Alkyl mercaptoacetates (C8): Human health tier II assessment

18 September 2014

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Acetic acid, mercapto-, 2-ethylhexyl ester	7659-86-1
Acetic acid, mercapto-, isooctyl ester	25103-09-7

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 group consists of octyl esters of mercaptoacetic acid. Given the close structural similarities of the chemicals in this group and their similar molecular weights, they are all expected to have essentially similar physicochemical properties.

Under physiological conditions, the esters can undergo hydrolysis of the ester linkage to form mercaptoacetic acid (MAA; CAS No. 68-11-1) and either 2-ethylhexanol (CAS No. 104-76-7) or isooctanol (CAS No. 26952-21-6), respectively. The isooctanol in this case is a mixture of 8-carbon alcohols, the major isomers being methylheptanols, and dimethylhexanols (but may also contain 2-ethylhexanol (NIOSH)).

Data available (see **Health Hazards** section) indicate that the mercaptoacetate anion is considered the main moiety responsible for systemic toxicity (with the exception of developmental toxicity (see **Reproductive and developmental toxicity**). There may be differences in absorption and distribution of the chemicals in the group compared with mercaptoacetate acid. However, as the toxicity of mercaptoacetate ion will be a major determinant of the effects of the chemicals, data available for mercaptoacetic acid (or its salts) can be 'read across' when data are lacking for the chemicals in this group for systemic toxicity (OECD, 2014).

The chemicals in this group have similar end uses.

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 European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening Information Dataset Initial Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; and eChemPortal: OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical IOTG (CAS No. 25103-09-7) has reported cosmetic use with the function of hair waving or straightening. Data from 2006 indicated use of IOTG at low concentrations (0.04%) although there was no reported use in 2007 (Burnett et al., 2009). IOTG is reported to be no longer used in this application or other personal care/cosmetic applications (OECD, 2010). In addition, there is currently no documented use of the chemicals in cosmetics in the US (Personal Care Products Council, 2011).

No domestic uses were identified.

The chemicals have reported commercial use including:

- process regulators

The chemicals have reported site-limited use as intermediates including:

- in the manufacture of organotin stabilisers for polyvinylchloride (PVC); and
- chain length transfer agents during polymerisation to control molecular weight.

Restrictions

Australian

No known restrictions have been identified.

Mercaptoacetic acid and its salts are listed in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP) in Schedules 6 and 5 (Department of Health, 2014). These entries exclude derivatives and therefore the chemicals in this group are not covered by these entries.

International

The chemicals are listed on the following (Galleria Chemica):

- EU Regulation (EC) No 1223/2009 Annex III: List of substances which cosmetic ingredients must not contain except subject to the restrictions laid down (reference 2b; thioglycolic acid esters);
- New Zealand: Cosmetic Products Group Standard—Schedule 5: Components cosmetic products must not contain except subject to the restrictions and conditions laid down; and
- Association of Southeast Asian Nations (ASEAN): Cosmetic Directive Annex III, part 1: List of substances which cosmetic products must not contain except subject to restrictions and conditions.

In the above listed directives the maximum allowable concentration of the mercaptoacetate esters (measured as mercaptoacetic acid) in preparations is limited according to the type of cosmetic product:

- Hair products for waving or straightening:

  (a) General use (8 %; pH 6 to 9.5);

  (b) Professional use (11 %; pH 6–9.5);

Labelling requirements are specified for all these uses.

The Expert panel of the Cosmetic Ingredient review (CIR) recommended that several alkyl mercaptoacetates, including IOTG, are safe for use in hair straighteners, permanent waves, tonic, dressings, etc., wave sets, other non-colouring hair products, and hair dyes and colours at concentrations up to 15.4 % (as thioglycolic acid); but hairdressers should avoid contact and minimise consumer skin exposure (Burnett et al., 2009).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available for the chemicals in this group.

International

No specific exposure standards are available for the chemicals in this group.

Health Hazard Information

Limited data are available for the chemicals in this group. With the exception of developmental toxicity, data for EHTG (CAS NO. 7659-86-1) are considered representative of the toxicity of the chemicals in this group for endpoints for which data are available. The chemicals are hydrolysed in the body to form the parent alcohol and mercaptoacetate anion. Therefore, where available, data from the parent alcohols and mercaptoacetic acid and its salts are considered suitable analogues for systemic effects, particularly for longer term toxicity.

