Benzene, methyl-: Human health tier II assessment

27 October 2017

CAS Number: 108-88-3

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.

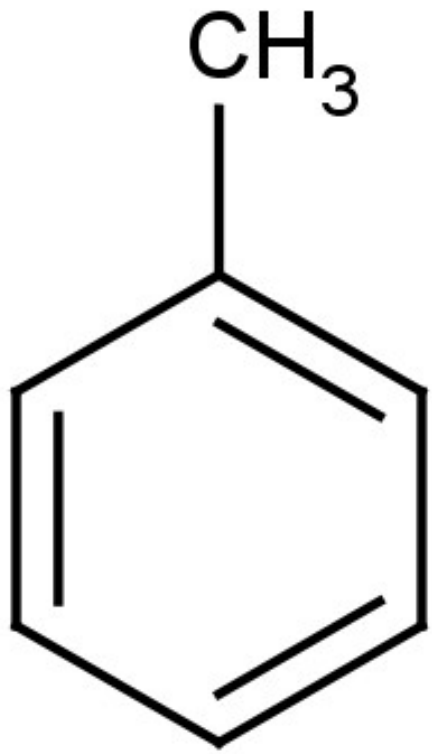
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Toluene Methylbenzene Toluol Phenylmethane Methacide
Structural Formula	

Molecular Formula	C7H8
Molecular Weight (g/mol)	92.14
Appearance and Odour (where available)	Colourless liquid, with a sweet, pungent, benzene-like odour.
SMILES	c1(C)ccccc1

Import, Manufacture and Use

Australian

The following Australian uses were reported under the 2006 High Volume Industrial Chemicals List (HVICL) and other NICNAS calls for information.

The chemical has reported domestic use including:

- cleaning products.

The chemical has reported commercial use including:

- in fuels and solvents;
- in adhesives;
- in printer inks;
- in degreasers; and
- as an aviation fuel additive.

International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossier, the European Chemicals Agency Risk Assessment Report (ECHA RAR), the Organisation for Economic Cooperation and Development Screening Information Dataset Initial Assessment Report (OECD SIAR), the European Commission Cosmetic Substances and Ingredients (CosIng) database, the US Agency for Toxic Substances and Disease Registry (ATSDR) report, the International Agency for Research on Cancer (IARC) report and the International Programme on Chemical Safety Environmental Health Criteria (IPCS EHC).

The chemical has reported cosmetic use as an antioxidant and solvent in nail products with a maximum concentration in the finished cosmetic product of 25 %.

The chemical has reported domestic use including as a cleaning agent.

The chemical has reported commercial use including use as a:

- component of gasoline to increase pyrolysis; and
- solvent in paints, coatings, adhesives, inks.

The chemical has reported site-limited use including as an intermediate in the organic synthesis of various chemicals which includes toluene diisocyanate, benzoic acid, and xylene.

Toluene is a component of many petroleum-derived UVCB substances.

Restrictions

Australian

The chemical is listed in the following:

- Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) in Schedule 6 when present at a concentration of > 50 % by volume and otherwise in Schedule 5;
- Australia New Zealand Food Standards Code—Processing Aids—Permitted extraction solvents. Maximum permitted level 1 mg/kg; and
- National Health and Medical Research Council. National Water Quality Management Strategy, Australian Drinking Water Guidelines 6 (2011). The guideline value for health effects is 0.8 mg/L (NHMRC, 2011).

International

The chemical is listed in the following:

- ASEAN Cosmetic Directive Annex III Part 1 List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down. The chemical is restricted to use in nail products at concentrations < 25 %;
- EU Cosmetic Directive 76/768/EEC Annex III Part 1: List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down. The chemical can only be used in nail products at concentrations < 25 %;
- Canadian Department of Justice, Hazardous Products Act, ingredient disclosure list (SOR/88-64) current to September 19, 2012. Must be disclosed at concentrations ≤ 1 %w/w;
- WHO (World Health Organization) Guidelines for drinking-water quality, Fourth Edition, 2011. The guideline value for the chemical is 0.7 mg/L; and
- US—California Proposition 65—Maximum allowable dose levels (MADLs) for chemicals causing reproductive toxicity. The MADL for the chemical is 7000 µg/d.

