CMR chemicals not registered under REACH: Human health tier II assessment

01 July 2016

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Acetamide	60-35-5
Acetamide, N-(4-ethoxyphenyl)-	62-44-2
Acetic acid, dichloro-	79-43-6
Methanone, bis[4-(dimethylamino)phenyl]-	90-94-8
Benzenamine, 4,4'-methylenebis[N,N-dimethyl-	101-61-1
Phenol, 4-nitroso-	104-91-6
Benzofuran	271-89-6
1-Propene, 1-chloro-2-methyl-	513-37-1
1-Propene, 1,3-dichloro-	542-75-6
9H-Fluorene, 2-nitro-	607-57-8

Chemical Name in the Inventory	CAS Number
Ethane, 1,2-diethoxy-	629-14-1
Phosphoric triamide, hexamethyl-	680-31-9
2-Butene, 1,4-dichloro-	764-41-0
9H-Carbazole, 9-ethenyl-	1484-13-5
1-Propanol, 2-methoxy-	1589-47-5
1,3-Benzenedicarbonitrile, 2,4,5,6-tetrachloro-	1897-45-6
4-Morpholinecarbonyl chloride	15159-40-7
Benzenamine, 4,4'-methylenebis[2-ethyl-	19900-65-3
Indium phosphide (InP)	22398-80-7
1-Aziridinepropanoic acid, 2-[[3-(1-aziridinyl)-1-oxopropoxy]methyl]-2-ethyl-1,3-propanediyl ester	52234-82-9
Amides, coco, N,N-bis(hydroxyethyl)	68603-42-9
1-Propanol, 2-methoxy-, acetate	70657-70-4
Phenol, nonyl-, lead(2+) salt	72586-00-6
Acetic acid, [[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]-, 2-ethylhexyl ester	80387-97-9
Tar acids, ethylphenol fraction	84989-03-7
1H-Benzimidazole-2-carboxamide, N-(4-ethoxyphenyl)-	120187-29-3

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

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are carcinogenic, mutagenic, and/or reproductive toxicants (CMRs). The characterisation of the CMR properties of these chemicals was identified based on one or more of the following criteria:

- Listing in the Hazardous Substances Information System (HSIS) for carcinogenicity, mutagenicity, and/or reproductive toxicity (Safe Work Australia);
- Harmonised classifications for carcinogenicity, mutagenicity, and/or reproductive toxicity, as listed in the European Chemicals Agency (ECHA) Classification, Labelling, and Packaging of substances and mixtures (CLP) database (ECHA C & L Inventory); and/or
- Carcinogenicity evaluations by the International Agency for Research on Cancer (IARC).

The CMR chemicals listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) that were imported in the European Union (EU) at above one tonne per year for industrial use were required to be registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) process prior to 30 November 2010 (ECHA, 2012b).

None of the chemicals in this group were registered under REACH at the time of writing of this report.

The ECHA conducted an initial screening of approximately 1,000 chemicals with harmonised CMR classifications under the CLP and found that approximately 40 % of the chemicals have not been registered under REACH, which could imply that the chemicals may no longer be manufactured or marketed in the EU (ECHA, 2012a).

Additionally, the Government of Canada has provisions for Significant New Activity (SNAc) for chemicals of high concern. The SNAc notices are issued for high concern chemicals not found to be in commerce in Canada or for which the current use of the chemicals is effectively managed (Government of Canada, 2015b). Three of the chemicals in this group (acetamide, CAS No. 60-35-5; 4,4-tetramethyldiaminodiphenylmethane, CAS No. 101-61-1; and chlorothalonil, CAS No. 1897-45-6) have current SNAc notices (Government of Canada, 2015a).

Based on this information, it is possible that the chemicals in this group are not used for industrial purposes in Australia, or are only used in very small quantities. It is also likely that special containment equipment, which precludes any human or environmental exposure, is used based on the hazards of the chemicals. Information on the use of these chemicals could therefore potentially remove the need to undertake complex and/or conservative risk assessments. Considering the severity of the hazards of these chemicals, the assumption that exposure would be negligible needs to be validated before NICNAS could draw a conclusion that no additional risk management would be required.

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 Galleria Chemica, the Substances and Preparations in Nordic countries (SPIN) database, the European Commission Cosmetic Ingredients and Substances (CosIng) database, the United States (US) Household Products Database (HPD), the US National Library of Medicine's Hazardous Substances Data Bank (HSDB), various international assessments, and internet sources:

Some of the chemicals have reported cosmetic uses including as:

- a stabiliser in hair preparations; and
- a surfactant in personal care products.

Some of the chemicals have reported domestic uses including:

- in paints, lacquers and varnishes;
- in detergents, cleaners and degreasers;
- as non-ionic surfactants; and
- as colouring agents.

Some of the chemicals have reported commercial uses including:

- as a soldering flux ingredient;
- as a wetting agent;
- as a plasticiser;
- as an epoxy hardener or curing agent;

- as an adhesion promoter;
- in semiconductors, laser diodes, solar cells and optoelectronic devices;
- as a corrosion inhibitor;
- as an antimigration agent; and
- as an antistatic agent.

Some of the chemicals have reported site-limited uses including:

- as an intermediate;
- as a catalyst, additive or stabiliser for other chemicals;
- as a heat transfer fluid; and
- for manufacturing refined petroleum products and nuclear energy.

Some of the chemicals have reported non-industrial uses including:

- in drugs and medication;
- as pesticides and fungicides; and
- as a food additive and preservative.

Some of the chemicals have no identified uses.

Restrictions

Australian

The chemicals below are listed in various Schedules of the *Poisons Standard* (the *Standard for the Uniform Scheduling of Medicines and Poisons*—SUSMP, 2015):

Phenacetin (CAS No. 62-44-2) is listed in Schedule 4:

Schedule 4:

‘PHENACETIN for therapeutic use (excluding when present as an excipient)’.

Chlorothalonil (CAS No. 1897-45-6) is listed in Schedule 6:

Schedule 6:

‘CHLOROTHALONIL except in water-based paint containing 0.5 per cent or less of chlorothalonil’.

Tar acids, ethylphenol fraction (CAS No. 84989-03-7) is listed in Schedule 6 as TAR ACIDS:

Schedule 6:

‘TAR ACIDS distilling within the range 230-290°C inclusive’.

The chemical 1,3-dichloropropene (CAS No. 542-75-6) is listed in Schedule 7 with the ‘Not to be available except to authorised or licensed persons’ under Appendix J of the SUSMP.

Phenol, nonyl-, lead(2+) salt (CAS No. 72586-00-6) is listed in Schedules 5, 6, and 10 (Appendix C) as LEAD COMPOUNDS:

Schedule 5:

‘LEAD COMPOUNDS in preparations for use as hair cosmetics’.

Schedule 6:

‘LEAD COMPOUNDS except:

(a) when included in Schedule 4 or 5;

(b) in paints, tinters, inks or ink additives;

(c) in preparations for cosmetic use containing 100 mg/kg or less of lead;

(d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

(e) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.’

