Butyl and isobutyl methacrylate: Human health tier II assessment

04 July 2014

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
2-Propenoic acid, 2-methyl-, 2-methylpropyl ester	97-86-9
2-Propenoic acid, 2-methyl-, butyl ester	97-88-1

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The two chemicals are alkyl esters of methacrylic acid. Both chemicals have similar physical–chemical properties and industrial applications/uses.

Due to their similarity, hazard data on both chemicals were used as read-across data for each other for different end points in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers (REACHa; REACHb).

Import, Manufacture and Use

Australian

The two chemicals are listed on the 2006 High Volume Industrial Chemicals List.

The chemicals have reported domestic/commercial use in adhesives and binding agents.

International

The following international uses have been identified through European Union (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).

Both these chemicals are used to manufacture polymers. However, some products used by professionals and hobbyists could contain significant quantities of the liquid monomer (Evonik Industries, 2013).

The OECD report (2004) stated that industry and consumers use these manufactured polymers. However, the presence of 'methacrylate monomers is likely to be extremely low' in consumer products.

The chemicals have reported cosmetic uses including:

- in personal care products;
- in perfumes;
- in artificial nails—very small quantities of isobutyl methacrylate are used to manufacture and repair artificial nails (OECD, 2004);
- as a film forming agent;
- as viscosity controllers; and
- for masking.

The chemicals have reported domestic uses including in:

- adhesives and sealants;
- disinfectants;
- paint, thinners and paint removers;
- washing and cleaning products;
- finger paints;
- colouring agents;
- surfactants; and
- insulating materials.

The chemicals are on the list of binders (monomers) in articles and materials–Annex 6, Part A, The Switzerland Ordinance of the Federal Department of Home Affairs.

The chemicals have reported commercial uses including:

- in inks and toners;
- in leather tanning, textile and paper coatings;
- in anti-freeze and de-icing products;
- in corrosion inhibitors;
- in formulations;
- in plastic films;
- in construction materials;
- as process regulators;
- in reprographic and photographic agents; and
- as viscosity adjustors.

The chemicals have reported site-limited uses including:

- as chemical intermediates;
- as monomers in polymer production;
- in manufacturing thermoplastics;
- as laboratory reagents; and
- as electroplating agents

The chemicals have reported non-industrial uses including in:

- non-agricultural pesticides; and
- pharmaceuticals.

Restrictions

Australian

No known restrictions have been identified for these two chemicals.

Two related chemicals with similar hazard profiles in the Hazardous Substances Information System (HSIS): methyl methacrylate (CAS No. 80-62-6) and ethyl methacrylate (CAS No. 97-63-2), are listed on Schedules 5 and 6 of the *Poisons Standard*—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), respectively. Cosmetic use of methyl methacrylate is prohibited (listed on Appendix C of the SUSMP) with exceptions for preparations containing 1 % or less as residual monomer in a polymer.

International

No known restrictions have been identified for the two chemicals.

Existing Worker Health and Safety Controls

Hazard Classification

Both chemicals are classified as hazardous, with the following risk phrases for human health in the HSIS (Safe Work Australia):

Xi; R36/37/38 (irritation)

R43 (skin sensitisation)

Exposure Standards

Australian

No specific exposure standards are available for these two chemicals.

International

The following exposure standards are identified (Galleria Chemica):

Isobutyl methacrylate

Time weighted average (TWA):

- 100 mg/m³ (17 ppm) in Poland
- 145 mg/m³ (25 ppm) in Denmark
- 300 mg/m³ (50 ppm) in Sweden, Norway, Iceland and Austria

Short-term exposure limits (STEL) of:

- 300 mg/m³ (50 ppm) in Poland
- 450 mg/m³ (75 ppm) in Sweden

n-butyl methacrylate

TWA:

- 30 mg/m³ (5 ppm) in Latvia and Russia
- 60 mg/m³ (10 ppm) in Norway
- 100 mg/m³ (17 ppm) in Poland
- 145 mg/m³ (25 ppm) in Denmark and Iceland
- 300 mg/m³ (50 ppm) in Canada and Sweden

STEL:

- 300 mg/m³ (50 ppm) in Poland
- 450 mg/m³ (75 ppm) in Sweden

Health Hazard Information

Toxicokinetics

The chemicals are readily absorbed by oral, dermal and inhalation routes and are rapidly metabolised to methacrylic acid (MAA) (CAS No. 79-41-4) and the corresponding alcohols (OECD, 2004). Metabolism of the chemicals occurs by two main pathways: conjugation with glutathione to form thioesters and hydrolysis via esterase activity to yield methacrylic acid, with subsequent conversion to carbon dioxide (NICNASa).

