Diglycidyl ether of bisphenol A-based epoxy resins: Human health tier II assessment

24 April 2015

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-	1675-54-3
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane	25068-38-6

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 chemical group is composed of the monomer bisphenol A diglycidyl ether (BADGE) (CAS No. 1675-54-3) and the oligomer (BADGE resin) (CAS No. 25068-38-6).

The following considerations justify the inclusion of these chemicals into a group:

- functional group structural similarity, which consists of glycidyl ethers of single or repeating units of bisphenol A;
- similarity in the toxicologically relevant human health effects including skin and eye irritation, and skin sensitisation; and
- similarity of use mainly as components of epoxy resin systems.

Import, Manufacture and Use

Australian

The following Australian industrial use was reported under previous mandatory and/or voluntary calls for information.

BADGE resin has reported commercial use in adhesives.

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) dossiers;
- 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;
- the International Agency for Research in Cancer (IARC);
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and
- various published sources (Hammarling et al., 2000; EFSA, 2004; Poole et al., 2004; Ramilo et al., 2006).

BADGE resin has cosmetic use as a film-forming chemical. Cosmetic use cannot be confirmed for BADGE.

The chemicals in this group are used as the major components of epoxy resin systems. Epoxy resins made from the chemicals in the group have domestic use in adhesives and paints.

Epoxy resins made from the chemicals have reported commercial uses including:

- as a stabiliser and plasticiser in vinylic organosols;
- as a component in reinforced plastic laminates and composites;
- in protective coatings in cans (foods and drinks); and
- in printed circuit boards and tooling.

Restrictions

Australian

These chemicals are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 5 and Appendices E & F (SUSMP, 2015) under 'Epoxy resins, liquid'.

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

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

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

- Xi; R36/38 (Irritating to eyes and skin)
- R43 (May cause sensitisation by skin contact)

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards for the chemicals are identified (Galleria Chemica):

An exposure limit of 0.1–1 mg/m^3 time weighted average (TWA) in countries such as Latvia and Russia.

Health Hazard Information

Toxicokinetics

BADGE is rapidly absorbed after ingestion but slowly absorbed through the skin (EFSA, 2004). The main metabolic pathway for BADGE is rapid hydrolysis by epoxide hydrolase to form the *bis*-diol form of the chemical, which is the main metabolite found in the urine. Further metabolic breakdown includes oxidation of the diol group to a hydroxycarboxylic acid, and partial subsequent decarboxylation, to produce the main faecal metabolite identity (EFSA, 2004; Poole et al., 2004). The formation of bisphenol A (BPA) (CAS No. 80-05-7) was not observed in any of the metabolic studies of BADGE (Poole et al., 2004). This is consistent with the stability of ether linkages; thus, the toxicological effects of BPA will not be considered in this assessment.

Although no metabolic studies are available for BADGE resin, it is expected to undergo similar metabolism to BADGE to produce the *bis*-diol polymer equivalent.

Based on the reactivity of the epoxy group, it is not likely that the chemicals will reach systemic circulation in the reactive epoxy form.

Acute Toxicity

Oral

The chemicals have low acute toxicity based on results from animals tests following oral exposure.

Several range-finding single-dose studies of BADGE in rats reported acute median lethal dose (LD50) values which exceed the maximum tested dose (>1000 mg/kg bw). Tests with defined LD50 values reported the following: 11400 mg/kg bw in rats; 15600 mg/kg bw in mice; and 19800 mg/kg bw in rabbits (Poole et al., 2004).

For BADGE resin, an oral LD50 value of 19600 mg/kg bw was reported in rats (Poole et al., 2004). Further studies for BADGE resin (molecular weight of <700 g/mol) indicated the following LD50 values: >2000 mg/kg bw in female Wistar rats; 19800 mg/kg bw in male rabbits; and >15000 mg/kg bw in male Long Evans rats (REACH).

Dermal

The chemicals have low acute toxicity based on results from animals tests following dermal exposure.

The following dermal LD50 values from BADGE exposure were quoted: >800 mg/kg bw in mice; >1200–>1600 mg/kg bw in rats; and 2000 mg/kg bw in rabbits (EFSA, 2004). However, details of the studies were not available.

