Benzene, (chloromethyl)-: Human health tier II assessment

17 May 2013

CAS Number: 100-44-7

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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

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Acronyms & Abbreviations

Chemical Identity

Synonyms	Benzyl chloride Alpha-chlorotoluene Chloromethylbenzene Chlorophenylmethane Omega-chlorotoluene	
Structural Formula	C	
Molecular Formula	C7H7CI	
Molecular Weight (g/mol)	126.58	
Appearance and Odour (where available)	Colourless clear liquid	
SMILES	c1(CCI)cccc1	

Import, Manufacture and Use

Australian

The chemical was reported during the 2006 High Volume Industrial Chemicals List (HVICL) compilation with a total reported introduction volume of less than 1000 tonnes.

No specific Australian uses have been identified.

International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers, the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR), Galleria Chemica, Substances in Preparations in Nordic countries (SPIN) database, the European Commission Cosmetic Substances and Ingredients (CosIng) database, United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) directory and other data sources via eChemPortal including the US Environmental Protection Agency's (EPA) Aggregated Computer Toxicology Resource (ACTOR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported site-limited use including:

- in the manufacture of quaternary ammonium compounds which are used primarily for hard surface sanitisers, corrosion inhibitors, fungicides in industrial cleaners, and for bactericides or surfactant in household and personal care products;
- in the manufacture of benzyl butyl phthalate and other flexible polyvinyl chlorides for food packaging;
- in the manufacture of benzyl compounds, synthetic tannins and artificial resins;
- in the manufacture of photographic developers;
- as a blocking agent to prepare monoalkylated piperazine; and
- as an intermediate in the organic synthesis of benzyl alcohol, dyes and perfumes.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

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):

T; R45 Carc. Cat. 2 (carcinogenicity)

T; R23 (acute toxicity)

Xn; R22 (acute toxicity)

Xn; R48/22 (repeat dose toxicity)

Xi; R37/38, R41 (irritation)

Exposure Standards

Australian

The chemical has an exposure standard of 5.2 mg/m³ (1 ppm) Time Weighted Average (TWA) (Safe Work Australia).

International

The following are identified (Galleria Chemica):

An exposure limit (OEL, TWA, STEL, PEL or STV) of 2.6 – 5.2 mg/m³ (0.5 – 1 ppm) in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Norway and United Kingdom.

Health Hazard Information

Toxicokinetics

The chemical is reported to be absorbed through the gastrointestinal tract after oral administration to dogs. The distribution following 48 hours after oral administration of ¹⁴C-benzyl chloride to rats revealed that the concentration of radioisotopes was highest in the stomach, gastric content, gastric wash, ileum, and the duodenum. Approximately 76 % of the initial dose was excreted through the kidneys within 72 hours. About 7 % was detected in expired air as ¹⁴CO₂, while less than 1.3 % was present as ¹⁴C-benzyl chloride or ¹⁴C-benzyl chloride metabolites in expired air within 72 hours. Mercapturic acid, benzyl alcohol, and benzaldehyde were the metabolites present in the urine (OECD, 1998).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). The data available support this classification.

The oral LD50 is 1231 mg/kg bw in rats and 625 - 1620 mg/kg bw in mice (ChemIDplus).

Dermal

No data are available.

Inhalation

The chemical is classified as hazardous with the risk phrase 'Toxic by inhalation' (T; R23) in HSIS (Safe Work Australia). The data available support this classification.

Inhalation LC50 is 740 mg/m³/2-h (150 ppm/2-h) in rats and, 390 mg/m³/2-h (80 ppm/2-h) in mice with respiratory depression (ChemIDplus; NIOSH, 2009).

The lowest published lethal concentration (LCL₀) is 1970 mg/m³/1-h (400 ppm/1-h) for rats and mice. The LCL₀ for cats is 1970 mg/m³/8-h (400 ppm/8-h), with corneal damage and acute pulmonary oedema (ChemIDplus; NIOSH, 2009).

