Australian Government
Department of Health and Ageing
NICNAS

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Acetaldehyde

CAS Registry Number: 75-07-0

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take three years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

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.

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

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

ACRONYMS & ABBREVIATIONS

ACToR	Aggregated Computational Toxicology Resource (US)
AICS	Australian Inventory of Chemical Substances
ASTDR	Agency for Toxic Substances and Disease Registry (US)
bw	bodyweight
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations (US)
CHO	Chinese hamster ovary
CosIng	Cosmetic Ingredients and Substances database (EU)
d	day
DNA	Deoxyribonucleic acid
EC	European Commission
EC3	Estimated concentration three
ECHA	European Chemicals Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU RAR	European Union Risk Assessment Report
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia and New Zealand
g	gram
g/mol	grams per mole
GHS	Globally Harmonized System of Classification and Labelling of Chemicals*
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPMT	Guinea Pig Maximisation Test
h	hour
HGPRT	hypoxanthine guanine phosphoribosyltransferase
HPV	high production volume
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
HVICL	High Volume Industrial Chemicals List
IARC	International Agency for Research on Cancer
INCHEM	International Programme on Chemical Safety (also known as IPCS)
INCI	International Nomenclature of Cosmetic Ingredients
ip	intraperitoneal
IRIS	Integrated Risk Information System (US)
IUCLID	International Uniform Chemical Information Database
iv	intravenous
kg	kilogram
L	litre
LC50	median lethal concentration
LD50	median lethal dose
LCLo	lowest published lethal concentration
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw/d	milligrams per kilogram bodyweight per day
min	minute
mL	millilitre
µg	microgram
µL	microlitre
(m)SDS	(material) Safety Data Sheet

NIOSH	National Institute for Occupational Safety and Health (US)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
PCBU	person conducting a business or undertaking
PEL	permissible exposure limit
PND	postnatal day
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
REACH	Registration Evaluation Authorisation of Chemicals (ECHA)
SD	Sprague Dawley
SIAP	SIDS Initial Assessment Profile (OECD)
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SMILES	simplified molecular-input line-entry system
SPIN	Substances in Preparations In the Nordic countries
STEL	short-term exposure limits
STV	short-term value
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)
TCLo	lowest published toxic concentration
TEEL	temporary emergency exposure limits
TSCA	Toxic Substances Control Act (US EPA)
TG	test guideline
TGA	Therapeutic Goods Administration
TLV	threshold limit values
TWA	time weighted average
UN	United Nations
US	United States of America
US EPA	United States Environmental Protection Agency
WHS	Work, Health and Safety
wt	weight
w/w	weight per weight

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:
Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and
Part 2: IPCS Glossary of Key Exposure Assessment Terminology.
The IPCS Risk Assessment Terminology can be accessed at:
http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

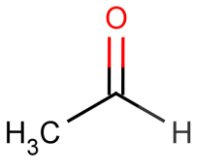
*****Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

******The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Acetaldehyde

CAS No: 75-07-0

Chemical Identity

Synonyms	Ethanal Acetic aldehyde Acetic ethanol Ethyl aldehyde
Structural Formula	
Molecular Formula	C2H4O
Molecular Weight (g/mol)	44.0526
Appearance and Odour (where available)	Colourless liquid (at standard temperature and pressure) with a pungent odour.
SMILES	C(C)=O

Import, Manufacture and Use

Australian

The total volume of the chemical introduced into Australia as reported under previous voluntary calls for information was less than 100 tonnes per annum. No specific Australian use information was provided or has 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 and Preparations in the 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 cosmetic use as:
- a masking and nail conditioning agent; and
- a fragrance or flavour compound in decorative cosmetics, perfumes, toiletries, essential oils and oral care products.

The chemical has reported domestic uses including:
- in household cleaning/washing agents such as disinfectants and detergents;
- room air deodorisers;
- lacquers and varnishes; and
- adhesives and binding agents.