The REACH dossiers for BADGE resin (molecular weight <700 g/mol) reported the following dermal LD50 values: >2000 mg/kg bw in Wistar rats and 23032 mg/kg bw (calculated from the actual dose of 20 mL/kg bw) in male New Zealand White rabbits (REACH).

Inhalation

Limited information is available. A study showed that a five-hour exposure to BADGE at a dose of 8×10^{-6} ppm did not cause any deaths or effects in six male albino rats (REACH). No information is available for BADGE resin.

Corrosion / Irritation

Respiratory Irritation

No data are available.

Skin Irritation

The chemicals are classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in the HSIS (Safe Work Australia). Although the limited information available for BADGE resin does not support this classification, in the absence of more comprehensive information, there is insufficient evidence to amend the current classification of the chemicals in the group.

In a study in three New Zealand White rabbits, 0.6 mL of undiluted BADGE resin (average molecular weight <700 g/mol) was applied to shaved skin occlusively for four hours. The animals were observed after 1, 24, 48, 72 hours and seven and 14 days post-application. Slight erythema was observed. The average irritation score after 24, 48, and 72 hours was 0.7. The effects were reversed within seven days (REACH).

Eye Irritation

The chemicals are classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in the HSIS (Safe Work Australia). Although the limited information available for BADGE resin does not support this classification, in the absence of more comprehensive information, there is insufficient evidence to amend the current classification of the chemicals in the group.

In an experiment conducted in three New Zealand White rabbits, a single dose of 0.1 mL of undiluted BADGE resin was applied to one eye. Ocular redness, congestion of the third eyelid and hyperaemia were observed in all the animals up to 72 hours post-application. However, all pathological changes resolved after seven days. The average irritation score after seven days was 0 (REACH).

Sensitisation

Respiratory Sensitisation

No data are available.

Skin Sensitisation

These chemicals are classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in the HSIS (Safe Work Australia). The information below including case studies in humans (see **Observations in humans**) supports the current classification.

In a local lymph node assay (LLNA) conducted in six female CBA/J mice, a single daily dose of BADGE (in an acetone/olive oil vehicle (4:1 v/v)) was applied to the dorsal surface of both ears at a dose of 0 % (vehicle only), 0.3 %, 1 %, 3 %, 10 % or 30 % for three consecutive days. No erythema or effects on body weight were observed. The estimated concentration needed to produce a three-fold increase in lymphocyte proliferation (EC3) was calculated to be 5.7 % (REACH).

BADGE and BADGE resin were also found to be moderately sensitising to guinea pigs based on various tests including the Buehler method and guinea pig maximisation test (GPMT) (REACH).

Observation in humans

In an epoxy resin production plant, it was found that patch testing with the resins containing BADGE produced positive reactions in 7–10 out of 14 patients. The authors also noted that the seven patients who tested positive when exposed to solid epoxy resin (a mixture of resins with different molecular weights) may be attributed to the BADGE resin content (10–15% by weight) (Prens et al., 1986). Additionally, the study authors indicated that the potential for sensitisation from exposure to BADGE resin is inversely proportional to the molecular weight of the oligomer.

In a retrospective study on patients who tested positive for dermatitis to BADGE, it was found that the majority who tested positive worked in the construction industry where there is high exposure to materials containing BADGE (such as insulation materials, coatings, varnishes, and glues). Other occupational sources of sensitisation to BADGE and BADGE resins includes workers in the painting, stonework, metal and electronics industries. It was also found that males accounted for 65 % of the patients who tested positive for occupational sensitisation. Non-occupational sensitisation was also noted from sources such as boat painting/coating, floor and roof painting, and hobby glues (Majasuo et al., 2011).

Repeated Dose Toxicity

Oral

Based on the available information, resins based on BADGE showed low toxicity at low repeated doses.

