# Ethanedial: Human health tier II assessment

**18 September 2014**

## CAS Number: 107-22-2



## 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.

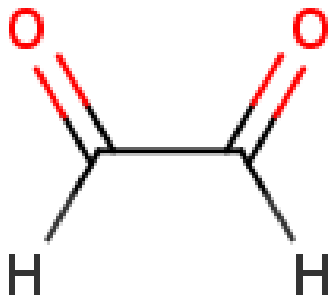
For more detail on this program please visit:www.nicnas.gov.au

**Disclaimer**



Acronyms & Abbreviations

## Chemical Identity

| | |
|---|---|
| Synonyms | Glyoxal (INCI)<br>1,2-Ethanedione<br>Biformal<br>Diformyl<br>Oxalaldehyde |
| Structural Formula |  |
| Molecular Formula | C2H2O2 |
| Molecular Weight (g/mol) | 58.04 |
| Appearance and Odour (where available) | Light yellow liquid with a mild odour at ambient temperature, and forming yellow prismatic crystals at 15 °C. |
| SMILES | C(=O)C=O |

# 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's (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers;  Galleria Chemica, Substances in Preparations in the Nordic countries (SPIN) database; European Commission's (EC) Cosmetic Ingredients and Substances (CosIng) database; Personal Care Products Council's International Nomenclature Cosmetic Ingredients (INCI) dictionary; United States (US) National Library of Medicine's Household Products database; US Environmental Working Group's (EGW) Skin Deep Cosmetics database; Haz-Map; and eChemPortal.

The chemical has reported cosmetic use including as:

- a fragrance ingredient;
- an antimicrobial, preservative in hair dyes and colours; and
- in hair conditioners, styling gel/lotions, and nail hardeners (six products) (Skin Deep).

The chemical has reported domestic use including as a disinfectant or a cleaning agent (three products) (US Household Products Database).

The chemical has reported commercial use including:

- in adhesives, sealants, construction materials, coatings, paints, lacquers and varnishes; and
- as a reducing agent in the photographic industry.

The chemical has reported site-limited use including:

- as an intermediate in the production of pharmaceuticals and dyes;
- as a cross-linking agent for textiles, resin component in pulp and paper processing;
- as a deodorising agent in the crude oil and gas industry through H2S scavenging;
- in manufacturing plastic composites and silvered mirrors; and
- in anti-lump treatment of cellulose ethers used in pharmaceuticals manufacturing.

# Restrictions

## Australian

No known restrictions have been identified.

## International

The chemical is listed in the EC CosIng Annex III (List of restricted substances). The maximum authorised concentration for ethanedial (glyoxal) in the finished cosmetic product is 100 mg/kg (0.01 %).

# Existing Work Health and Safety Controls

## Hazard Classification

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

Muta. Cat. 3; R68 (genotoxicity)

Xn; R20 (acute toxicity)

Xi; R36/38 (irritation)

R43 (sensitisation)

## Exposure Standards

### Australian

No specific exposure standards are available.

### International

The chemical has workplace exposure standards (Galleria Chemica).

Time weighted average (TWA):

- 0.1 mg/m$^3$ [Belgium, Colombia, Canada (Alberta, British Columbia, Saskatchewan), Italy, Nicaragua, Portugal, Spain, the United States of America];
- 0.5 mg/m$^3$ [Denmark].

Short term exposure limit (STEL):

- 0.3 mg/m$^3$ [Canada (Saskatchewan)].

# Health Hazard Information

## Toxicokinetics

Anhydrous ethanedial does not exist in a stable form at room temperature, and therefore it is commonly supplied in the form of an aqueous solution at 30–40 %.

There is evidence of systemic absorption of ethanedial based on oral, dermal and inhalational toxicity studies. Data on qualitative and quantitative absorption are limited; a default bioavailability of 100 % is assumed for ethanedial exposure via these routes of exposure. Due to the reactivity of ethanedial, local effects at site of contact are expected to be important.

Distribution occurs to erythrocytes, liver, lung, kidney, pancreas, and adrenal glands after acute and chronic oral administration; and to liver, kidney, and pancreas after dermal application (WHO, 2004; SCCP, 2005).

Ethanedial is produced endogenously during normal cellular metabolism by several enzyme-independent pathways. Ethanedial or glyoxal is highly reactive and its effects are limited by the high catalytic efficiency of the glutathione (GSH)-dependent glyoxalase system (which converts glyoxal to the less reactive glycolate), as well as by the rapid reaction of ethanedial with proteins. The concentration of ethanedial in human blood plasma has been reported to be 0.1–1 µmol/L, with higher levels reported for patients with diabetes or renal failure. Also, less than 10 % of the ethanedial present is in unbound forms in aqueous solution (free ethanedial and hydrates), as most is reversibly bound to cysteinyl, lysyl, and arginyl residues of proteins (WHO, 2004). In rats, ethanedial is extensively metabolised, and it is not detected in excreta, tissues or plasma. Residues are commonly present as oxalate and other organic acids such as citrate and succinate (REACH).