Schedule 10/Appendix C:

‘LEAD COMPOUNDS in paints, tinters, inks or ink additives except;

(a) in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive;

(b) when in Schedule 4;

(c) when in Schedule 5; or

(d) when in Schedule 6.’

‘Schedule 4 chemicals are ‘Prescription Only Medicine, or Prescription Animal Remedy’. These are substances with the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription’.

‘Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.’

‘Schedule 6 chemicals are labelled with ‘Poison’. These are substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label’.

‘Schedule 7 chemicals are labelled with ‘Dangerous Poison’. These are substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply’.

Appendix C chemicals are substances of such danger to health as to warrant prohibition of sale, supply and use.

International

The following chemicals are listed on the EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products, the New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain, and the Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products (Galleria Chemica):

- acetamide (CAS No. 60-35-5);
- Michler's ketone (CAS No. 90-94-8);
- 4,4-tetramethyldiaminodiphenylmethane (CAS No. 101-61-1);
- 4-nitrosophenol (CAS No. 104-91-6);
- 1-chloro-2-methylpropene (CAS No. 513-37-1);
- 1,4-dichloro-2-butene (CAS No. 764-41-0);
- 9-vinylcarbazole (CAS No. 1484-13-5);
- 2-methoxypropanol (CAS No. 1589-47-5);
- chlorothalonil (CAS No. 1897-45-6);
- 4-morpholinecarbonyl chloride (CAS No. 15159-40-7);
- 4,4'-methylenebis(2-ethylaniline) (CAS No. 19900-65-3);
- indium phosphide (CAS No. 22398-80-7);
- 2-methoxypropyl acetate (CAS No. 70657-70-4);
- phenol, nonyl-, lead(2+) salt (CAS No. 72586-00-6);
- 2-ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]acetate (CAS No. 80387-97-9); and
- 4'-ethoxy-2-benzimidazoleanilide (CAS No. 120187-29-3).

The following chemicals are listed on the Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient ‘Hotlist’) (Galleria Chemica):

- phenacetin (CAS No. 62-44-2);
- dichloroacetic acid (CAS No. 79-43-6);
- 4-nitrosophenol (CAS No. 104-91-6);
- 1,3-dichloropropene (CAS No. 542-75-6);
- 1,4-dichloro-2-butene (CAS No. 764-41-0);
- 2-methoxypropanol (CAS No. 1589-47-5);
- chlorothalonil (CAS No. 1897-45-6);
- 4-morpholinecarbonyl chloride (CAS No. 15159-40-7);
- indium phosphide (CAS No. 22398-80-7);
- 2-methoxypropyl acetate (CAS No. 70657-70-4); and
- phenol, nonyl-, lead(2+) salt (CAS No. 72586-00-6).

The following chemicals are restricted by Annex XVII—Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles— to the REACH Regulations (Galleria Chemica):

- Michler's ketone (CAS No. 90-94-8);

- 1,2-diethoxyethane (CAS No. 629-14-1);
- hexamethylphosphoramide (CAS No. 680-31-9);
- 1,4-dichloro-2-butene (CAS No. 764-41-0);
- 2-methoxypropanol (CAS No. 1589-47-5);
- 2-methoxypropyl acetate (CAS No. 70657-70-4);
- 2-ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]acetate (CAS No. 80387-97-9); and
- tar acids, ethylphenol fraction (CAS No. 84989-03-7).

For phenol, nonyl-, lead(2+) salt (CAS No. 72586-00-6), lead compounds (several CAS Nos.) and phenol, nonyl- (CAS No. 25154-52-3) are listed as separate entries in Annex XVII of the REACH Regulations (Galleria Chemica).

Existing Worker Health and Safety Controls

Hazard Classification

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

Acetamide (CAS No. 60-35-5)

- R40 Carc. Cat 3 (carcinogenicity).

Dichloroacetic acid (CAS No. 79-43-6)

- C; R35 (corrosivity).

Michler's ketone (CAS No. 90-94-8)

- R45 Carc. Cat. 2 (carcinogenicity);
- R68 Muta. Cat. 3 (genotoxicity); and
- Xi; R41 (eye irritation).

4,4-Tetramethyldiaminodiphenylmethane (CAS No. 101-61-1)

- R45 Carc. Cat. 2 (carcinogenicity).

4-Nitrosophenol (CAS No. 104-91-6)

- R68 Muta. Cat. 3 (genotoxicity);
- Xn; R22 (acute toxicity); and
- Xi; R41 (eye irritation).

1,3-Dichloropropene (CAS No. 542-75-6)

- T; R24/25 (acute toxicity);
- Xn; R20–65 (acute toxicity, aspiration hazard); and
- Xi; R36/37/38 (irritation).

1,2-Diethoxyethane (CAS No. 629-14-1)

- R61 Repr. Cat. 2 (developmental toxicity);
- R62 Repr. Cat. 3 (reproductive toxicity); and
- Xi; R36 (irritation).

Hexamethylphosphoramide (CAS No. 680-31-9)

- R45 Carc. Cat. 2 (carcinogenicity); and
- R46 Muta. Cat. 2 (genotoxicity).

1,4-Dichloro-2-butene (CAS No. 764-41-0)

- R45 Carc. Cat. 2 (carcinogenicity);
- T+; R26 (acute toxicity);
- T; R24/25 (acute toxicity); and
- C; R34 (corrosivity).

9-Vinylcarbazole (CAS No. 1484-13-5)

- R68 Muta. Cat. 3 (genotoxicity);
- Xn; R21/R22 (acute toxicity); and
- Xi; R38 (irritation).

2-Methoxypropanol (CAS No. 1589-47-5)

- R61 Repr. Cat. 2 (developmental toxicity);
- Xi; R37/38 (irritation); and
- Xi; R41 (irritation).

Chlorothalonil (CAS No. 1897-45-6)

- R40 Carc. Cat 3 (carcinogenicity);
- T+; R26 (acute toxicity); and
- Xi; R37–38 (irritation).

4-Morpholinecarbonyl chloride (CAS No. 15159-40-7)

- R40 Carc. Cat 3 (carcinogenicity); and
- Xi; R36/38 (irritation).

4,4'-Methylenebis(2-ethylaniline) (CAS No. 19900-65-3)

- R40 Carc. Cat 3(carcinogenicity); and
- Xn; R22 (acute toxicity).

Indium phosphide (CAS No. 22398-80-7)

- R45 Carc. Cat. 2 (carcinogenicity);

- R62 Repr. Cat. 3 (reproductive toxicity); and
- T; R46/23 (repeat dose toxicity).

Trimethylopropane tri(3-aziridinylpropanoate) (CAS No. 52234-82-9)

- R68 Muta. Cat. 3 (genotoxicity);
- Xi; R41 (irritation); and
- R43 (sensitisation).

2-Methoxypropyl acetate (CAS No. 70657-70-4)

- R61 Repr. Cat. 2 (developmental toxicity); and
- Xi; R37 (irritation).

2-Ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]acetate (CAS No. 80387-97-9) (CAS No. 80387-97-9)

- R61 Repr. Cat. 2 (developmental toxicity); and
- R43 (sensitisation).