Observation in humans

The lowest published toxic concentration (TCLo) in humans is 160 mg/m³ (NIOSH, 2009).

Corrosion / Irritation

Respiratory Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (safe Work Australia). The limited data available support this classification.

Respiratory tract irritation was reported in rabbits and cats exposed to the chemical at 462 mg/m³ (95 ppm) for 8 hours/day for six days (OECD, 1998). Irritation symptoms were also observed in the repeat dose inhalation studies discussed below.

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The data available support this classification.

Severe reddening, swelling and subsequent necrotic skin changes were observed when the chemical (0.5 mL) was applied to rabbit ear skin for 24 hours (OECD, 1998).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). The limited data available support this classification.

Eye irritation was reported in rabbits and cats exposed to the chemical at 462 mg/m³ (95 ppm) for 8 hours/day for six days (OECD, 1998).

Observation in humans

In humans, the chemical is reported to cause eye lacrimation and conjunctival irritation (NIOSH, 2009).

Sensitisation

Skin Sensitisation

Based on the data available, the chemical is considered to be a skin sensitiser.

In a mouse local lymph node assay (OECD TG 429), groups of five female mice were treated with the chemical (by open application on the ears) at concentrations of 10, 25 or 50 %w/w, on three consecutive days. Slight irritation was observed in

animals at 10 % and 25 %. Irritation was observed in one animal at 25 % and in all animals at 50 %. No oedema was observed in any of the treated animals. All auricular lymph nodes of the treated animals and one control animal, were considered to be enlarged. No macroscopic abnormalities of the surrounding area were noted in any of the treated animals. There were no mortalities or systemic toxicity. The stimulation index (SI) was higher than three for all test concentrations (SI for 10, 25 and 50 % were 6.1, 12.0 and 10.6, respectively) and therefore, the chemical was considered to be a skin sensitiser (REACH). The EC3 value (the test substance concentration that gives a SI of 3) was less than 10 %.

In a skin sensitisation study, guinea pigs were intracutaneously injected with the chemical at 0.01 mg/animal, twice a week for 12 weeks (induction phase). Two weeks after the last injection, the animals were challenged with a drop of the chemical by applying epicutaneously on the clipped skin. Positive skin reactions were observed after challenge, indicating the skin sensitising potential of the chemical (REACH).

Repeated Dose Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Danger of serious damage to health by prolonged exposure, if swallowed' (Xn; R48/22) in HSIS (Safe Work Australia). The data available support this classification.

In a repeat dose oral toxicity study, 10 male and 10 female rats (F-344) were dosed at 0, 15, 30, 62, 125 or 250 mg/kg bw/day (equivalent to daily doses of 6.4, 12.9, 26.6, 53.6 or 107.1 mg/kg bw/day), three times per week for 26 weeks. At 250 and 125 mg/kg bw/day doses, all rats died within three weeks, mainly from severe acute and chronic gastritis of the forestomach (with ulcers). At the highest dose, acute myocardial necrosis and oedema of the heart were also observed. Acute myocardial necrosis and hyperplasia of the forestomach in female rats at 62 mg/kg bw/day and hyperkeratosis of the forestomach in a few female rats at 30 mg/kg bw/day were also observed. A statistically significant depression of weight gain was reported only in male rats at 62 mg/kg bw/day (OECD, 1998). The no observed adverse effect level (NOAEL) was 62 mg/kg bw/day for males (26.6 mg/kg bw/day) and 30 mg/kg bw/day for females (12.9 mg/kg bw/day).

In an oral study, mice (B6C3F1) were dosed three times a week for 26 weeks with the chemical at 0, 6.3, 12.5, 50 or 100 mg/kg bw/day (equivalent to daily doses of 2.7, 5.4, 10.7, 21.4 or 42.9 mg/kg bw/day). The growth was affected by treatment in all treated groups. Severe hyperplasia of the liver was frequently observed at 100 mg/kg bw/day. At or below 50 mg/kg bw/day, the hyperplasia was occasionally severe, but was mostly moderate (OECD, 1998).