Existing Work Health and Safety Controls

Hazard Classification

The chemical 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):

Skin irritation – category 2; H315 (Causes skin irritation)

Specific target organ toxicity (repeated exposure) – category 2; H373 (May cause damage to organs through prolonged or repeated exposure)

Reproductive toxicity – category 1A; H360 (May damage fertility or the unborn child)

Physical hazard (Flammable liquids) – category 2; H225 (Highly flammable liquid and vapour)

Exposure Standards

Australian

The chemical has an exposure standard of 191 mg/m³ (50 ppm) TWA and 574 mg/m³ (150 ppm) STEL.

International

The following exposure standards are identified (Galleria Chemica):

- exposure limits (TWA) of 37–375 mg/m³ (10–100 ppm) and STEL of 384–760 mg/m³ (100–200 ppm) in different countries such as USA (California, Hawaii, Minnesota, Tennessee, Washington), Canada (Quebec), Germany, Japan, Norway, Switzerland and the United Kingdom.

Health Hazard Information

Toxicokinetics

Following inhalation by humans, 40–60 % of the chemical is absorbed from the respiratory tract. The chemical is absorbed through the skin at a rate of 14–23 mg/cm²/h, although absorption from the gastrointestinal (GI) tract appears to be slower (IPCS, 1986).

Toluene is extensively metabolised to produce the major metabolite: hippuric acid, which is excreted in the urine, with benzyl glucuronide also formed in smaller amounts (HSDB, 2012).

Acute Toxicity

Oral

The chemical is of low acute toxicity from oral exposure in rats with a median lethal dose (LD50) of 2600–7500 g/kg bw (WHO, 2004).

Dermal

The chemical is of low acute toxicity from dermal exposure with an LD50 in rabbits of 12125 mg/kg bw (Registry of Toxic Effects of Chemical Substances).

Inhalation

The chemical is of low acute toxicity from inhalation exposure, with LC50 values in the range of 20000–26000 mg/m³ for mice, and approximately 45000 mg/m³ for rats (IPCS, 1986). However, the chemical is known to cause central nervous system (CNS) toxicity immediately after exposure to high concentrations of the chemical by inhalation or ingestion (ATSDR, 2000; IPCS, 1986).

The available information support classification as hazardous with hazard category 'Specific target organ toxicity (single exposure) Category 3' and hazard statement 'May cause drowsiness or dizziness' (H336) in the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Observation in humans

Acute exposure of humans to the chemical at concentrations up to 375 mg/m³ or less for single periods of 20 minutes to 3.5 hours did not result in adverse effects being observed (Government of Canada, 1992). Acute exposure to the chemical in the range of 750–5625 mg/m³ (200–1500 ppm) caused dose-related central nervous system effects (IPCS, 1986). High acute exposures to the chemical (e.g. 37500 mg/m³) during industrial accidents were characterised by initial central nervous system excitative effects (e.g., exhilaration, euphoria, hallucinations), followed by a progressive impairment of consciousness, eventually resulting in seizures and coma (IPCS, 1986).

Corrosion / Irritation

Respiratory Irritation

The chemical is not classified as a respiratory irritant. The data available support this classification.

Respiratory tract irritation, particularly in the nasal cavity, has been reported in animal studies with the chemical at concentrations of 600 ppm and greater. However, in lifetime and 28-day studies, no changes were seen in the nasal epithelium following exposure to concentrations of 300 ppm of the chemical (US EPA, 2005).

Skin Irritation

The chemical is classified as hazardous with hazard category 'Skin irritation Category 2' and hazard statement 'Causes skin irritation' (H315) in the Hazardous Chemical Information System (HCIS) (Safe Work Australia). The data available support this classification.

The chemical is a slight to moderate skin irritant in rabbits and guinea pigs (IPCS, 1986).

Eye Irritation

The chemical is not classifiable as an eye irritant based on the available data.

The chemical was a slight to severe irritant to the conjunctival membrane in rabbits (WHO, 1986). In the one study where severe irritation was seen, 2 mg was placed into the eye of a rabbit for 24 hours. Mild effects were seen in two studies where 870 µg and 100 mg were applied for 72 hours or 30 seconds respectively before the eyes were rinsed (WHO, 1986). In a more recent study (1995), the chemical produced slight irritation in the eyes of rabbits tested in accordance with good laboratory procedure (GLP) and OECD TG 405 (WHO, 2004).

Observation in humans

Single, short-term exposures to the chemical (750 mg/m³ for eight hours) have reportedly caused transient eye and respiratory tract irritation with lachrymation at 1500 mg/m³ (WHO, 1986). Nasal or ocular irritation in humans has been reported from airborne concentrations of the chemical of 100 ppm or above (US EPA, 2005).