Tar acids, ethylphenol fraction (CAS No. 84989-03-7)

- R45 Carc. Cat. 2 (carcinogenicity); and
- R46 Muta. Cat. 2 (genotoxicity).

4'-Ethoxy-2-benzimidazoleanilide (CAS No. 120187-29-3)

- R68 Muta. Cat. 3 (genotoxicity).

The rest of the chemicals are not listed on the HSIS.

Exposure Standards

Australian

1,3-Dichloropropene has an exposure standard of 4.5 mg/m^3 (1 ppm) time weighted average (TWA) (Galleria Chemica).

Indium phosphide has an exposure standard of 0.1 mg/m^3 TWA (Galleria Chemica).

For phenol, nonyl-, lead(2+) salt, lead (CAS No. 7439-92-1) as inorganic dusts and fumes has an exposure standard of 0.15 mg/m^3 TWA as listed in the HSIS (Safe Work Australia).

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

International

The following exposure standards are identified (Galleria Chemica):

Acetamide

A TWA of 25 mg/m^3 (10 ppm) and a short-term exposure limit (STEL) of 60 mg/m^3 (25 ppm) in Estonia, Norway and Sweden.

Phenacetin

A TWA of 0.5–5.0 mg/m^3 in Bulgaria, Poland and Russia.

Dichloroacetic acid

A TWA of 2.4–4.0 mg/m^3 (0.5 ppm) in Canada (Alberta, British Columbia and Saskatchewan), Latvia, Russia and the United States of America (USA).

A STEL of 1.5 ppm in Canada (Saskatchewan).

1-Chloro-2-methylpropene

A TWA of 0.3 mg/m^3 in Russia, and 104 mg/m^3 in the USA.

1,3-Dichloropropene

A TWA of 4–5 mg/m^3 (1 ppm) in Canada, Denmark, Iceland, Norway, and the USA, and 0.5 mg/m^3 (0.11 ppm) in Germany and Switzerland.

A STEL of 50 mg/m^3 (10 ppm) in Ireland and South Africa, and 2 ppm in Canada (Saskatchewan).

1,2-Diethoxyethane

A TWA of 24 mg/m^3 (5 ppm) in the USA.

Hexamethylphosphoramide

A TWA of 0.05 mg/m^3 in Poland.

1,4-Dichloro-2-butene

A TWA of 0.025–0.05 mg/m^3 (0.005–0.010 ppm) in Canada, Denmark, Ireland and the USA (California), and 0.01 mg/m^3 (0.05–0.10 ppm) in Germany, Russia and Switzerland.

2-Methoxypropanol

A TWA of 19 mg/m^3 (5 ppm) in Germany, Spain and Switzerland, 75 mg/m^3 (20 ppm) in Canada, Denmark, Iceland and Norway, and 190 mg/m^3 (50 ppm) in Sweden.

STEL of 300 mg/m^3 (75 ppm) in Sweden, and 152 mg/m^3 (40 ppm) in Switzerland.

Indium phosphide

A TWA of 0.1 mg/m^3 in Canada, Denmark, Ireland, Singapore, Switzerland, and the USA, 0.01 mg/m^3 in Malaysia, and 4 mg/m^3 in Russia.

A STEL of 0.3 mg/m^3 in Canada (Saskatchewan and Yukon), China, Ireland, Mexico, South Africa, the United Kingdom and the USA (Hawaii and Washington).

2-Methoxypropyl acetate

A TWA of 110 mg/m^3 (20 ppm) in Canada (British Columbia), Denmark, Iceland, Norway and Spain, and 28 mg/m^3 (5 ppm) in Germany and Switzerland.

A STEL of 220–224 mg/m^3 (40 ppm) in Canada (British Columbia), Poland, Spain and Switzerland.

Phenol, nonyl-, lead(2+) salt

A TWA for lead and its inorganic compounds of 0.05–0.10 mg/m^3 in France, Japan, Russia, and 0.20 mg/m^3 in the USA.

Health Hazard Information

The critical concern for the chemicals in this group relates to carcinogenicity, mutagenicity, and/or reproductive toxicity. As such, these health hazards will be the focus of this assessment, with other hazards not considered.

Genotoxicity

The chemicals hexamethylphosphoramide, and tar acids, ethylphenol fraction are classified as hazardous with the risk phrase ‘May cause heritable genetic damage’ in the HSIS (Safe Work Australia). Both of these chemicals have a harmonised mutagenicity classification ('May cause genetic defects') in the ECHA CLP database (ECHA C & L Inventory). Limited data are available for both these chemicals.

The chemicals Michler's ketone, 4-nitrosophenol, 9-vinylcarbazole, trimethylopropane tri(3-aziridinylpropanoate), and 4'-ethoxy-2-benzimidazoleanilide are classified as hazardous with the risk phrase ‘Possible risk of irreversible effects’ in the HSIS (Safe Work Australia). These chemicals have a harmonised mutagenicity classification ('Suspected of causing genetic defects') in the ECHA CLP database (ECHA C & L Inventory). The available information for Michler's ketone (Government of Canada, 2010; IARC, 2010; US NTP) supports the classification. Limited data are available for the other chemicals.

Carcinogenicity

The chemicals Michler's ketone, 4,4-tetramethyldiaminodiphenylmethane, hexamethylphosphoramide, 1,4-dichloro-2-butene, indium phosphide, and tar acids, ethylphenol fraction are classified as hazardous with the risk phrase ‘May cause cancer’ in the HSIS (Safe Work Australia). These chemicals have a harmonised carcinogenicity classification ('May cause cancer') in the ECHA CLP database (ECHA C& L Inventory). Limited information is available for tar acids, ethylphenol fraction. The available data for the following chemicals support the classification:

- Michler's ketone (Government of Canada, 2010; IARC, 2010; US NTP, 2014);
- benzenamine, 4,4'-methylenebis[N,N-dimethyl- (IARC, 2010; US NTP, 2014);
- hexamethylphosphoramide (IARC, 1999c);
- 1,4-dichloro-2-butene (IARC, 1977; OECD, 2007); and
- indium phosphide (US NTP, 2001b; IARC, 2006a).

The chemicals acetamide, chlorothalonil, 4-morpholinecarbonyl chloride, and 4,4'-methylenebis(2-ethylaniline) are classified as hazardous with the risk phrase ‘Limited evidence of carcinogenic effect’ in the HSIS (Safe Work Australia). These chemicals have a harmonised carcinogenicity classification ('Suspected of causing cancer') in the ECHA CLP database (ECHA C & L Inventory). Limited information is available for 4,4'-methylenebis(2-ethylaniline). The available data for the following chemicals support the classification:

- acetamide (IARC, 1999b);
- chlorothalonil (WHO-IPCS, 1996; IARC, 1999d; US NTP); and

- 4-morpholinecarbonyl chloride (The MAK-Collection, 2012).

Some of the chemicals in this group are not listed on the HSIS (Safe Work Australia) for carcinogenicity. However, EU CLP notifications for some of these chemicals (marked with * below) have been submitted (ECHA C & L Inventory) with recommended classifications for carcinogenicity. Additionally, the carcinogenicity potential for some of these chemicals was evaluated by IARC.