In a study conducted in Fischer 344 (F344) rats (65 animals/sex/dose), undiluted BADGE (suspension in 0.5 % methyl cellulose ethers with 0.1 % Tween 80) was administered by oral gavage at doses equivalent to 0, 50, 250, or 1000 mg/kg bw/d for seven days per week for 14 weeks. This study was initially intended to be a two-year study but had to be terminated at days 99 (male) or 101 (females) due to excessive toxicity. Before the study termination at 14 weeks, six animals died or had to be euthanised due to moribund conditions (three died incidentally during dosing or blood collection; three in the high dose group had moderate to severe acute tubular necrosis of the kidneys). Slight decreases in body weights and feed consumption were observed in the 250 and 1000 mg/kg bw/d groups compared with controls. The only other significant treatment-related effects that were observed were increased serum cholesterol (in the 50 mg/kg group) and increased caecum size (in the 250 and 1000 mg/kg groups). While the effect on cholesterol was only seen at the low dose and could therefore be discounted, this finding was also made at low doses in a further study below. The no observed adverse effect level (NOAEL) value cannot be established for this study (REACH).

In a two-year study conducted in F344 rats (65 animals/sex/dose), undiluted BADGE (suspended in Tween 80 and methylcellulose) was administered by oral gavage at doses equivalent to 0, 2, 15, and 100 mg/kg bw/d for up to two years. No statistically significant mortalities were observed in the study groups. Similar to the study above, serum cholesterol was increased in the 15 and 100 mg/kg bw/d group and caecal enlargement was observed in the 100 mg/kg bw/d group. There were also statistically significant decreases in absolute and relative spleen weights and very slight atrophy of the red pulp was observed in the 100 mg/kg bw/d group. The NOAEL value was determined to be 15 mg/kg bw/d (EFSA, 2004).

Furthermore, other studies reported that the chemical does not cause systemic toxicity in various strains of rats at doses of up to 4500 mg/kg bw/d. The only significant effect that was reported were from malnutrition due to feed rejection in groups fed with BADGE at a dose of 4500 mg/kg bw/d (Poole et al., 2004).

Dermal

Based on a 13-week dermal study conducted in male B6C3F1 mice, BADGE did not cause any systemic effects with doses of up to 100 mg/kg bw/d. However, mild to moderate dermatitis was observed in the highest dose group (100 mg/kg bw/d). The maximum tolerated dose (MTD) was determined to be 100 mg/kg bw/d based on spongiosis and epidermal micro abscess. The NOAEL for dermal effects was not determined in this study (REACH).

Inhalation

No data are available.

Genotoxicity

The chemicals are not considered to be genotoxic based on the available information.

In vitro

The EU Food Safety Authority (EFSA) Scientific Panel on Food Additives Flavourings, Processing Aids and Materials in Contact with Food concluded that BADGE was a direct-acting mutagen in vitro (EFSA, 2004). BADGE (pure and/or technical) showed positive results in the following tests: reverse mutation assay in *Salmonella typhimurium* strains TA 1535 and TA 98 with and without S9 metabolic activation; and a forward mutation assay in mouse lymphoma cells without exogenous metabolic activation system at a dose of 0.03 µg/mL (EFSA, 2004).

Furthermore, evaluation of BADGE (at 200 µM) on Caco-2 cells showed significant cell detachment, decreased cell proliferation, and disruption/complete depolymerisation of the F-actin cytoskeleton (Ramilo et al., 2006).

In vivo

Studies have shown that BADGE was not mutagenic in vivo. Negative results were observed in the following tests (EFSA, 2004):

- micronucleus test in the bone marrow of female mice;
- induction of DNA repair synthesis in human mononucleated white cells;
- dominant lethal test in mice through topical and single oral administration of BADGE;
- induction of liver DNA damage in rats; and
- nuclear abnormalities and chromosome aberrations in Chinese hamster bone marrow.

Although the chemical was considered to cause genotoxic effects in vitro, studies evaluating the mutagenic potential in vivo were negative. The chemical was concluded to not cause any mutagenic effects and classification for this particular endpoint is not warranted.

Carcinogenicity

The IARC concluded that BADGE is 'not classifiable as to its carcinogenicity to humans' (Group 3) (IARC, 1989). The available data evaluated by IARC included the following (IARC,1989; REACH):

- dermal application in F344 rats did not produce neoplasia in any tissue at doses of 1000 mg/kg;
- subcutaneous injections of BADGE resins in male Long Evans rats produced malignant tumours at the site of injection;
- a dietary study in 30 male Heston A strain mice using 2 % BADGE had incidences of pulmonary tumours (12/23) compared with the controls (15/29);
- a dermal application of 5% BADGE in C3H mice and albino rabbits did not produce any skin tumours;
- a dermal application of undiluted BADGE resulted in the occurrence of a single skin papilloma in one of the tested C3H mice. However, the authors noted that in a second, similar experiment, skin tumours were not observed; and
- experiments in CF1 mice that were exposed to resins containing BADGE and epichlorohydrin by skin application exhibited skin tumours.