The half-life for metabolic hydrolysis was 11.6 min for isobutyl methacrylate and 7.8 minutes for butyl methacrylate (REACHa; REACHb). The rapid hydrolysis and low systemic toxicity of n-butanol (NICNASb) and isobutanol (NICNASc) indicate that the two chemicals are good analogues for systemic toxicity.

Acute Toxicity

Oral

The two chemicals have low acute toxicity in animal tests following oral exposure.

The median lethal dose (LD50) in rats and mice is >2000 mg/kg bw for both chemicals (OECD, 2004; REACHa; REACHb).

Dermal

The two chemicals have low acute dermal toxicity.

In a dermal toxicity study with butyl methacrylate (OECD TG 402), the LD50 was determined to be >2000 mg/kg bw in New Zealand White rabbits, indicating low acute dermal toxicity for both chemicals (OECD, 2004).

Inhalation

The data available indicate low acute inhalation toxicity.

No data are available for butyl methacrylate.

The median lethal concentration (LC50) in mice is 29.7 mg/L (approximately 5000 ppm) for isobutyl methacrylate vapour (OECD, 2004; REACHa).

Corrosion / Irritation

Respiratory Irritation

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

In acute inhalation toxicity studies, respiratory irritation was observed in Sprague Dawley (SD) rats exposed to butyl methacrylate (REACHb).

In a 28-day repeated dose inhalation study (OECD TG 412), Crl:CDBR rats (n = 5/sex/dose) were exposed to butyl methacrylate at concentrations of 0, 310, 952 or 1891 ppm (0, 1832, 5626 or 11175 mg/m³) for six hours/day, five days/week. Irritation of the nasal cavity was observed from 952 ppm (REACHb). Lesions in the olfactory region of the respiratory tract were reported in rats (OECD, 2004).

No data are available for isobutyl methacrylate.

Skin Irritation

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

The two chemicals are considered to irritate the skin of rabbits when applied under occluded conditions (OECD, 2004).

In a study performed in accordance with OECD Test Guideline (TG) 404, butyl methacrylate produced erythema (mean score of 2.3 in 3/4) and mild oedema (mean score of 0.4 in 1/4) in rabbits, following four hours of exposure. After 10–14 days, the effects seen on the exposed areas were not reversed (OECD, 2004; REACHb).

In another study (guideline not stated), butyl methacrylate was reported to produce extremely strong erythema, blistering oedema and 'burn effects to some degree', and was reported to be highly irritating (mean score of 3/3) in rabbits. Exposure durations were not available (OECD, 2004; REACHb).

In a study with New Zealand White rabbits (guideline not stated), butyl methacrylate produced erythema (mean score of 2.0 in 8/4) and oedema (mean score of 1.8 in 3/4), following 24 hours of exposure (REACHa).

In a study with New Zealand White rabbits (guideline not stated) (n = 6), isobutyl methacrylate produced slight erythema (mean score of 0.9 in 2/4) and slight oedema (mean score of 0.6 in 6/4), following 24 hours of exposure (REACHa).

Eye Irritation

Both chemicals are classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The available information does not support this classification. However, the data available are insufficient (study details not available) to recommend changes to the existing classification.

The two chemicals 'produce, at worst, slight eye irritation' (OECD, 2004). The irritation scores are not available.

The two chemicals produced minimal to no corneal or iris irritation (maximum scores of 0.1 in 7/4 and 0/1, respectively), slight conjunctival reaction (scores of 0–1 in 7/4) and slight chemosis (scores of 0–0.5 in 5/4) in several guideline studies in rabbits (REACHa; REACHb).

Sensitisation

Respiratory Sensitisation

There is no evidence of the two chemicals producing respiratory sensitisation (OECD, 2004).