IARC Group 2A (probably carcinogenic to humans) carcinogens

- phenacetin* (IARC, 2012a) for which the evaluation is supported by studies conducted by the US NTP (2014); and
- phenol, nonyl-, lead(2+) salt has not been specifically evaluated by IARC; however, the chemical is an inorganic lead-based compound, which the IARC has classified as Group 2A (IARC, 2006b). This evaluation of inorganic lead is supported by several studies (ATSDR, 1995; NICNAS, 2007; US EPA, 2008; US NTP, 2014).

IARC Group 2B (possibly carcinogenic to humans) carcinogens

- dichloroacetic acid (IARC, 2014), for which the evaluation is supported by studies conducted by the US NTP (2007);
- benzofuran* (IARC, 1995b) for which the evaluation is supported by studies conducted by the US NTP (1989);
- 1-chloro-2-methylpropene* (IARC, 1995a) for which the evaluation is supported by studies conducted by the US NTP (1986);
- 1,3-dichloropropene (IARC, 1999a) for which the evaluation is supported by studies conducted by the US NTP (1985);
- 2-nitro-9H-fluorene* (IARC, 2013); and
- amides, coco, N,N-bis(hydroxyethyl) (IARC, 2012b) for which the evaluation is supported by studies conducted by the US NTP (2001a).

Reproductive and Developmental Toxicity

The chemicals 1,2-diethoxyethane, 2-methoxypropanol, 2-methoxypropyl acetate, and 2-ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]acetate are classified as hazardous with the risk phrase ‘May cause harm to the unborn child’ in the HSIS (Safe Work Australia). These chemicals have a harmonised reproductive toxicity classification ('May damage the unborn child. Suspected of damaging fertility') in the ECHA CLP database (ECHA C & L Inventory). The available information for 2-methoxypropanol (Government of Canada, 2009) supports the classification. Limited data are available for the other chemicals.

The chemicals 1,2-diethoxyethane, and indium phosphide are classified as hazardous with the risk phrase ‘Possible risk of impaired fertility’ in the HSIS (Safe Work Australia). Both of these chemicals have a harmonised reproductive toxicity classification ('Suspected of damaging fertility') in the ECHA CLP database (ECHA C & L Inventory). The available information for indium phosphide (US NTP, 2001b; IARC, 2006a) supports the classification. Limited information is available for 1,2-diethoxyethane.

Phenol, nonyl-, lead(2+) salt is not listed on the HSIS for reproductive toxicity. However, phenol, nonyl- (CAS No. 25154-52-3) is classified as hazardous with the risk phrases “Possible risk of impaired fertility’ and ‘Possible risk of harm to the unborn child’ in the HSIS (Safe Work Australia). Additionally, lead compounds are classified as hazardous with the risk phrases ‘May cause harm to the unborn child’ and ‘Possible risk of impaired fertility’ in the HSIS (Safe Work Australia).

Risk Characterisation

Critical Health Effects

The chemicals have been identified as having the potential to cause systemic long-term effects (carcinogenicity, mutagenicity, and reproductive toxicity). Other health hazards have not been considered.

Public Risk Characterisation

The public could be exposed to the chemicals in this group if they are used in cosmetic and/or domestic products in Australia. The extent of current usage is unknown as no Australian use data are available for any of the chemicals in this group.

Several of the chemicals are prohibited or restricted internationally, particularly for use in cosmetic and domestic products (see ***Restrictions: International***).

Overall, there is uncertainty regarding the safety of these chemicals in cosmetic and domestic products; therefore, a Tier III assessment may be required, depending on the outcomes of industry consultations (see ***Recommendation***), to determine the extent of use in Australia and the availability of carcinogenicity, mutagenicity, and/or reproductive toxicity data.

Occupational Risk Characterisation

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

Overall, there is uncertainty regarding the other hazards of these chemicals in the workplace; therefore, a Tier III assessment may be required, depending on the outcomes of industry consultations (see ***Recommendation***), to determine the extent of use in Australia and the availability of other toxicity data.

NICNAS Recommendation

It is recommended that NICNAS undertake further consultation with industry to determine to what extent these chemicals are used in Australia, and the specialised containment measures that may be required based on the pattern or type of use.

Should the consultation identify additional evidence pertaining to the use of the chemicals that may pose a risk to workers and/or the public, a Tier III assessment should be undertaken to characterise the risk and recommendations required if considered appropriate.

Regulatory Control

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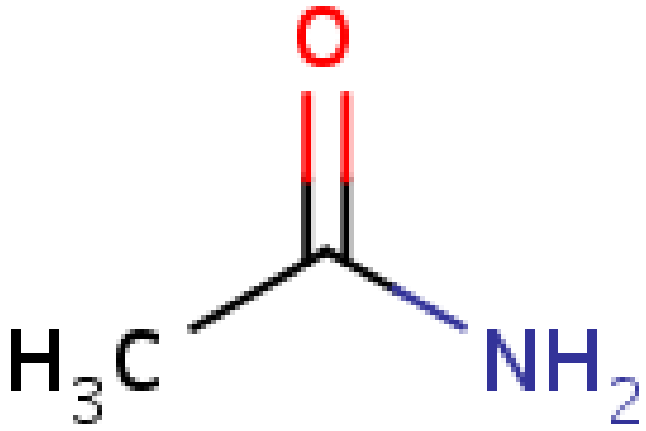
Last Update 01 July 2016

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Acetamide** acetic acid amide acetimidic acid ethanamide
CAS Number	60-35-5
Structural Formula	

