lungs. All of the animals in the 26 mg/L group died. The gross necropsy study in the highest dose group showed congested lungs and liver. Based on this result, it was calculated that the four-hour median lethal concentration (LC50) in rats is 16 mg/L (OECD, 2010).

Based on the available data, there is evidence to classify the chemical as hazardous with the risk phrase 'Harmful by inhalation' (Xn; R20) in the HSIS in addition to the current classification for aspiration hazard (Xn; R65).

Corrosion / Irritation

Respiratory Irritation

No data are available.

Skin Irritation

No data are available for the chemical. The reference chemicals are shown to cause low to moderate skin irritation in animal studies. The chemicals identified with CAS Nos. 64741-55-5 (olefinic), 64741-66-8 (paraffinic) and 68955-35-1 (aromatic) are moderately irritating to rat or rabbit skin (US EPA, 2011).

Low boiling point range (< 250 °C) petroleum solvents are reported to have the greatest defatting action and dermatitis potential among the hydrocarbon solvents (Chew et al., 2006).

The component chemical, benzene (CAS No. 71-43-2), is classified as hazardous with the risk phrase 'Irritating to skin' (R38) in the HSIS (Safe Work Australia). In humans, vapour levels >60 ppm have been associated with skin irritation, including second degree burns (NICNAS, 2001).

Reported concentrations of benzene in the chemical, up to 0.1 % (OECD, 2010), are not above the cut-off concentrations for classification for skin irritation (Safe Work Australia, 2004; GHS, 2009). Therefore, while the classification for skin irritation is not warranted for the chemical (refer to **Recommendation** section), the chemical should be classified for repeated exposure causing skin dryness or cracking.

Eye Irritation

No data are available for the chemical. In eye irritation studies in rabbits, the reference chemicals were found to cause low to moderate eye irritation. The chemicals identified with CAS Nos. 64741-55-5 (olefinic) and 64741-66-8 (paraffinic) were not irritating to rabbit eyes, whereas the chemical with CAS No. 68955-35-1 (aromatic) was moderately irritating to rabbit eyes (US EPA, 2011).

The component chemical, benzene, is classified as hazardous with the risk phrase 'Irritant: Irritating to eyes' (R36) in the HSIS (Safe Work Australia). Benzene vapours have been reported to cause eye irritation in humans and rats at concentrations ≥33 ppm and ≥10 ppm, respectively (NICNAS, 2001).

Reported concentrations of benzene in the chemical, up to 0.1 % (OECD, 2010), are not above the cut-off concentrations for classification for eye irritation (Safe Work Australia, 2004; GHS, 2009). Therefore, classification for eye irritation is not warranted for this chemical.

Sensitisation

Respiratory Sensitisation

No data are available.

Skin Sensitisation

No data are available for the chemical. The reference chemicals were not found to induce dermal sensitisation when tested in guinea pigs in various skin sensitisation studies. The chemicals with CAS Nos. 64741-55-5 (olefinic), 64741-66-8 (paraffinic), and 68955-35-1 (aromatic) were found to be non-sensitising to guinea pig skin in the reported studies (US EPA, 2011).

Repeated Dose Toxicity

Oral

No data are available for the chemical for this type of exposure. Based on the results of i.p. injections of the chemical in rats, the chemical is not likely to cause severe effects from repeated oral exposure.

In an experiment equivalent or similar to OECD TG 407 in SD rats (four animals/sex/group), daily i.p. administration of analytical grade petroleum ether (reported boiling point: 40–60 °C) at doses of 250 or 500 mg/kg bw for 14 days caused the following effects in all the dosed groups: decreased body weight gain; decreased food intake; salivation; hair loss; reduced muscular activity; and piloerection (Parasuraman et al., 2014).

Dermal

No data are available for the chemical.

Occluded applications of the reference chemical CAS No. 64741-55-5 (olefinic) resulted in no treatment-related systemic effects in 28–90-day repeated dose toxicity studies in SD rats at doses up to 652 mg/kg bw/day (US EPA, 2011).

Studies in rabbits (strain not specified) using the reference chemical CAS No. 68955-35-1 (aromatic) reported the lowest observed adverse effect level (LOAEL) value of 1000 mg/kg bw/day in 28-day repeated dermal dose toxicity studies, based on increased mortality (Government of Canada, 2011).

Inhalation

In an experiment equivalent or similar to the OECD TG 413, male Wistar rats (25 animals/dose) were exposed to the chemical at doses of 1.3, 2.8, or 5.8 mg/L via inhalation for six hours/day, five days/week, for 13 weeks. Two animals died in the 1.3 mg/L group due to lung abscesses and pneumonia. However, since no other effects occurred in the higher dose groups, the deaths were not considered to be toxicologically relevant. In the highest dose group, changes in blood parameters (statistically significant increase in neutrophils, decreased leukocyte and erythrocyte counts) were considered as minor effects. The no observed adverse effect concentration (NOAEC) for this study was determined to be 5.8 mg/L (OECD, 2010).

Genotoxicity

The chemical is classified as hazardous—Category 2 mutagenic substance—with the risk phrase ‘May cause heritable genetic damage’ (T; R46) in the HSIS (Safe Work Australia). This classification need not apply if it can be shown that the chemical contains less than 0.1 % w/w benzene. Although there are no available data for the chemical, the data from the reference chemicals, apart from benzene, are overall negative and thus support the current classification.