Sensitisation

Skin Sensitisation

The chemical did not cause skin sensitisation in a study using the guinea pig maximisation test (WHO, 2004).

Repeated Dose Toxicity

Oral

Based on the available information, no hazard classification for repeated dose oral toxicity is recommended.

The principal studies on the chemical, used by the United States Environmental Protection Agency (US EPA) to set a reference dose for chronic oral exposure, were studies where groups of 10 rats or mice/sex/group were administered the chemical in corn oil at doses of 0, 312, 625, 1250, 2500, or 5000 mg/kg bw/day, five days/week for 13 weeks (US EPA, 2005). A no observed adverse effect level (NOAEL) of 312 mg/kg bw/day was set, based on increases in kidney weights of male rats, with a lowest observed adverse effect level (LOAEL) of 625 mg/kg bw/day (US EPA, 2005). The increases in absolute kidney weights were 107 % and 112 % of controls; and the relative kidney weights were 100 % and 106 % of controls for the 312 and 625 mg/kg bw/day dose groups respectively. Although the increases in absolute kidney weight over the controls were slight in the 625 mg/kg bw/day dose group, the change was statistically significant and, due to a dose response relationship, even greater changes were seen at the higher doses. Therefore, the changes were considered to be adverse.

Inhalation

The chemical is classified as hazardous with hazard category 'Specific target organ toxicity (repeated exposure) Category 2 and hazard statement 'May cause damage to organs through prolonged or repeated exposure' (H373) for repeat dose inhalation toxicity in the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

The chemical has a lowest observed effect level (LOEL) of 600 ppm (2250 mg/m³) based on irritation of the upper respiratory tract, specifically the nasal epithelium in female rats (Government of Canada, 1992). However, neurological effects following the inhalation of the chemical were seen at even lower concentrations. One study on 30 male Sprague Dawley (SD) rats exposed to the chemical at a concentration of 80 ppm (302 mg/m³) for six hours/day, four days/week for four weeks showed adverse neurobehavioural alterations; the effects were not present after a four-week recovery period (US EPA, 2005).

Observation in humans

There are a number of studies looking at the occupational inhalation exposure of humans to the chemical The most sensitive effects, noted after inhalation exposure, were neurological including impaired colour vision, impaired hearing, decreased performance in neurobehavioural analysis, changes in motor and sensory nerve conduction velocity, headache and dizziness. NOAELs in the range of 25–50 ppm of the chemical were identified for individual neurological effects, with statistically significant neurological effects seen in workers in the range of 83–132 ppm. Respiratory irritation and various effects in the eyes and kidneys have also been observed in humans following chronic exposure to the chemical. However, these occurred at higher exposure concentrations than those resulting in neurological effects. The US EPA calculated the arithmetic mean (34 ppm, 128 mg/m³) of the available NOAELs from 10 occupational studies that they considered adequate. A neurological function deficit was chosen as the critical effect in these studies, due to the overall preponderance of evidence for this hazard indicator at low doses (US EPA, 2005).

Genotoxicity

Based on the weight of evidence, the chemical is not mutagenic in mammalian or microbial systems (Government of Canada, 1992).

The chemical was found to be non-genotoxic in a number of in vitro systems. However, in vivo studies on insects, rats and mice produced conflicting results, with chromosomal aberrations in rat bone marrow cells observed in some studies, but not in others. In mice, the induction of micronuclei in erythrocytes was observed, but not consistently. In more recent studies, the chemical failed to induce sister chromatid exchange in vitro or in vivo in human lymphocytes, and did not induce micronuclei in vitro in human lymphocytes (WHO, 2004).

Carcinogenicity

The chemical is classified by the International Agency for Research on Cancer (IARC) as 'not classifiable as to its carcinogenicity to humans' (Group 3) (IARC, 1999).

The chemical did not induce a significant increase in tumours in rats or mice following inhalation or application to the skin (IARC, 1999). None of the human epidemiological studies identified any tumours that were significantly associated with exposure to the chemical (IARC, 1999).

Reproductive and Developmental Toxicity

The chemical is classified as hazardous with hazard category 'Reproductive toxicity Category 1A' and hazard statement 'May damage fertility or the unborn child' (H360) in the Hazardous Chemical Information System (HCIS) (Safe Work Australia). The available data support this classification (refer to **Recommendation** section).