	
Molecular Formula	C2H5NO
Molecular Weight	59.07

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	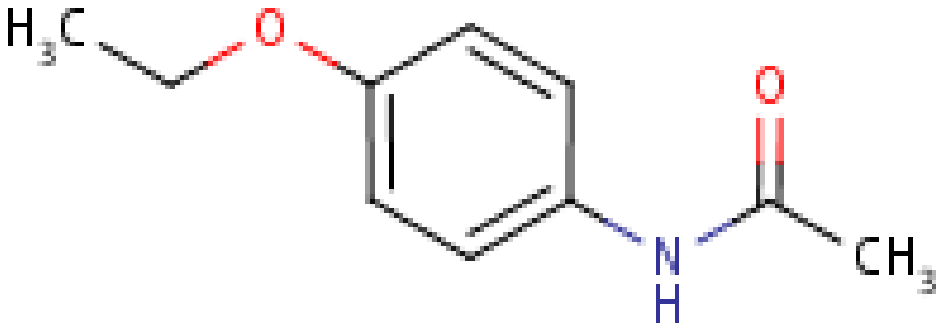
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	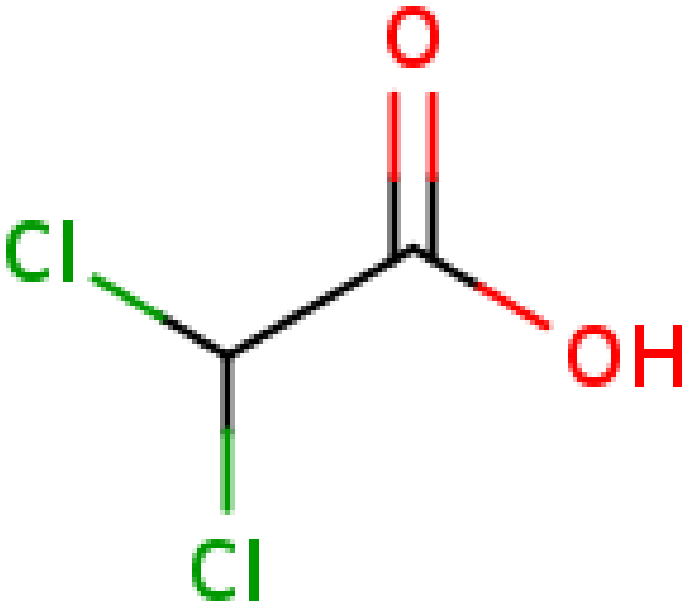
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	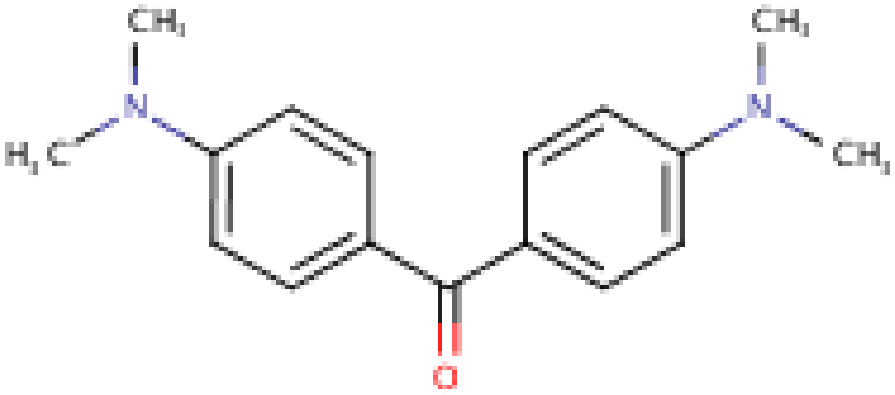
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Molecular Weight	268.36

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	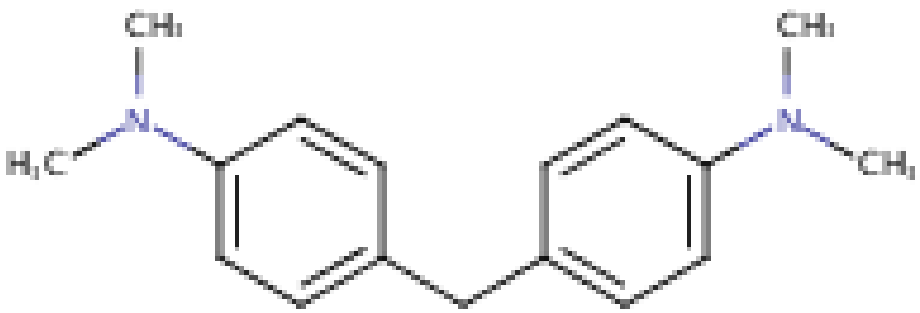
Molecular Formula	C17H22N2
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	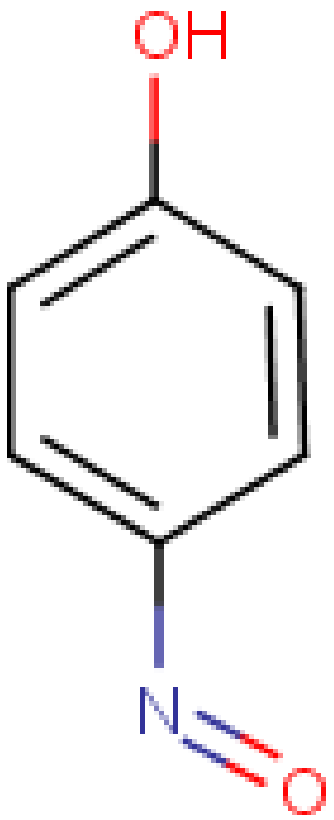
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	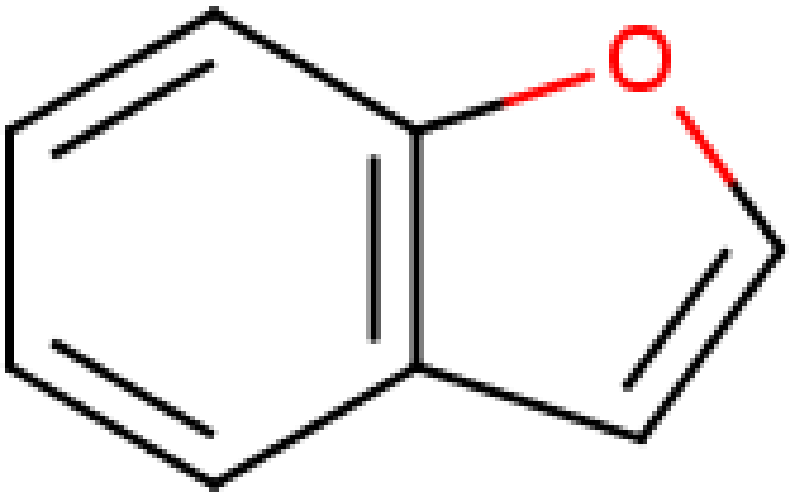
Molecular Formula	C8H6O
Molecular Weight	118.13

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	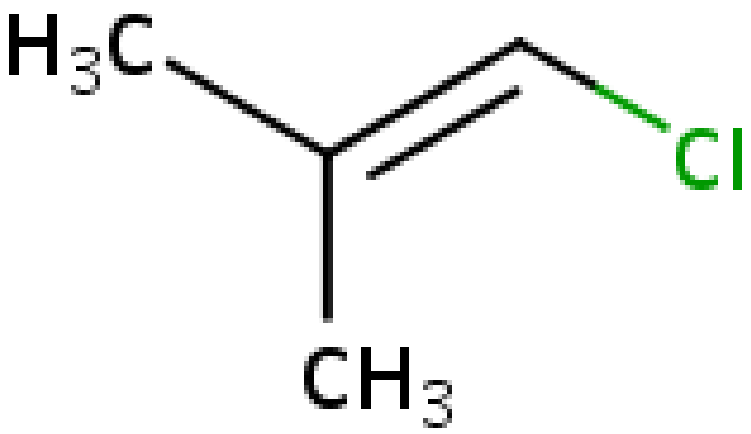
Molecular Formula	C4H7Cl
Molecular Weight	90.55

Chemical Name in the Inventory and Synonyms	**1-Propene, 1,3-dichloro-** 1,3-dichloropropene 3-chloroallyl chloride
CAS Number	542-75-6
Structural Formula	