The chemical has reported commercial uses including:
- silvering of mirrors;

- leather tanning;
- fuel mixtures;
- denaturant for alcohol;
- finishing agent such as a hardener for gelatin fibres;
- glue casein products; and
- reprographic and photographic chemicals

The chemical has reported site-limited use including:
- as an intermediate in the production of acetic acid, acetic anhydride, cellulose acetate, vinyl acetate resins, acetate esters, pentaerythritol, synthetic pyridine derivatives, terephthalic acid and peracetic acid; and
- as an intermediate in the manufacture of aniline dyes, plastics and synthetic rubber.

Restrictions

Australian

Illicit Drug Precursors/Reagents - Category II: Requires an End User Declaration. *Code of Practice for Supply Diversion into Illicit Drug Manufacture.*

International

No known restrictions have been identified.

Existing Worker Health And Safety Controls

Hazard classification

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

Carc. Cat. 3; R40 (Carcinogenicity)
Xi; R36/37 (Irritation)

Exposure standards

Australian

The chemical has a Time Weighted Average (TWA) exposure standard of 36 mg/m³ (20 ppm) and a Short Term Exposure Limit (STEL) of 91 mg/m³ (50 ppm).

International

TWA: 37 mg/m³ (20 ppm) [Netherlands, USA Workplace Exposure Limits (WELs)]
TWA: 45 mg/m³ (25 ppm) [Ireland]
TWA: 90 mg/m³ (50 ppm) [Austria maximum workplace concentration (MAK), Korea (South), Switzerland]
TWA: 91 mg/m³ (50 ppm) [Germany]
TWA: 180 mg/m³ (100 ppm) [Argentina, Canada (North West Territories, Yukon), Egypt, France, India, South Africa, USA (Alaska, Hawaii, Michigan, Minnesota, North Carolina, Tennessee, Vermont, Washington)]

STEL: 45 mg/m³ (25 ppm) [Ireland, Singapore]
STEL: 90 mg/m³ (50 ppm) [Austria (MAK), Switzerland]
STEL: 92 mg/m³ (50 ppm) [Netherlands, USA (WELs)]
STEL: 270 mg/m³ (150 ppm) [Argentina, Canada (North West Territories, Yukon), Egypt, India, Korea (South), South Africa, USA (Alaska, Hawaii, Michigan, Minnesota, North Carolina, Tennessee, Vermont, Washington)]

Health Hazard Information

Toxicokinetics

The European Commission Scientific Committee on Consumer Safety (SCCS) reported that the chemical is the first metabolite found in the oxidation of ethanol (SCCS, 2012). Ethanol is metabolised to the chemical by three major pathways: the alcohol dehydrogenase pathway; the microsomal ethanol oxidising cytochrome P450 pathway; and the catalase - H2O2 system. The chemical is oxidised to acetate primarily by acetaldehyde dehydrogenases. Several degradation reactions are known to produce the chemical endogenously in the human body. Inter-individual and genetic variations will affect the metabolism and levels of the chemical. Without external alcohol ingestion, the chemical is expected to be at concentrations below the level of detection, except in the gastrointestinal tract.

Acute Toxicity

Oral

The chemical was reported to have moderate acute toxicity via the oral route (SCCS, 2012).

Median lethal doses (LD50s) in rats were between 660 and 1930 mg/kg bw. Oral LD50 value in mice was 1230 mg/kg bw.

Dermal

The chemical was reported to have low acute toxicity via the dermal route (LD50 in rabbits of 3540 mg/kg bw) (SCCS, 2012).

Inhalation

The chemical was reported to have low acute toxicity via inhalation (median lethal concentration (LC50) in rats has been calculated as 24040 mg/m³ (13300 ppm)) (REACH, 2012).

A 4 hour inhalation toxicity study was conducted with exposure levels of 10436 ppm, 12673 ppm, 15683 ppm and 16801 ppm. The experimental study was similar to the method described in OECD Test Guideline (TG) 403. Clinical signs of toxicity reported included restlessness and laboured respiration.

Corrosion / Irritation

Skin irritation

The chemical was reported to cause slight skin irritation when tested in rabbits for 4 hours under occlusive conditions in a guideline (OECD TG 404) study (REACH, 2012). In a non-guideline study on rabbits, 500 mg of the chemical produced slight irritation of the skin. Effects reported are not sufficient to warrant classification.