Several in vitro assays for some of the reference chemicals indicated the following mixed results (Government of Canada, 2011; US EPA, 2011; Government of Canada, 2013):

- positive results in chromosomal aberrations in mouse lymphoma assays with metabolic activation (doses up to 400 µg/mL for the chemical with CAS No. 68955-35-1(aromatic));
- negative results in chromosomal aberrations in mouse lymphoma assays with and without metabolic activation (the chemicals with CAS Nos. 64741-55-5 (olefinic) and 64741-66-8 (paraffinic)); and,
- equivocal results for sister chromatid exchange (SCE) in Chinese hamster ovary (CHO) cells without metabolic activation (the chemical with CAS No. 64741-55-5 (olefinic)).

The chemicals gave negative results in several in vivo genotoxicity assays, which included induction of bone marrow chromosomal aberration of SD rats (inhalation exposure and i.p. injection of the chemical with CAS No. 64741-55-5 (olefinic);

i.p. injection of the chemicals with CAS Nos. 64741-66-8 (paraffinic) and 68955-35-1 (aromatic)).

The component chemical, benzene, is classified as hazardous—Category 2 mutagenic substance—with the risk phrase ‘May cause heritable genetic damage’ (T; R46) in the HSIS (Safe Work Australia). The reported concentration of benzene in the chemical is a maximum of 0.1 % (OECD, 2010) which is the cut-off concentration for classification (Safe Work Australia, 2004; GHS, 2009). Classification for mutagenicity could be warranted for the chemical if it can be demonstrated that the benzene content is at or above the cut-off concentrations for this classification (refer to **Recommendation** section).

Carcinogenicity

The chemical is classified as hazardous, Category 2 carcinogenic substance, with the risk phrase 'May cause cancer' (T; R45) in the HSIS (Safe Work Australia). This classification need not apply if it can be shown that the chemical contains less than 0.1 % w/w benzene. While there is no available information related to the carcinogenicity of the chemical, it is expected that any carcinogenic activity from exposure to the chemical will be caused, predominantly, by the levels of aromatic content such as benzene.

The component chemical, benzene, is classified as hazardous—Category 1 carcinogenic substance—with the risk phrase ‘May cause cancer’ (T; R45) in the HSIS (Safe Work Australia). The reported concentration of benzene in the chemical is 0.1 % (OECD, 2010), which is the cut-off concentration for classification (Safe Work Australia, 2004; GHS, 2009). Classification for carcinogenicity could be warranted for the chemical if it can be demonstrated that the benzene content is at or above the cut-off concentrations for this classification (refer to **Recommendation** section).

Reproductive and Developmental Toxicity

No data are available for the chemical. The reference chemicals did not cause any reproductive or developmental adverse effects.

In several combined reproductive/developmental toxicity screening tests, SD rats exposed by inhalation to the chemicals with CAS Nos. 64741-41-9, 64741-55-5, and 64741-66-8 showed no adverse effects on reproductive and developmental toxicity parameters at doses up to 13.4, 23.9, and 25 mg/L, respectively (Government of Canada, 2011; US EPA, 2011).

Risk Characterisation

Critical Health Effects

The critical health effects of this UVCB chemical depend on its benzene content, which is typically low for the chemical. If the benzene content is atypically high, effects include systemic long-term effects (carcinogenicity and mutagenicity), systemic acute effects (potential acute toxicity from inhalation exposure) and local effects (repeated exposure causing skin dryness or cracking). Components other than benzene are associated with a range of hazardous properties, but the available data for the chemical indicate that the content of hazardous components is generally low. The likely risks associated with exposure to the chemical will depend on the actual concentration of the hazardous components, especially in cosmetic products.

Public Risk Characterisation

Given the uses identified for the chemical, very high exposure to the public is anticipated, especially when the chemical is used in cosmetics. The risks from exposure to the chemical depend on its benzene content, which is generally low for the chemical. The *Poisons Standard* (Schedule 7) requires hydrocarbon solvents containing benzene at 15 mL/L or greater to not be available to the public. Therefore, the public risk from this chemical is not considered to be unreasonable.

Occupational Risk Characterisation

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

Any air monitoring should include benzene.

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

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2015).

Work Health and Safety

The chemical is recommended for classification and labelling under the current Approved Criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

For chronic health effects, the classification will be dependent on the concentration of benzene.

Genotoxicity

In the absence of specific test data, the classification should be determined based on the concentration of benzene.

Carcinogenicity

In the absence of specific test data, the classification should be determined based on the concentration of benzene.

The classification criteria for mixtures (Safe Work Australia, 2004; GHS, 2009) should be applied to this UVCB substance, based on its concentration of benzene. The classifications below represent the highest possible classifications for each endpoint under these rules. Should empirical data become available for the chemical to indicate that a lower (or higher) classification is appropriate, this may be used to amend the default classification for the chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful by inhalation (Xn; R20) Harmful: may cause lung damage if swallowed (Xn; R65)*	Harmful if inhaled - Cat. 4 (H332) May be fatal if swallowed and enters airways - Aspi. Cat. 1 (H304)
Irritation / Corrosivity	Repeated exposure may cause skin dryness or cracking (R66)	Repeated exposure may cause skin dryness and cracking (AUH066)

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
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)

[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 chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular, and inhalation exposure to the chemical 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 could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical[s], 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 chemical.

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 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 the chemical has not been undertaken as part of this assessment.

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