Dermal

No data are available.

Inhalation

Based on the limited data available, the chemical is considered to have low repeat dose inhalation toxicity.

Mice (Swiss OF1) were exposed to the chemical at concentrations of 22 ppm (107 mg/m³) or 46 ppm (224 mg/m³), 6 hours/day for 4, 9 or 14 days. Respiratory and olfactory epithelial lesions in the dorsal meatus were observed at 46 ppm. This effect was severe in the four and 14 days' exposure groups and very severe in the nine days' exposure group. No change in the trachea or lungs was observed. Based on pathological changes observed at the high dose, the no observed effect level (NOEL) is 22 ppm (107 mg/m³ or approximately 40 mg/kg bw/day) (OECD, 1998).

Genotoxicity

Based on the data available, the chemical is not considered genotoxic.

The chemical showed negative or weakly positive results in some in vitro genotoxicity studies. Negative results were reported for all in vivo genotoxicity studies (OECD, 1998).

The chemical showed negative results in the following in vitro genotoxicity tests:

- Ames test with Salmonella typhimurium strain TA 98, at 0, 10, 50, 100, 250, 500, 1000, or 2500 μg/plate, with or without metabolic activation;
- Chromosomal aberration test in human peripheral lymphocyte at 5, 25 and 40 μg/mL, without metabolic activation; and
- Unscheduled DNA assay at concentrations of 10⁻¹⁰ 10⁻³ M, with and without metabolic activation.

Positive results were reported for an Ames assay with *S. typhimurium* strain TA 100 and *Escherichia coli* strain WP2 uvrA, with and without metabolic activation and; in a DNA damage and repair test in A549 cells (non-bacterial) at 125, 250 and 500 μg/mL. The damage was repairable at 125 and 250 μg/mL (OECD, 1998).

Weakly positive results were reported in a micronucleus test with Syrian hamster embryo fibroblasts, without metabolic activation at $10 - 1000 \,\mu\text{M}$. In a sister chromatid exchange (SCE) assay without metabolic activation, the chemical at $10 - 1000 \,\mu\text{M}$, weakly induced SCE in Chinese hamster ovary (CHO) cells (OECD, 1998).

Negative results were reported in an in vivo micronucleus test in mice which received the chemical intraperitoneally at 0, 75, 150, 300 or 600 mg/kg bw. In a *Drosophila melanogaster* mutation assay, the chemical applied at 0, 0.5, 1.0 or 2.0 mM, induced somatic mutations more readily than sex-linked alterations (OECD, 1998).

Carcinogenicity

The chemical is currently classified as a Category 2 carcinogen with the risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia). The data available support this classification.

The International Agency for Research on Cancer (IARC) has stated that 'There is sufficient evidence in experimental animals for the carcinogenicity of benzyl chloride' (IARC, 1999).

In a carcinogenicity study, rats (F344) were exposed to the chemical orally at 15 or 30 mg/kg bw/day, three times/week for 104 weeks. The only statistically significant increase in tumour incidence attributed to the treatment was thyroid C-cell adenoma/carcinoma in the high dose females (OECD, 1998).

Mice (B6C3F1) were administered the chemical orally at 50 or 100 mg/kg bw/day, three times a week for 104 weeks. In male mice, a statistically significant increase in tumour incidence was observed (haemangioma/haemangiosarcoma, forestomach carcinoma and forestomach carcinoma/papilloma) in the high dose male mice, and hepatocellular carcinoma/adenoma in all treated male mice. In female mice, a statistically significant increase in the incidence of forestomach carcinoma/papilloma, and a slightly increased incidence of lung bronchoalveolar adenoma/carcinoma, were observed in the high dose group (OECD, 1998).

Groups of 20 mice (ICR) were dermally administered the chemical $(2.3 \,\mu\text{L})$, twice a week for 50 weeks. Two of 20 control animals developed lung adenomas, while 5/20 treated mice developed tumours, including two lung adenomas and three skin carcinomas. Two of the skin carcinomas metastasised to the primary lymphatic organs liver or kidneys. These tumour incidences were reported as not statistically significant (OECD, 1998).