	
Molecular Formula	C3H4Cl2
Molecular Weight	110.97

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	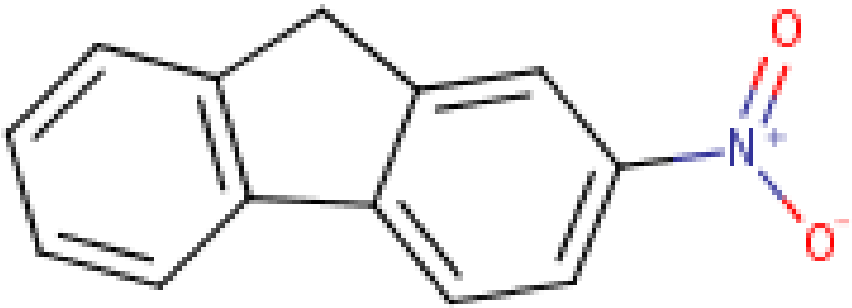
Molecular Formula	C13H9NO2
Molecular Weight	211.22

Chemical Name in the Inventory and Synonyms	**Ethane, 1,2-diethoxy-** 1,2-diethoxyethane diethyl cellosolve ethylene glycol diethyl ether
CAS Number	629-14-1
Structural Formula	

	
Molecular Formula	C6H14O2
Molecular Weight	118.18

Chemical Name in the Inventory and Synonyms	**Phosphoric triamide, hexamethyl-** hexamethylphosphoramide hexametapol phosphoric acid hexamethyltriamide
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	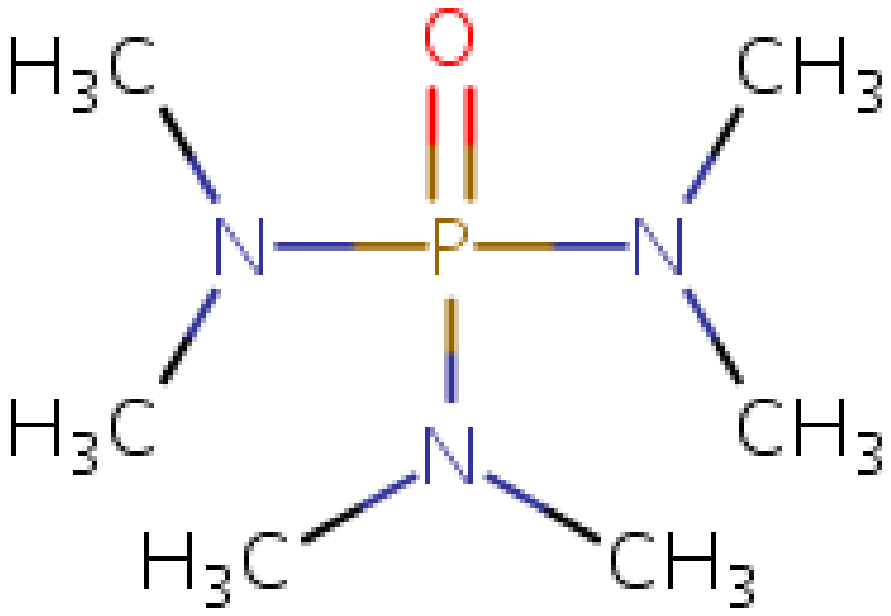
Molecular Formula	C6H18N3OP
Molecular Weight	179.20

Chemical Name in the Inventory and Synonyms	**2-Butene, 1,4-dichloro-** 1,4-dichloro-2-butene 2-butylene dichloride
CAS Number	764-41-0
Structural Formula	

	
Molecular Formula	C4H6Cl2
Molecular Weight	125.00

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	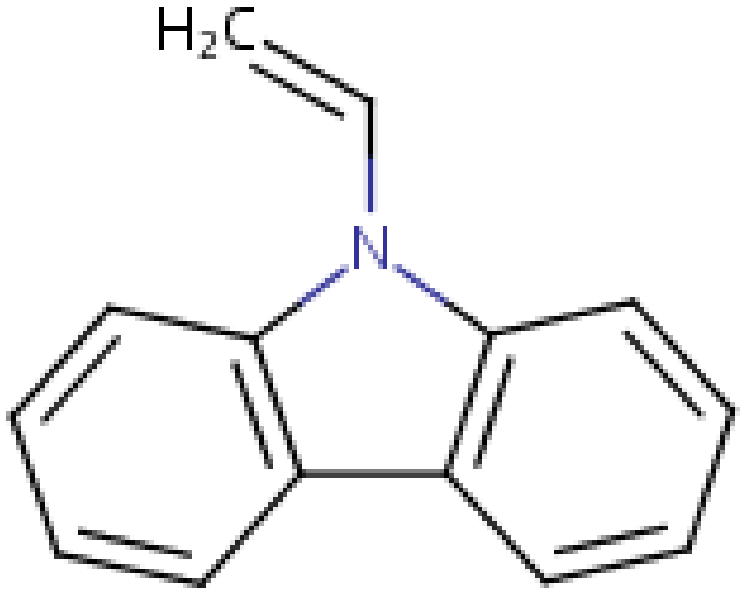
Molecular Formula	C14H11N
Molecular Weight	193.25

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	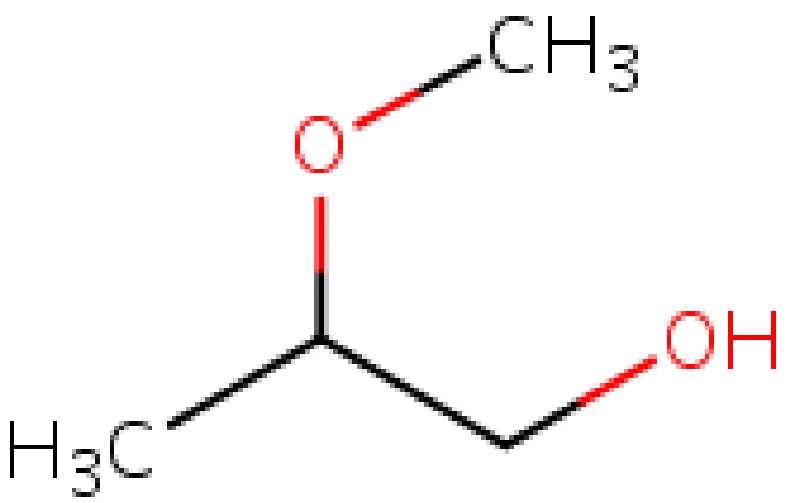
Molecular Formula	C4H10O2
Molecular Weight	90.12