Skin Sensitisation

Both chemicals are classified as hazardous with the risk phrase ‘May cause sensitisation by skin contact’ (R43) in HSIS (Safe Work Australia). The limited information available does not strongly support this classification. However, there is insufficient evidence for a change to the classification.

The chemicals have shown equivocal results in some adjuvant studies in guinea pigs and have been considered to have weak skin sensitising potential (OECD, 2004).

Butyl methacrylate is considered to be a skin sensitiser based on the positive results seen in several guinea pig maximisation tests (REACHb). However, isobutyl methacrylate was not found to induce dermal sensitisation in guinea pigs (maximisation test) (REACHa).

Observation in humans

Butyl methacrylate is used to test (dermatological patch) humans exposed to acrylates. A very few cases have confirmed the weak skin sensitisation potential of butyl methacrylate (OECD, 2004).

The chemical, isobutyl methacrylate, gave ambiguous results in two human patch tests (REACHa).

Although butyl methacrylate gave positive challenge responses in humans, the inducing agent could be another methacrylate ester (OECD, 2004).

Repeated Dose Toxicity

Oral

Based on the data available for butyl methacrylate, neither chemical is considered to cause serious damage to health from repeated oral exposure.

In a three-month oral gavage study (OECD TG 408), Wistar rats (n = 10–15/sex/dose) were administered butyl methacrylate at concentrations of 0, 60, 120 or 360 mg/kg bw/d. A no observed adverse effect level (NOAEL) of 120 mg/kg was reported based on decreased (by 12 %) body weight, increased (by 11 %) prothrobin time, and increased liver and kidney weights at 360 mg/kg bw/d (REACHb).

In a combined repeated dose and reproductive and developmental toxicity study (OECD TG 422), butyl methacrylate was administered to Crj:CD(SD) rats at 0, 30, 100, 300 and 1000 mg/kg bw/d, for 44 days in males; and 14 days before mating, and up to day three of lactation in females. A no observed effect level (NOEL) of 30 mg/kg bw/d was established for male rats, based on decreased spleen weights and atrophy of the splenic red pulp (OECD, 2004). Increased prothrobin times were observed in rats at the highest dose group (REACHb).

No data are available for isobutyl methacrylate.

Dermal

There are no data available on the chemicals.

Inhalation

Based on the available data, the two chemicals are not considered to have systemic repeat dose inhalation toxicity. However, both chemicals are classified as hazardous based on respiratory irritation effects.

In a 28-day repeated dose inhalation study (OECD TG 412), Crl:CDBR rats (n = 5/sex/dose) were exposed to the butyl methacrylate at concentrations of 0, 310, 952 or 1891 ppm (0, 1832, 5626 or 11175 mg/m³), for six hours/day five days/week. Rats in the two higher dose groups had 'localized bilateral degeneration of olfactory epithelium lining the dorsal meatus of the nasal cavity'; the lowest observed adverse effect level (LOAEL) for this was 952 ppm and the NOAEL was 310 ppm (OECD, 2004). The mechanism for the local degeneration of the olfactory tissue within the nasal cavity was explained 'as hydrolysis of the parent ester by tissue carboxylesterases to release methacrylic acid' (CAS No. 79-41-4). Studies with methyl methacrylate (MMA) (CAS No. 80-62-6) 'indicate that there is little or no progression of the effect from acute through to chronic exposures' (OECD, 2004).

No data are available for isobutyl methacrylate.

Genotoxicity

Based on the available data, neither chemical is considered genotoxic.

The chemicals showed no indication of causing gene mutations at relevant doses (OECD, 2004).

The chemicals gave negative results in several in vitro assays for genotoxicity (OECD, 2004; REACHa; REACHb):

- bacterial reverse mutation assays (Ames test, OECD TG 471) with *Salmonella typhimurium* (TA 98, 100, 1535 and 1537), with or without metabolic activation;
- bacterial reverse mutation assays (Ames test, OECD TG 471) with *Escherichia coli* WP2 uvr A, with or without metabolic activation;
- mammalian cell gene mutation assays (OECD TG 476) that used Chinese hamster lung fibroblasts (V79), with or without metabolic activation.