Toxicokinetics

No experimental data are available for the chemicals in this group. However, observed acute toxicity indicates that the chemicals are significantly absorbed via oral route and to a less extent by dermal route. The chemicals are expected to be initially hydrolysed in several tissues by carboxylesterases to thioglycolic acid and corresponding alcohols (2-ethylhexanol for EHTG and isooctanol for IOTG) (OECD, 2010).

Acute Toxicity

Oral

The chemicals have moderate acute toxicity based on results from animal tests following oral exposure. A hazard classification is recommended based on the available data.

A LD50 of 500 mg/kg bw was reported in rats administered IOTG at doses in the range of 126 and 3980 mg/kg bw. Observed sub-lethal effects included tremors, kidney and liver effects (no further details reported on the effects) (REACH). An LD50 value

of 485 mg/kg bw has also been reported (OECD, 2010).

The chemical EHTG had reported LD50 values in rats ranging from 303–334 mg/kg bw (OECD, 2010).

Dermal

The chemicals have low acute toxicity based on results from animal tests following dermal exposure. The median LD50 in rats is > 2000 mg/kg bw (both chemicals) and in rabbits is > 5000 mg/kg bw (IOTG) . For EHTG, at 2000 mg/kg bw 20 % of rats died. Observed sub-lethal effects include decreased spontaneous activity. No mortality or clinical changes were reported in either study with IOTG (OECD, 2010; REACH).

Inhalation

The chemicals have low toxicity based on results from animal test following inhalation exposure.

Rats (SD, n=6) exposed to vapours of IOTG (CAS No. 25103-09-7) for 7 hours had no treatment related changes for vapours generated at room temperature (43 ppm, 0.36 mg/L) or at 135°C (1710 ppm, 14.3 mg/L). No mortality or pathological changes were reported at either dose (OECD, 2010; REACH).

In a 6 hr-inhalation study with EHTG, no mortality was observed in a group of 5 rats/sex exposed to 0.51 mg/L (OECD, 2010).

Corrosion / Irritation

Respiratory Irritation

No data are available.

Skin Irritation

The chemicals produced slight skin irritation reactions in studies that were performed in accordance with OECD Test Guideline (TG) 404 (OECD, 2010; REACH). Effects were not sufficient to warrant classification.

The chemical, EHTG (undiluted, CAS No. 25103-09-7) was found to be slightly irritating to rabbit skin when tested under a semi-occlusive dressing for four hours (OECD TG 404). Moderate cutaneous reactions were observed for up to 48 hours after removal of the dressing. Erythema but not oedema was observed in three animals. The mean scores over 24, 48 and 72 hours for individual animals were 1.0, 1.7 and 1.7 for erythema. Between days three and seven, dryness of the skin was observed at the treatment site in 1 animal. No ulceration or necrosis was seen (OECD, 2010; REACH).

A single dose of 0.5 mL undiluted EHTG was applied to the skin of three male New Zealand White rabbits under a semi-occlusive dressing for four hours following OECD TG 404. The mean scores over 24, 48 and 72 hours for individual animals were 1.3, 1.7, and 1.3 for erythema and 0.0, 0.0, and 0.3 for oedema. No ulceration of necrosis was seen. All effects had reversed within six days.

In non guideline studies with IOTG, redness of the skin and exfoliation were observed following repeated applications or covering with non-occlusive dressing (OECD, 2010).

Eye Irritation

Based on the available data, the chemicals are considered to be at most slight eye irritants. Effects observed were not sufficient to warrant a hazard classification.

The chemical IOTG was reported to very slightly irritate the eyes when tested according to OECD TG 405. The average scores for cornea/iris/conjunctivae (redness)/conjunctivae (chemosis) were given as 0/0/0/0. The effects were reversible within 72 hours (OECD, 2010; REACH).

No ocular reactions were observed during a study with EHTG conducted according to OECD TG 405. In two other non-guideline studies no to slight irritation was observed (REACH).

Sensitisation

Skin Sensitisation

Limited data are available for the chemicals in this group. Although only a weak sensitisation response was observed for IOTG, given the positive result for EHTG and known sensitisation potential in humans of mercaptoacetate salts, the chemicals in this group are considered to be skin sensitisers. Classification is considered warranted (refer **Recommendation** section).

In a guinea pig maximisation test (OECD TG 406), the chemical IOTG tested positive in 5/20 animals (25%). A positive response characterised by a well-defined erythema was observed (in the absence of oedema) in two animals (out of 5 positive animals) after 24 and 48 hours. Dryness of the skin was noted after 48 hours in 5/20 animals of the treated group (OECD, 2010).