Excretion of ethanedial has been studied using $^{14}C$ labelled compound under a range of conditions. Seven days after single oral doses of either 25 or 250 mg/kg bw, the amount of excretion is comparable, 30–32 % (as $CO_2$) in exhaled air, 12–13 % in urine, and 24–27 % in faeces. After administration of 250 mg/kg bw/d for 14 days, the excreted amount of isotope was higher in urine, lower in faeces, and higher in exhaled air, compared with single doses, indicating changes in kinetics and pattern of ethanedial metabolism after multiple dosing. In both single and repeated dose studies, comparable amounts of radioactivity remained in the carcass as bound residues (REACH).

## Acute Toxicity

### Oral

The chemical has low to moderate acute oral toxicity, depending on its concentration in the test samples and also depending on laboratory species. The results from the one available guideline study (OECD TG 401) in rats are consistent with classification as 'harmful if swallowed' (Xn, R22).

The median lethal doses (LD50) for ethanedial were 1680 mg/kg bw (20 % aqueous solution), 2200–4700 mg/kg bw (30 %), and 640–8979 mg/kg bw (40 %) in rats, 4064 mg/kg bw (40 %) in mice, and 3175 mg/kg bw (40 %) in rabbits. In an OECD TG 401 study, mortality rates in rats of 10 %, 40 % and 90% were reported for 2000, 3150 and 5000 mg/kg bw of 40 % ethanedial, corresponding to 800, 1260 and 2000 mg/kg bw of ethanedial, respectively. Macroscopic observations included irritation of the gastrointestinal (GI) tract and congestion in the GI, lung, kidneys, and adrenal glands. In the pancreas and kidney, severe degenerative changes resembling those induced during diabetes were observed (OECD, 2003; WHO, 2004; SCCP, 2005; REACH).

### Dermal

The chemical has low acute dermal toxicity.

The LD50s for 40 % aqueous ethanedial were >2000 mg/kg bw (corresponding to 800 mg/kg bw of ethanedial) in rats, 12700 mg/kg bw in rabbits, and >5000 mg/ kg bw in guinea-pigs (OECD, 2003; WHO, 2004; SCCP, 2005; REACH).

### Inhalation

The chemical is classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in HSIS (Safe Work Australia).

The median lethal concentration (LC50) for an aerosol of 40 % aqueous ethanedial was 2.44 mg/L/4-hour in rats, which supports this classification. Reported signs of toxicity include irregular breathing, nasal secretion, partly closed eyes, ruffled fur, dizziness, abnormal postures, and macroscopic findings. Necropsy of the animals which died during the course of the study showed dark-red lungs (WHO, 2004; SCCP, 2005).

## Corrosion / Irritation

### Skin Irritation

The chemical is classified as hazardous with the risk phrase ‘Irritating to skin’ (Xi; R38) in HSIS (Safe Work Australia). Collective results of all available studies provide insufficient grounds for a recommendation to amend the current classification.

The 40 % aqueous solution of ethanedial caused no irritation following a 4-hour semi-occlusive exposure (OECD TG 404), although it was clearly irritating (erythema and oedema) in earlier studies. With an application period of 5 and 15 minutes on the shaved back rabbit skin, slight erythema and oedema, respectively, were observed at 24 hours, as well as yellowing and scaling of the skin eight days after exposure. With 20-hour applications, occasional strong erythema and oedema were noted, with scaling, scab formation and superficial necrosis observed after eight days. A 20-hour exposure to the rabbit ear also led to erythema and inflammation as well as minor skin defects after 24 hours. In addition, an acute dermal toxicity study in rats reported erythema in all five animals following 24-hour exposure to 40 % aqueous ethanedial at a dose corresponding to 800 mg/kg bw of ethanedial. Thus, slight to pronounced irritation could be seen, depending on the application periods and conditions (OECD, 2003; WHO, 2004; SCCP, 2005).

### Eye Irritation

The chemical is classified as hazardous with the risk phrase ‘Irritating to eyes’ (Xi; R36) in HSIS (Safe Work Australia). The data support this classification.

In a study conducted according to OECD TG 405, the 40 % aqueous ethanedial caused reversible reddening and chemosis of the conjunctivae during the following eight days. This is consistent with older studies reporting that ethanedial caused irritation and even necrotic changes in the rabbit eye (OECD, 2003; WHO, 2004; SCCP, 2005).