Positive results were reported for butyl methacrylate in one bacterial reverse mutation assay (Ames test, OECD TG 471) with *S. typhimurium* strain TA 1538, with or without metabolic activation (REACHb).

Butyl methacrylate gave negative results in the following in vivo assay (OECD, 2004; REACHb):

- a mammalian erythocyte micronucleus assay (OECD TG 474) in Swiss CD1 mice receiving butyl methacrylate (intraperitoneal injections) up to 2000 mg/kg bw.

Carcinogenicity

There are no data available for the two chemicals. Based on the information available for MMA (CAS No. 80-62-6), the two chemicals are not expected to be carcinogenic.

There were no concerns on carcinogenicity of MMA in humans and animals (OECD, 2004). Carcinogenicity studies showed no neoplastic changes in Fischer 344 rats and B6C3F1 mice exposed to MMA up to 500 or 1000 ppm (up to 4.1 mg/L) for two years (OECD, 2004; REACHa; REACHb).

The common, rapid metabolism to methacrylic acid and rapid clearance of the two chemicals (similar to MMA), do not raise concerns for a carcinogenic risk (OECD, 2004).

Reproductive and Developmental Toxicity

Based on the available data, the two chemicals are not considered to have specific reproductive or developmental toxicity.

In a one-generation combined repeated dose and reproductive and developmental toxicity study (OECD TG 422), CD(SD) rats (n = 10/sex/dose) were administered butyl methacrylate by oral gavage doses of 0, 30, 100, 300 or 1000 mg/kg bw/d for 44 days in males; and from 14 days before mating to day three of lactation. The NOAELs for reproductive toxicity were: 1000 mg/kg bw/d in males (no effects at the highest dose) and 300 mg/kg bw/d in females based on reduced number of corpora lutea (by 18 %) and implantation sites (by 15 %). The NOAEL for developmental toxicity was 1000 mg/kg bw/d (OECD, 2004; REACHb).

In a prenatal developmental toxicity study (OECD TG 414), female SD rats (n = 22–25/dose) were exposed to butyl methacrylate at concentrations of 0, 100, 300, 600 or 1200 ppm (0, 0.6, 1.8, 3.6 or 7.2 mg/mL) for six hours/day during gestation days (GD) 6–20. The NOAEL for developmental toxicity was 300 ppm, based on decreased foetal body weight observed in female foetuses at 600 ppm and in both sexes at 1200 ppm. At 300 ppm, decreased maternal body weight gain and decreased food consumption were observed (REACHb).

In the only developmental toxicity study available for isobutyl methacrylate, female SD rats (n = 5/group) were administered the chemical intraperitoneally (a route not relevant for human exposure) at doses of 0, 124, 248 or 413 mg/kg bw/d on GD 5, 10 and 15. Increased resorptions were observed in the highest dose group. In pups, gross abnormalities (not stated) (0, 6.7, 6.3 and 10.9 % in the 0, 124, 248 and 413 mg/kg bw/d dose groups, respectively) and skeletal abnormalities (1 (5 %), 0, 2 (7.7 %) and 2 (8 %) in the 0, 124, 248 and 413 mg/kg bw/d dose groups, respectively) were reported (REACHa).

The OECD report (2004) concluded that: 'It is unlikely that exposure to butyl methacrylate esters with subsequent hydrolysis to methacrylic acid and the corresponding alcohol would produce blood levels of the alcohol high enough to result in developmental toxicity'.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include only local effects (skin sensitisation, and irritation to the eyes, skin and respiratory system).

Public Risk Characterisation

In Australia, the chemicals are likely to be used in making additives and binding agents. The OECD report (2004) stated that the presence of 'methacrylate monomers is likely to be extremely low' in consumer products.

The international uses indicate cosmetic use, including in artificial nails at very small quantities (OECD, 2004). A producer of the chemicals has recommended not to use them in 'artificial nail products and other non-medical/dental applications involving direct skin/nail contact with the liquid monomer' (Evonik Industries, 2013).

Currently, there are no restrictions in Australia on using these chemicals in cosmetics or domestic products. Based on the information available, public exposure to high amounts or concentrations of the chemicals are not expected through cosmetic or domestic uses in Australia. Therefore, these chemicals are not considered to pose an unreasonable risk to public under the uses identified.