In humans, the chemical has been shown to cause congenital defects in infants born to mothers who were exposed to high doses during pregnancy. Long-term exposure in humans at lower doses produced no effects on the fertility of male workers exposed to the chemical, but female workers showed significantly reduced fertility (US EPA, 2005).

In animals, the reproductive and developmental effects of the chemical have been tested in inhalation studies with rats, mice and rabbits, and in oral studies with mice. In the inhalation studies, embryotoxicity and foetotoxicity were observed at doses ≥ 100 mg/m³. In one developmental study where the chemical was administered by gavage, increased embryonic mortality was observed at all doses, reduced foetal weight was observed at the top two doses, and an increased incidence of cleft palate was observed at the highest dose level (780 mg/kg bw/day). No effects on sperm morphology or vaginal cytology were observed in a 15-week inhalation study in rats (WHO, 2004).

Risk Characterisation

Critical Health Effects

The critical effects for risk characterisation include long-term effects (reproductive and developmental toxicity), acute effects (CNS toxicity) and local effects (skin irritation). The chemical may also cause systemic effects through prolonged or repeated inhalation exposure (neurological effects).

Public Risk Characterisation

The chemical is used in domestic cleaning products within Australia and is used in cosmetic nail products overseas. The concentration of the chemical in these products in Australia is not known.

The general public may be exposed to the chemical through dermal and/or inhalation routes when using products containing the chemical. The Scientific Committee on Consumer Products (SCCP) has released an opinion on the use of the chemical in nail products at concentrations up to 25 %, concluding that the chemical 'is not considered to be of concern with regard to acute neurological effects' (European Commission, 2008). In the European Union Risk Assessment Report (EU RAR) for toluene (2003), concern was raised about consumer use of the chemical in spray painting and carpet laying (EU RAR, 2003).

The use of this chemical as an ingredient in cosmetics or domestic products raises concern given the health effects and the bioavailability of the chemical through the oral, dermal and inhalation routes. This chemical is currently listed on Schedule 6 when present at a concentration > 50 % by volume, otherwise on Schedule 5 of the Poisons Standard (SUSMP). The current controls are considered adequate to minimise the risk to public health posed by domestic and cosmetic products containing the chemical, therefore, the chemical is not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation, dermal and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term and acute health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure to the chemical 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 appropriate controls.

Exposure should be avoided where possible and the chemical should be appropriately classified and labelled to ensure that a person conducting a business or an employee at a work place has adequate information to determine appropriate controls for worker safety.

The data support an amendment to the hazard classification in HSIS.

Based on the available data, the current exposure standard may not be adequate to mitigate the risk of adverse effects The current Australian exposure standard of 191 mg/m³ (50 ppm) TWA, and 574 mg/m³ (150 ppm) STEL, may require reconsideration. In the repeated dose inhalation study, the US EPA calculated the arithmetic mean of the available NOAELs from 10 occupational studies that they considered adequate to be 34 ppm, 128 mg/m³, which is below the current exposure standard (US EPA, 2005). Inhalation studies with laboratory animals showed adverse reproductive and developmental effects at doses ≥ 100 mg/m³ (WHO, 2004).

NICNAS Recommendation

The chemical is recommended for Tier III assessment to examine the adequacy of the current exposure standard and any associated public risks. All other aspects have been sufficiently assessed at the Tier II level, provided that the recommendations for classification and labelling are followed.

Regulatory Control

Public Health

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

Work Health and Safety

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below.

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.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment. However, the following classification for physico-chemical hazards should be as follows:

- Aspiration Hazard – category 1; H304 (May be fatal if swallowed and enters airways); and
- Physical hazard (Flammable liquids) – category 2; H225 (Highly flammable liquid and vapour).

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

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	May cause drowsiness or dizziness - Specific target organ tox, single exp Cat. 3 (H336)
Irritation / Corrosivity	Not Applicable	Causes skin irritation - Cat. 2 (H315)*
Repeat Dose Toxicity	Not Applicable	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)*
Reproductive and Developmental Toxicity	Not Applicable	May damage fertility or the unborn child - Cat. 1A (H360)*

[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 industry

Control measures

Control measures to minimise the risk from dermal or 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 storage, handling and use of 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 closed systems or isolation of operations;
- health monitoring for any worker who is at risk of exposure to the chemical 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 selection of personal protective equipment can be obtained from Australia, 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 hazardous 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 physical hazards of the chemical has not been undertaken as part of this assessment. The chemical is classified for physico-chemical hazards on the HCIS.

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