Chemical Name in the Inventory and Synonyms	**1,3-Benzenedicarbonitrile, 2,4,5,6-tetrachloro-** 2,4,5,6-tetrachloro-1,3-benzenenedicarbonitrile chlorothalonil
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	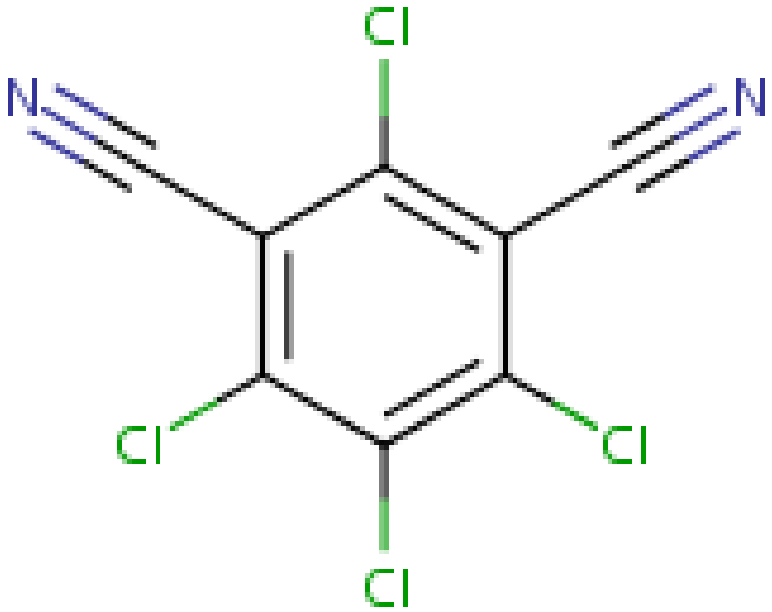
Molecular Formula	C8Cl4N2
Molecular Weight	265.91

Chemical Name in the Inventory and Synonyms	**4-Morpholinecarbonyl chloride** N-morpholinocarbonyl chloride 4-(chloroformyl)morpholine
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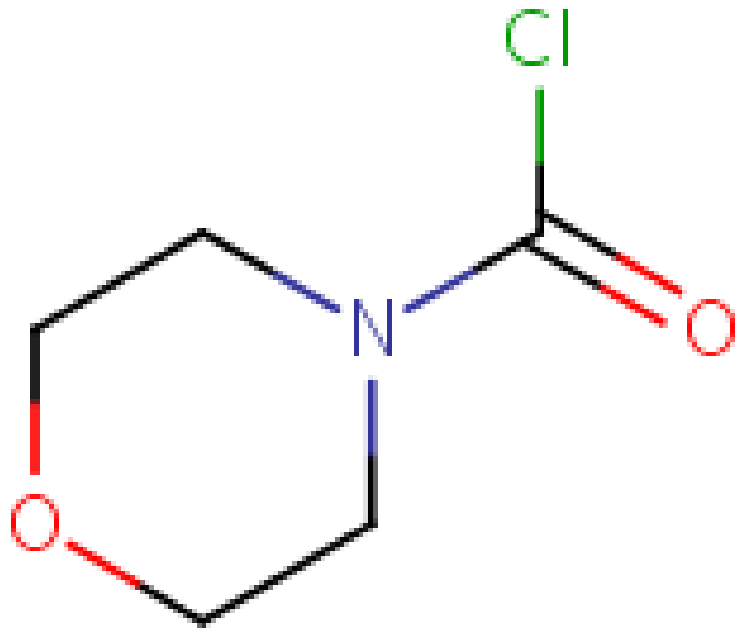
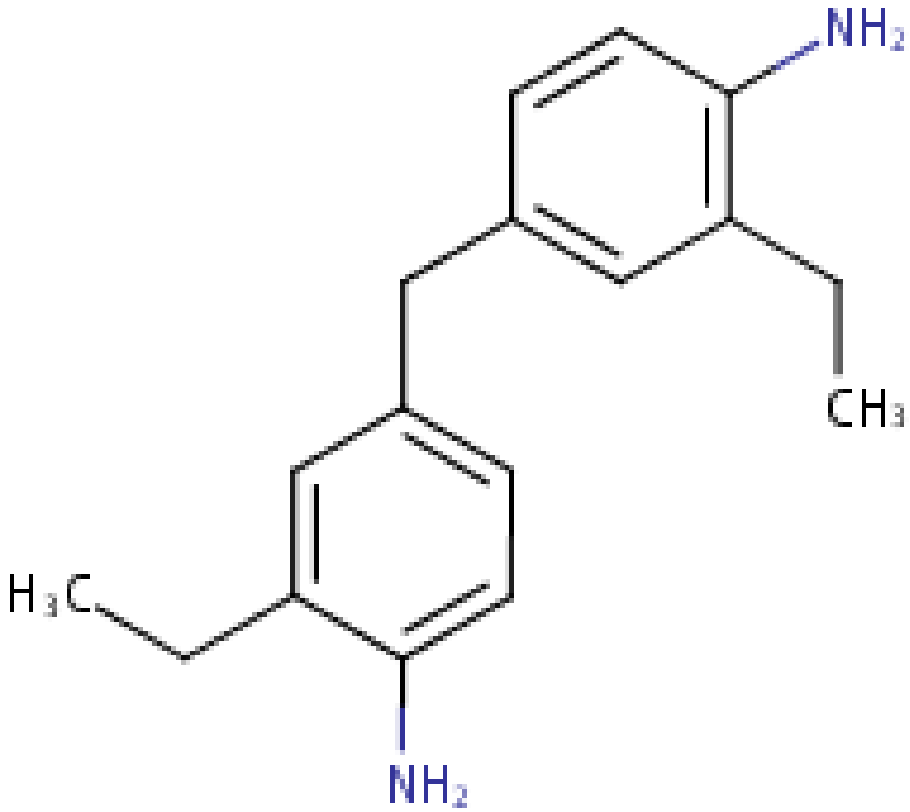
	
Molecular Formula	C5H8ClNO2
Molecular Weight	149.58

Chemical Name in the Inventory and Synonyms	**Benzenamine, 4,4'-methylenebis[2-ethyl-** bis(4-amino-3-ethylphenyl)methane 4,4'-methylenebis(2-ethylaniline)
CAS Number	19900-65-3
Structural Formula	

	
Molecular Formula	C17H22N2
Molecular Weight	254.38

Chemical Name in the Inventory and Synonyms	**Indium phosphide (InP)** indium phosphide
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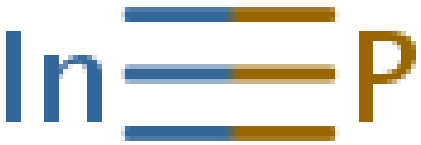
Structural Formula	