The studies given above contain mixed results as to the carcinogenicity of BADGE and BADGE resin. Studies that showed positive results used chemicals that include epichlorohydrin as an impurity and this is a known carcinogen. In the absence of more comprehensive information resolving the potential for carcinogenic effects of BADGE and BADGE resins, classification for this particular endpoint is not recommended.

Reproductive and Developmental Toxicity

Based on the available information, the chemicals are not reproductive toxicants.

In a reproductive and developmental toxicity study, female Sprague Dawley (SD) rats (12 animals/dose) were exposed daily to BADGE (in corn oil) by oral gavage at doses of 0, 375, 1500, and 3000 mg/kg bw/d on gestation days (GD) 6–20 and postnatal days 0–21. All the animals in the 3000 mg/kg bw/d group died before labour. Significant mortality at the 1500 mg/kg bw/d group was also reported. The pups exhibited no pathological changes in any of the major organs. Although transient changes in relative organ weights were observed, these were not supported by histopathological findings (Hyoung et al., 2007).

Testicular effects were explored in another study in male SD rats. Male SD rats (five animals/dose) were administered with a single dose of BADGE (in corn oil) through gastric lavage at doses of 0 (corn oil only), 500, 750, 1000 and 2000 mg/kg bw/d. The body weight and the relative testes weight of the treated groups were lower compared with controls. In terms of sperm parameters, no significant differences were observed except for two animals in the 2000 mg/kg group, which showed lower sperm head count and motility as well as higher sperm abnormalities compared with controls (Yang et al., 2010).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (irritation and skin sensitisation).

Public Risk Characterisation

Although the public could be exposed to the chemicals through potential cosmetic and domestic uses, given the low hazard of the chemicals, which can be managed through appropriate labelling, the chemicals are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

Based on the available data, the hazard classification in the HSIS (Safe Work Australia) is considered appropriate.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Public Health

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

Work Health and Safety

The chemicals are 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.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to skin (Xi; R38)*	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)

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

Advice for industry

Control measures

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

- 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;

- 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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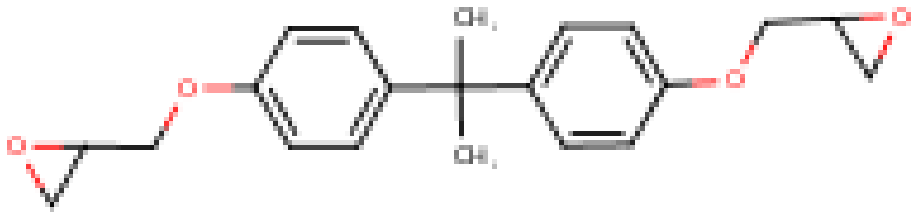
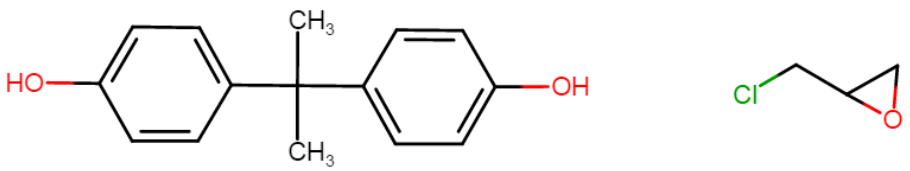
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-** bisphenol A, diglycidyl ether BADGE
CAS Number	1675-54-3
Structural Formula	

	
Molecular Formula	C21H24O4
Molecular Weight	340.42

Chemical Name in the Inventory and Synonyms	**Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane** bisphenol A, (chloromethyl)oxirane polymer bisphenol A, epichlorohydrin polymer epichlorohydrin, bisphenol A resin UP 5-207
CAS Number	25068-38-6
Structural Formula	
Molecular Formula	(C15H16O2.C3H5ClO)x
Molecular Weight	

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