Eye irritation

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

Respiratory irritation

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

Observation in humans

In an inhalation exposure study, 24 volunteers were exposed to the chemical for 15 minutes at concentrations $\geq$ 91 mg/m³ (SCCS, 2012). Eye irritation was reported for the majority of the volunteers, with effects observed in some cases at concentrations as low as 45 mg/m³. Irritation of the upper respiratory tract was reported at concentrations $\geq$ 246 mg/m³. Mild irritation to the upper respiratory tract was also reported in 14 humans exposed to the chemical vapour at 135 ppm (240 mg/m³) for 30 minutes.

In a skin patch test (non-occlusive), all 13 volunteers were reported with erythema following application of a 10% preparation of the chemical. The test vehicle is not specified, therefore it is unclear whether concurrent exposure to other chemicals in the preparation contributed to the effects reported.

Sensitisation

Skin sensitisation

The chemical was not found to induce dermal sensitisation when tested according to OECD TG 406 (REACH, 2012). Several skin sensitisation studies were also considered by the SCCS who concluded there is limited evidence of skin sensitisation following exposure to the chemical (SCCS, 2012).

Repeat Dose Toxicity

Oral

In a 4 week drinking water study in rats, the no observed adverse effect level (NOAEL) of 125 mg/kg bw/day was reported (SCCS, 2012). At the higher dose (675 mg/kg bw/day), relative kidney weights were slightly increased in males, while urine production was decreased. The effects and variations in serum biochemistry were considered to be attributed to reduced water intake. Effects on liver function or histology were not reported.

Dermal

No data are available.

Inhalation

In a 4 week repeat dose inhalation toxicity study in male Wistar rats, the no observed adverse effect concentration (NOAEC) for the chemical was reported to be 270 mg/m³ (150 ppm) (REACH, 2012). At higher concentrations (900 mg/m³ (500 ppm)), degeneration of the olfactory epithelium was reported.

Genotoxicity

The chemical is considered genotoxic based on several in vitro and in vivo studies.

In vitro

The chemical did not exhibit mutagenic activity in *Salmonella typhimurium* with and without metabolic activation (REACH, 2012). The chemical was reported to induce chromosomal aberrations and micronuclei in SD rat primary skin fibroblasts (CERI, 2007). The chemical also induced sister chromatid exchanges in Chinese hamster ovary (CHO) cells, aneuploidy in embryonic diploid fibroblasts of Chinese hamster, and nondisjunction in *Aspergillus nidulans*. In human lymphocytes, dose-dependent gene mutation, sister chromatid exchange and chromosomal aberration were induced. The chemical induced DNA strand breaks and DNA cross-links in human lymphocytes, and DNA protein cross links in rat nasal mucosa cells. In addition, in a DNA binding study using calf thymus DNA, positive results were obtained. In a modified OECD Test Guideline 471 (a single test was performed with one plate per strain and concentration), the chemical induced chromosomal aberrations in human TK6 cells without metabolic activation at levels $\geq$ 0.25 mM and was cytotoxic at 1 mM.

In vivo

The chemical induced sister chromatid exchanges in Chinese hamster and mouse bone marrow (CERI, 2007). Chromosomal aberrations were also reported in a study using rat embryo cells administered the chemical through the amnion. In intraperitoneal studies, micronuclei were induced in rat bone marrow cells, rat peripheral lymphocytes and mouse bone marrow cells. Induced micronuclei or morphological abnormalities were not found in mouse spermatids.

Although effects were not seen in the single study examining germ calls, there is sufficient evidence to classify the chemical as possibly causing mutagenic effects.

Carcinogenicity

The chemical is classified as hazardous as with the risk phrase 'Limited evidence of carcinogenic effect' (Carc. Cat. 3; R40) in HSIS (Safe Work Australia). The available data support this classification.

The chemical is classified by the International Agency for Research on Cancer (IARC) as Group 2B (possibly carcinogenic to humans) based on sufficient evidence of carcinogenicity in experimental animals (IARC, 1999). The chemical produced tumours of the respiratory tract in rats and hamsters following inhalation exposure, particularly adenocarcinomas and squamous cell carcinomas of the nasal mucosa in rats and laryngeal carcinomas in hamsters.