	
Molecular Formula	InP
Molecular Weight	145.79

Chemical Name in the Inventory and Synonyms	**1-Aziridinepropanoic acid, 2-[[3-(1-aziridinyl)-1-oxopropoxy]methyl]-2-ethyl-1,3-propanediyl ester** trimethylolpropane, tris[3-aziridinylpropanoate 1-aziridinepropanoic acid, 1,1'-(2-((3-(1-aziridinyl)-1-oxopropoxy)methyl)-2-ethyl-1,3-propanediyl) ester trimethylopropane tri(3-aziridinylpropanoate)
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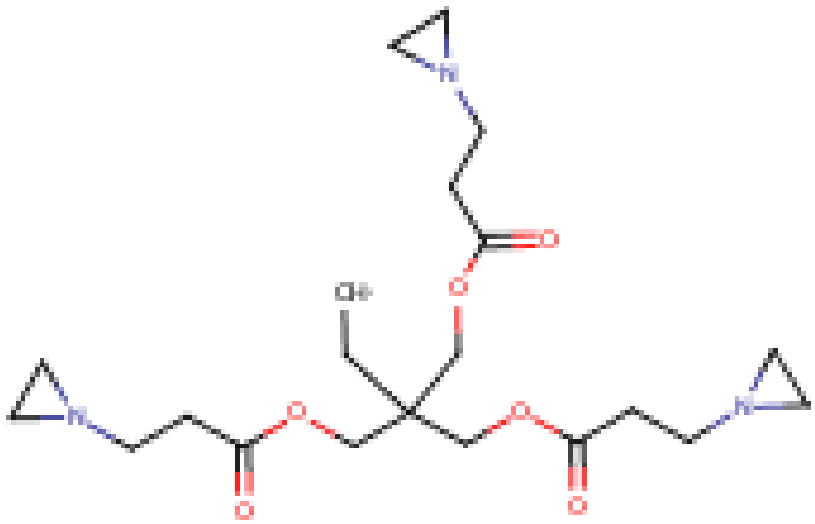
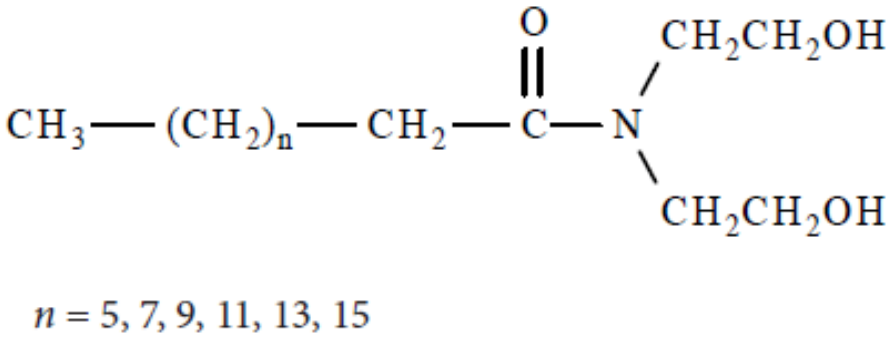
	
Molecular Formula	C21H35N3O6
Molecular Weight	425.52

Chemical Name in the Inventory and Synonyms	**Amides, coco, N,N-bis(hydroxyethyl)** coconut oil fatty acids, diethanolamide n,n-bis(2-hydroxyethyl) coconut oil amide
CAS Number	68603-42-9
Structural Formula	 $n = 5, 7, 9, 11, 13, 15$

Molecular Formula	Unspecified
Molecular Weight	231-371

Chemical Name in the Inventory and Synonyms	**1-Propanol, 2-methoxy-, acetate** 2-methoxy-1-propyl acetate acetic acid, 2-methoxypropyl ester 2-methoxypropyl acetate
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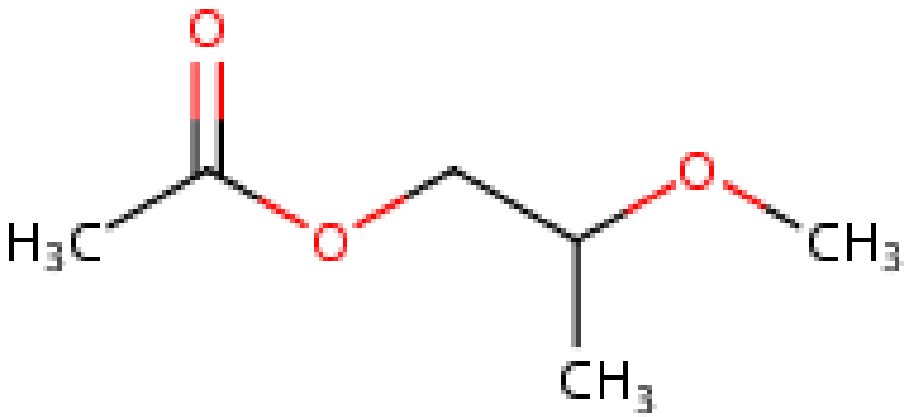
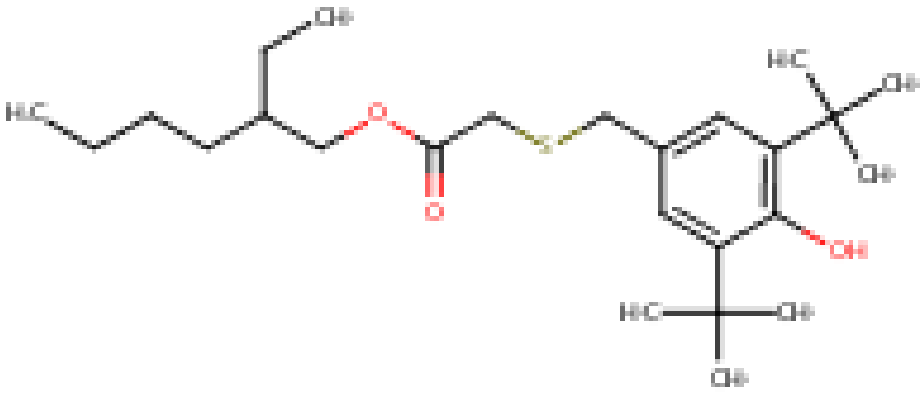
Structural Formula	
Molecular Formula	C6H12O3
Molecular Weight	132.16

Chemical Name in the Inventory and Synonyms	**Phenol, nonyl-, lead(2+) salt** lead bis(nonylphenolate)

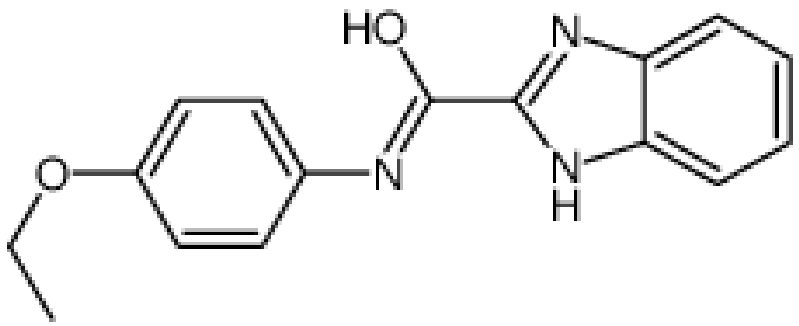
CAS Number	72586-00-6
Structural Formula	
Molecular Formula	C15H24O.1/2Pb
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Acetic acid, [[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]-, 2-ethylhexyl ester** (((3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl)methyl)thio)acetic acid 2-ethylhexyl ester 2-ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]thio]acetate
CAS Number	80387-97-9
Structural Formula	

	
Molecular Formula	C25H42O3S
Molecular Weight	422.67

Chemical Name in the Inventory and Synonyms	**Tar acids, ethylphenol fraction**
CAS Number	84989-03-7
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**1H-Benzimidazole-2-carboxamide, N-(4-ethoxyphenyl)-** 4'-ethoxy-2-benzimidazoleanilide
CAS Number	120187-29-3
Structural Formula	
Molecular Formula	C16H15N3O2
Molecular Weight	281.309

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