Similar sensitisation results were observed in guinea pigs treated with EHTG in another maximisation study. Positive skin sensitisation cutaneous reactions were seen in 10 out of 20 animals (50%) in the GPMT (OECD, 2010).

Mercaptoacetate salts tested positive in Local Lymph Node Assay (LLNA) and guinea pig maximisation tests (NICNAS). In humans, formulations containing the salts of mercaptoacetic acid, particularly ammonium mercaptoacetate (CAS No. 5421-46-5), gave positive results for skin sensitisation in several studies (NICNAS).

Repeated Dose Toxicity

Oral

Limited data are available for the chemicals. Based on the available studies for EHTG; the chemicals in this group are not considered to cause serious damage to health from repeated oral exposure.

In a 28-day study in rats, a no observed adverse effect level (NOAEL) of 0.2% EHTG in the diet (the highest dose tested; 168 mg/kg bw/day for males; 173 mg/kg bw/day for females) was reported. No treatment-related effects were observed (OECD, 2010).

In a reproductive/developmental screening test (OECD TG 421), groups of male and female rats were exposed to EHTG up to 150 mg/kg bw/day by gavage. Males and females were dosed prior to mating and through the mating period; females were also dosed through lactation. Systemic toxicity was observed at 150 mg/kg bw/day, including mortality (3 males and 1 female died). Decreased mean body weight and body weight gain were seen in males without any effect on food consumption; females had decreased maternal body weight during gestation days 17-20; increased relative kidney weights were seen in males; increased relative liver weight were seen in males and females; and hepatocellular vacuolisation was seen in the animals that died but not in the surviving animals. The systemic NOAEL was established at 50 mg/kg/day based on the range of effects seen at 150 mg/kg/day (OECD, 2010).

Dermal

No data are available for the chemicals in this group. Based on the lower dermal toxicity compared to oral toxicity following acute exposure, bioavailability from dermal route can be assumed to be no higher than the oral route. As the chemicals are not of high toxicity by oral route, they are not considered to cause serious damage to health from repeated dermal exposure.

Inhalation

Limited data is available for the chemicals.

Repeated inhalation exposure (vapours to whole body) of up to 3.2 ppm (0.38 mg/m^3; highest concentration tested) of IOTG did not cause any clinical signs of irritation or toxicity in Sprague Dawley (SD) rats. There were no exposure-related effects on haematology, urinalysis, clinical chemistry, organ and terminal body weights. No exposure-related lesions were observed at necropsy (OECD, 2010).

Genotoxicity

Limited data are available for the chemicals. Based on the weight of evidence from the available studies for the chemicals in the group and the metabolite chemicals, the chemicals in this group are not considered to be genotoxic.

Both chemicals were negative in reverse mutation assays using *Salmonella typhimurium* with and without metabolic activation (OECD, 2010).

EHTG was negative in an in vivo micronucleus assay up to 700 or 900 mg/kg in male and female mice or rats, respectively (OECD, 2010).

The rapidly produced metabolites (mercaptoacetate ion and 2-ethylhexanol) are not considered to be genotoxic (NICNASa; NICNASb).

Carcinogenicity

No data are available for the chemicals.

Data available for the rapidly produced metabolites (mercaptoacetate anion and 2-ethylhexanol, parent alcohol) indicate that these chemicals are not likely to be carcinogenic (NICNASa; NICNASb).

Reproductive and Developmental Toxicity

Limited data are available. The chemical EHTG caused developmental effects. Whilst effects in the pups occurred at doses at which maternal toxicity was observed, a direct neonatal effect from the compound in maternal milk can not be discounted (OECD, 2010). Given that the metabolite 2-ethylhexanol also causes developmental toxicity (NICNAS), in the absence of further information, classification is considered warranted for EHTG. Data available support the finding that developmental effects are not likely for IOTG.

In rats administered ethylhexyl thioglycolate (CAS No. 7659-86-1) by gavage (OECD test guideline 421), the no observed adverse effect level (NOAEL) was 50 mg/kg bw/day for reproductive and developmental effects, based on foetal and systemic toxicity seen at higher doses (OECD, 2010). Treatment related effects at this dose include dystocia (obstructed delivery) and mucification of the vaginal epithelium in the dams and adverse effects on pup growth and survival. Whilst effects in the pups occurred at doses at which maternal toxicity was observed, a direct neonatal effect from the compound in maternal milk can not be discounted (OECD, 2010).

Based on the available data, the mercaptoacetate anion metabolite is not considered to have reproductive or developmental toxicity (NICNASa).