Reproductive and Developmental Toxicity

Based on the data available, the chemical is not considered to have reproductive or developmental toxicity.

An oral teratogenic study was performed in female rats (SD Crj:CD) at doses of 0 (vehicle: corn oil), 50 or 100 mg/kg bw/day, administered from day six through to day 15 of gestation. No symptoms of toxicity were observed in the dams. The number of implantations, resorptions, live foetuses and the mean foetal weight were not affected at both dose groups. The only significant change was the reduction of foetal length at 100 mg/kg bw/day. All live foetuses appeared normal externally. No major skeletal or visceral abnormalities resulting from treatment with the chemical were noted. No significant increase was detected in the number of skeletal and visceral variations. Based on the reduction of foetal length, NOEL for foetal toxicity was considered to be

50 mg/kg bw/day. The NOEL for teratogenicity (causing structural defects in the offspring) was considered to be 100 mg/kg bw/day (OECD, 1998).

In a sperm head abnormality assay, male mice (F1) were subcutaneously injected with the chemical at 0 (vehicle; Tween), 125, 250 or 500 mg/kg bw/day, once daily for five days. In a second assay, male mice (F1) were injected intraperitoneally at 0, 50, 100, 200 or 400 mg/kg bw/day, once daily for five days. All surviving mice from both studies were killed and scored for sperm head abnormalities, 35 days after the last dose. Small increases in sperm head abnormalities were observed. The NOEL was 250 mg/kg bw/day in the subcutaneous study and 100 mg/kg bw/day in the intraperitoneal study. These abnormalities were reported to be reproducible in a second study (OECD, 1998).

Other Health Effects

Neurotoxicity

The chemical was reported to cause neurotoxic/behavioural effects in a mouse study. The data available are not conclusive to determine whether the effects warrant a hazard classification.

In an inhalation study, 10 male mice (Swiss-OF-1) exposed to the chemical vapours at 0.06, 0.08, 0.09 or 0.12 mg/L (12, 17, 18 or 22 ppm) for four hours, showed behavioural changes. After exposure, behavioural swimming tests were conducted in mice, by forcing them to swim in a cylinder filled with water. Avoidance behaviour was observed followed by a resting stage. The duration of the immobility phase (keeping heads above the water) was measured, and a change in the length of this phase was considered as the criterion for an effect of the chemical on behaviour controlled by the central nervous system (CNS). The chemical was reported to cause a concentration dependent decrease in the immobility phase (by 32, 52, 71 and 84 %, respectively). The study indicated that the decrease in duration of immobility is caused by prolongation of escape-directed activity, and the reinforced swimming activity may result from neurotoxic effects (OECD, 1998).

Risk Characterisation

Critical Health Effects

The main critical effects to human health are acute oral and inhalation toxicity, irritation effects and skin sensitisation from short term exposure. Repeated or long term exposure may cause serious systemic/organ effects and/or carcinogenicity.

Public Risk Characterisation

There are no known consumer or domestic uses in Australia. Given the use as an intermediate in the manufacture of dyes and other chemicals, it is unlikely that the public will be exposed to this chemical. Hence, the public risk from this chemical is low.

Occupational Risk Characterisation

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

NICNAS Recommendation

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

by the relevant state or territory.

Regulatory Control

Public Health

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

Work Health and Safety

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

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Harmful if swallowed (Xn; R22)* Toxic by inhalation (T; R23)*	Harmful if swallowed - Cat. 4 (H302) Toxic if inhaled - Cat. 3 (H331)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)
Repeat Dose Toxicity	Harmful: Danger of serious damage to health by prolonged exposure if swallowed (Xn; R48/22)*	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)
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)].

Advice for industry

Control measures

Control measures to minimise the risk from dermal/ocular/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.

^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

Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using 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 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 assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

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

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

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

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

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