Occupational Risk Characterisation

Given the critical local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation 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.

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.

If any information becomes available to indicate significant consumer exposure to the chemicals in Australia (i.e. higher concentrations or amounts in cosmetics or domestic products), risks to public health and safety might have to be managed by changes to poisons scheduling.

Regulatory Control

Public Health

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

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 hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)

[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 instruction on the label.

Advice for industry

Control measures

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

- 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;
- 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 chemicals has not been undertaken as part of this assessment.

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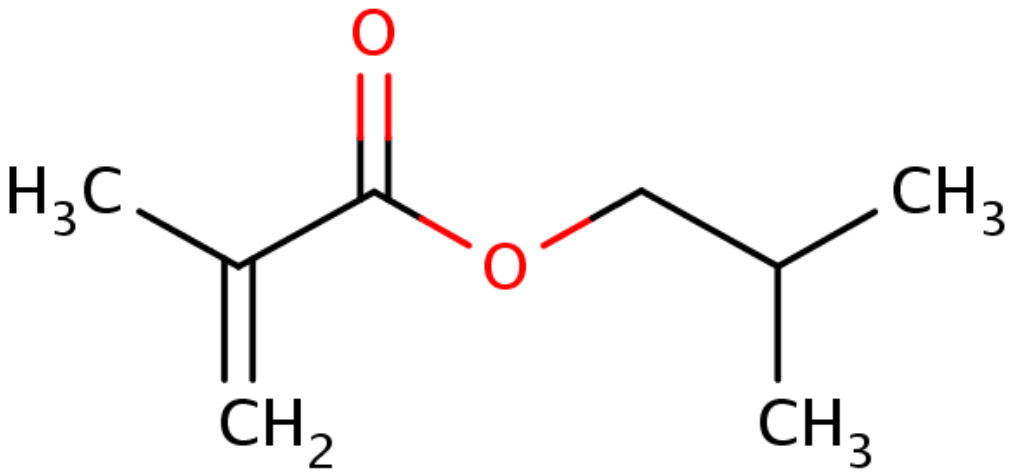
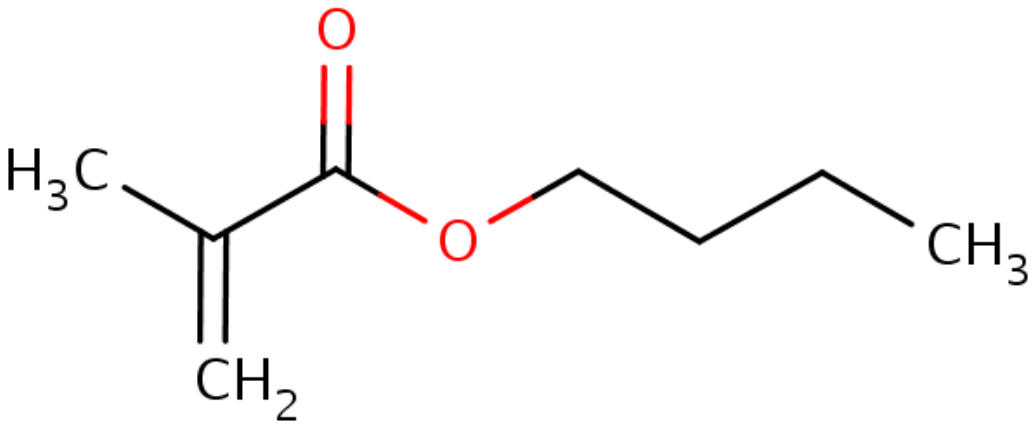
Last Update 04 July 2014

Chemical Identities

Chemical Name in the Inventory and Synonyms	**2-Propenoic acid, 2-methyl-, 2-methylpropyl ester** isobutyl methacrylate
CAS Number	97-86-9
Structural Formula	

	
Molecular Formula	C8H14O2
Molecular Weight	142.20

Chemical Name in the Inventory and Synonyms	**2-Propenoic acid, 2-methyl-, butyl ester** butyl methacrylate n-butyl methacrylate
CAS Number	97-88-1
Structural Formula	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