In a subsequent report, IARC also classified the chemical as a Group 1 (Carcinogenic to Humans) when associated with the consumption of alcoholic beverages (IARC, 2012; REACH, 2012). However, it must be noted that this IARC Group 1 classification relates to a non-industrial use of the chemical.

Reproductive and developmental toxicity

A NOAEL of greater than 400 mg/kg bw/day was reported for reproductive and developmental toxicity in rats (REACH, 2012).

In a reproductive and developmental toxicity screening test the chemical was administered orally to 22 rats at 400 mg/kg bw/day from day 6 through to day 15 of gestation. There were no maternal or developmental effects recorded at that dose level.

The chemical was also investigated in several studies for developmental effects following intraperitoneal injection of either a single dose of 0, 50, 75 or 100 mg/kg bw/day on gestation day 10, 11 or 12, or repeated doses of 0, 50, 75 or 100 mg/kg bw/day on gestation days 10 to 12 (CERI 2007). Foetal resorptions, malformation (oedema, microcephaly, micrognathia, exencephaly and hydrocephaly), retarded development, and decreases in foetal body and placenta weight were observed in the groups given 50 mg/kg and above. However, exposure via the intraperitoneal route is not appropriate for the evaluation of a hazard or risk to humans from industrial use of the chemical. One CERI reported study did examine the developmental effects of the chemical after oral exposure to rats. Pregnant rats were administered a dose of 200 mg/kg/day (3% water solution) on gestation days 6 to 18. An anomaly of the ribs and vertebrae was observed in the foetuses. In addition, delayed ossification and hypoplasia of the cranial bones and sternum were observed. However, a reliable NOAEL could not be derived from this study due to insufficient data.

Other Health Effects

Neurotoxicity

There is limited evidence to indicate that the chemical causes neurological effects in animals, including central nervous system depression and neural degeneration (EPA, 1994).

In dogs exposed to levels of >134 ppm for 30 minutes, inhibition of the central nervous system and subsequent decrease in respiratory rate were reported. A single intraperitoneal injection (dose not reported) of the chemical produced sustained neural degeneration in the cerebral cortex of rats.

The results of one study in human volunteers indicated that the chemical penetrates the human blood-cerebrospinal fluid barrier. However, the neurotoxic potential of the chemical in humans cannot be determined from the available information.

Risk Characterisation

Critical Health Effects

The main critical effects to human health for risk characterisation are carcinogenicity and potential

genotoxicity. On acute exposure to vapours, eye and respiratory system irritation may occur. The chemical is also acutely toxic via the oral route.

Public Risk Characterisation

Although use in cosmetic or domestic products in Australia is not known, the chemical is reported to be used in cosmetic and domestic products overseas. Currently there are no restrictions identified in the use of this chemical in Australia.

Considering the health effects and the bioavailability of the chemical, there is concern regarding the use of this chemical as an ingredient in cosmetics products in the absence of any regulatory controls.

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

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemical in cosmetics and/or domestic products be managed through changes to poisons scheduling.

Regulatory Control

Public Health

It is recommended that the use of this chemical in cosmetic products such as perfumes, toiletries and essential oils, be restricted through scheduling.

Matters for consideration for scheduling include the carcinogenicity and potential genotoxicity of the chemical, in addition to the European Commission Scientific Committee on Consumer Safety (SCCS) recommendation that the chemical can be safely used as a cosmetic fragrance or flavour ingredient at a maximum concentration of 0.0025% (25 ppm) of a fragrance compound, resulting in approximately a 5 ppm concentration in the final finished product.

Occupational Health and Safety

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

	Approved Criteria (HSIS)[a]	***GHS Classification***
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to respiratory system (Xi; R37)*	Causes serious eye irritation - Cat. 2A (H319) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 3 - Limited evidence of a carcinogenic effect (Xn; R40)*	Suspected of causing cancer - Cat. 2 (H351)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

* 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, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storage, handling and use of a hazardous chemical are dependent 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:

- use of closed systems or isolation of operations;
- use of 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;
- minimisation of 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 be relied upon on its own 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 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 and physicochemical (physical) hazards) of chemicals are prepared; and
- management of 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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