## Sensitisation

### Skin Sensitisation

The chemical is classified as hazardous with the risk phrase ‘May cause sensitisation by skin contact’ (Xi; R43) in HSIS (Safe Work Australia). The data support this classification.

Ethanedial was positive in two maximisation tests (at induction concentrations of 10–20 % and challenge concentrations of 5–10 %), one Buehler test and one local lymph node assay (LLNA) (OECD, 2003; WHO, 2004; SCCP, 2005).

### Observation in humans

Ethanedial has skin sensitising potential in humans. Positive skin reactions were observed after patch tests with 1–20 % ethanedial. Patch tests with disinfectants containing the chemical at concentrations of 0.5 % and 1 % also yielded positive results. Eczema, preceded by itching and skin dryness, was reported in workers handling adhesives and disinfectants containing the chemical, as well as those in contact with a 40 % aqueous ethanedial solution (OECD, 2003; WHO, 2004; SCCP, 2005).

## Repeated Dose Toxicity

### Oral

Based on the weight of evidence, a no observed adverse effect level (NOAEL) of 100 mg/kg bw/d (although it is not clear whether this concentration has been adjusted to 100 % ethanedial) is established for the chemical from a 28-day drinking-water

study (conducted according to OECD TG 407), based on dose-related decreases in body weight gain, food and water consumption at higher doses. A number of 90-day studies have been conducted in several species. The results included a:

- lowest observed adverse effect level (LOAEL) of 107 mg/kg bw/d in rats (decreased serum protein level);
- NOAEL of 125 mg/kg bw/d in rats (decreased body weight gain, increased liver and kidney weight at 250 mg/kg bw/d); and
- NOAEL of 115 mg/kg bw/d in dogs (the highest dose tested).

These short- and medium-term studies have similar outcomes, and there is no evidence of systemic effects, which could suggest that exogenous ethanedial is efficiently detoxified and does not accumulate in the body. This resembles endogenous ethanedial (reviewed by WHO, 2004; SCCP, 2005).

The most recent 2012 study conducted according to OECD TG 453 (combined chronic toxicity and carcinogenicity studies of up to 24 months) reported a LOAEL of 300 mg/kg bw/d (40 % ethanedial) for reduced body weight gain and changes in clinical chemistry (alanine aminotransferase (ALT), cholesterol, and globulin). The NOAEL for systemic effects in this study was 75 mg/kg bw/d. This was also determined to be the LOAEL for non-adverse vasodilation in fundus oculi, and for adversely increased erosions/ulcers in the glandular stomach of the rat, see **Carcinogenicity** section) (REACH).

### Dermal

No data are available.

### Inhalation

In a 29-day nose-only inhalation toxicity study in rats with an aerosol of 40 % aqueous ethanedial, a no observed effect concentration (NOEC) of 0.6 mg/m$^3$/6-hour (nominal concentration 0.4 mg/m$^3$) was determined for local effects seen in the larynx at higher doses. A NOEC of >8.9 mg/m$^3$/6-hour (nominal concentration 10 mg/m$^3$) was found for systemic effects; this was the highest concentration tested (OECD, 2003; WHO, 2004; SCCP, 2005).

## Genotoxicity

The chemical is classified as mutagenic category 3 with the risk phrase ‘Possible risk or irreversible effects’ (Xn; R68) in HSIS (Safe Work Australia). The data support this classification.

In vitro, ethanedial was directly genotoxic in bacterial and mammalian cells, causing chromosomal aberrations, gene mutations and DNA damage. In vivo, ethanedial was positive in genotoxicity tests (e.g. unscheduled DNA synthesis) and negative in somatic cell mutagenicity tests in mammals (including micronucleus test, sex-linked recessive/dominant lethal tests, reciprocal translocation or chromosome loss tests). Given that ethanedial induced unscheduled DNA synthesis in the pyloric mucosa of the stomach and DNA single strand breaks in the liver and stomach, but did not cause DNA damage in the kidney, bone marrow, pancreas or lung, it was considered to have a direct genotoxic effect not mediated by systemic absorption. Overall, ethanedial caused DNA single strand breaks in rat hepatocytes following both in vitro and in vivo exposure (with a lowest effective dose (LED) of 200 mg/kg bw) (OECD, 2003; WHO, 2004; SCCP, 2005).

## Carcinogenicity

Available animal data do not indicate that ethanedial is likely to have carcinogenic potential in humans.