The parent alcohol metabolite for EHTG, 2-ethylhexanol (CAS No. 104-76-7), was reported to cause developmental toxicity, but not teratogenicity, in rats following treatment via the oral route (NICNASb). These effects were noted in the absence of signs of marked maternal toxicity. The NOAEL for developmental toxicity was reported to be 130 mg/kg bw/day.

No data are available for the parent alcohol metabolite for IOTG, isooctanol (CAS No. 26952-21-6). In a developmental study, isooctanoic acid (CAS RN 25103-52-0), did not cause any changes to foetal weight, malformation incidence, or foetal viability at

800 mg/kg bw/day (Ambroso et al., 1999). Therefore, the developmental effects associated with 2-ethylhexanol are not expected for isooctanol.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (skin sensitisation) and systemic acute effects (acute toxicity by the oral exposure). The chemical EHTG may cause systemic long tem effects (developmental toxicity).

Public Risk Characterisation

International information indicate that the chemicals are not likely to be widely available for domestic and cosmetic use (refer **Import, manufacture and use** section). Hence, the public risk from these chemicals is not considered to be unreasonable.

Additional regulatory controls could be required should information become available to indicate that the chemicals are used in domestic and cosmetic products in Australia.

Occupational Risk Characterisation

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

Given the critical health effects, the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure to the chemicals are implemented. The chemicals 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 data available support an amendment to the hazard classification in the HSIS (refer to the **Recommendation** section).

NICNAS Recommendation

Assessment of the chemicals in this group 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.

Additional regulatory controls could be required should information become available to indicate that the chemicals are used in domestic and cosmetic products in Australia.

Regulatory Control

Work Health and Safety

The chemicals in this group are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

NOTE: The reproductive and developmental classification applies to EHTG (CAS No. 7659-86-1) only.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)	Suspected of damaging the unborn child - Cat. 2 (H361d)

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

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures 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 chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- 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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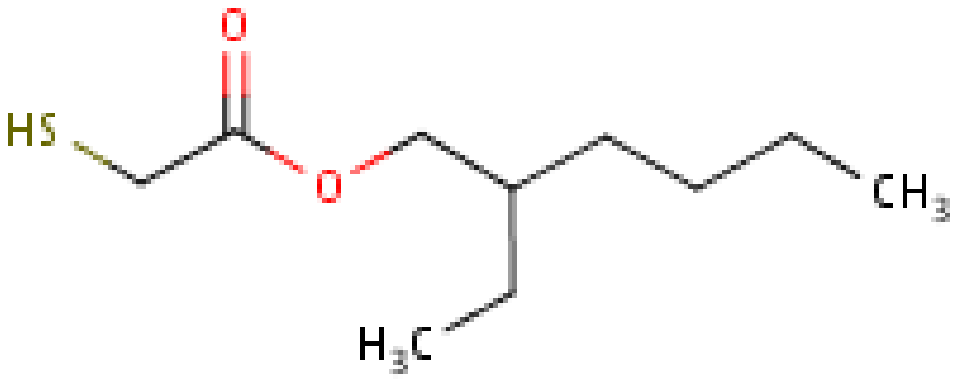
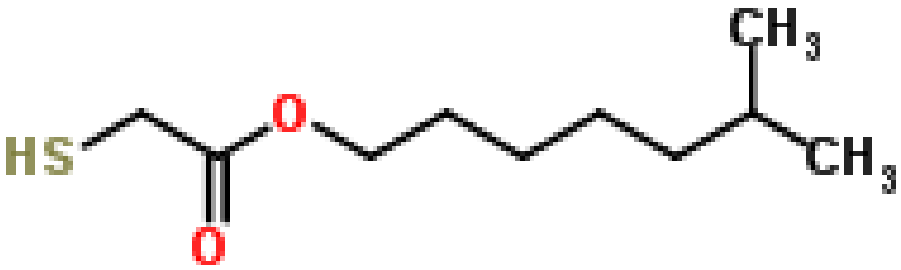
Last Update 18 September 2014

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Acetic acid, mercapto-, 2-ethylhexyl ester** 2-ethylhexyl mercaptoacetate (EHMA) 2-ethylhexyl thioglycolate EHTG
CAS Number	7659-86-1
Structural Formula	
Molecular Formula	C10H20O2S
Molecular Weight	204

Chemical Name in the Inventory and Synonyms	**Acetic acid, mercapto-, isooctyl ester** Isooctyl thioglycolate Isooctyl mercaptoacetate (IOMA) IOTG
CAS Number	25103-09-7

Structural Formula	
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