The chemical did not cause cell transformation in mouse embryonic cell lines. It also did not induce carcinogenic or tumour-initiating effects in mice after 18 or 53 months of dermal exposure, respectively. In the most recent 2012 study (see **Repeated dose toxicity** section), while glandular stomach erosions/ulcers were seen, 40 % aqueous ethanedial did not produce any neoplastic lesions in either male or female rats after 12 or 24 months of treatment (REACH). The finding of increased ulcers in the glandular stomach in the rat was considered not applicable to humans, as humans have no such comparable tissues. Although the chemical was considered a tumour-promotor after initiation in rats following a 32-week exposure, it did not show

this activity in an eight-week liver foci assay with treatment via drinking water (CIR, 2000; OECD, 2003; WHO, 2004; SCCP, 2005).

### Reproductive and Developmental Toxicity

There is no evidence of reproductive toxicity, and developmental effects were only observed secondary to maternal toxicity induced by the chemical.

In the most recent 2011 study conducted according to OECD TG 416 (a two-generation reproduction toxicity study), 40 % aqueous ethanedial did not adversely affect fertility or reproductive performance in rats at ≤400 mg/kg bw/d. Also in this study, no signs of developmental toxicity (including postnatal survival, post weaning development until sexual maturity) or abnormal clinical/gross necropsy examination findings were noted at ≤100 mg/kg bw/d, while parental animals showed treatment-related clinical signs (not specified) and changes in clinical chemistry at ≥100 mg/kg bw/d (REACH).

In a prenatal developmental toxicity study (OECD TG 414), no dose-dependent effects on reproductive organs were reported after a 90-day exposure of pregnant rats to 100 % ethanedial at ≤250 mg/kg bw/d, and no foetotoxic effects were seen at ≤125 mg/kg bw/d. A NOAEL for maternal toxicity was found to be 25 mg/kg bw/d in this study, based on reduced body weight gain and food consumption at 125 mg/kg bw/d (SCCP, 2005).

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation are harmful effects following a single oral or inhalational exposure, and skin sensitisation. The chemical can also cause local mutations and local irritant effects to the skin and eyes.

### Public Risk Characterisation

Australian information on use of the chemical is not available, therefore overseas data are used.

The World Health Organization (WHO, 2004) has calculated the risks for consumers using disinfectants containing ethanedial at up to 0.1 % (the recommended use level after 1 % dilution of typical domestic or commercial products). They are considered applicable to Australian exposure scenarios and hence acceptable on the basis that worst-case dermal exposure estimates (0.004 mg/kg bw/d) are less than the tolerable daily intake (TDI) of 0.2 mg/kg bw for lifetime oral exposure to ethanedial. This TDI is derived based on a NOAEL of 100 mg/kg bw/d (repeated dose toxicity) and use of uncertainty factors of 10 each for interspecies and intraspecies differences, and of 5 for less-than-lifetime exposure (WHO, 2004).

Ethanedial has a reported 'low frequency of use' in cosmetic products, mainly in hair and nail products (CIR, 2000; CIUCUS, 2011; Skin Deep), and in domestic cleaning products (US Household Products Database), and hence the risk of causing sensitisation via skin contact in the general population is low.

However, because ethanedial can induce skin sensitisation and even very low concentrations of ethanedial in solution might elicit an allergic reaction in individuals who have been sensitised, dermal exposure should be minimised or prevented wherever possible.

If any information becomes available to indicate significant consumer exposure to the chemical in Australia (i.e. higher concentrations or more widespread use in different types of cosmetic or domestic products), risks to public health and safety might need to be managed by changes to poisons scheduling.

Given exogenous ethanedial is efficiently detoxified in humans and there is no evidence of germ cell mutagenicity or carcinogenic potential, the public health risks of mutagenicity for use of ethanedial in hair and nail products are also considered low.

### Occupational Risk Characterisation

Given the critical systemic acute and local health effects, the chemical can pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalational 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.

The available data support an amendment to the hazard classification in HSIS (refer to **Recommendation** section).

## 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

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below:

| Hazard | Approved Criteria (HSIS)[a] | GHS Classification (HCIS)[b] |
|---|---|---|
| Acute Toxicity | Harmful if swallowed (Xn; R22) Harmful by inhalation (Xn; R20)* | Harmful if swallowed - Cat. 4 (H302) Harmful if inhaled - Cat. 4 (H332) |
| 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) |
| Genotoxicity | Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)* | Suspected of causing genetic defects - Cat. 2 (H341) |

[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 label instructions.

### Advice for industry

***Control measures***

Control measures to minimise the risk from dermal 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 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 can 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 automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of 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 the chemical are prepared; and
- managing risks arising from storage, handling and use of 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.

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