Appendices

1. Forms

See the NICNAS web site, for the latest version.

2. Definitions

Definitions in this publication are consistent with those in the Act and relevant NOHSC documents.

The Act

The Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth).

Administrative Appeals Tribunal

The tribunal created by the Administrative Appeals Tribunal Act 1975 (Cwlth).

agricultural chemical

A substance or mixture of substances that is a means of directly or indirectly:

a. destroying, stupefying, inhibiting, attracting or repelling a pest in relation to a plant, a place or a thing; or
b. destroying a plant; or
c. modifying the physiology of a plant so as to alter its natural development, productivity or reproductive capacity; or
d. modifying the effect of another agricultural chemical product;

but does not include:

e. a veterinary chemical product; or
f. a substance or mixture of substances of a kind that is declared by the Regulations not to be an agricultural chemical product for the purposes of the Agricultural and Veterinary Chemicals Code Act 1994 (Cwlth).

article

An object that:

a. is manufactured for use for a particular purpose, being a purpose that requires that the object have a particular shape, surface or design; and
b. is formed to that shape, surface or design during manufacture; and
c. undergoes no change of chemical composition when used for that purpose except as an intrinsic aspect of that use,

but does not include a particle or a fluid (see Appendix 9 - Description of an Article).

Australian Inventory of Chemical Substances (AICS)

AICS is a key tool that lists the chemicals that are available for use in Australia. Some chemicals may only be available for specified/conditional use.

basic information

In relation to a chemical, means all the following information:

a. the name or names by which the chemical is known to the public or is intended by its importer or manufacturer to be so known; and
b. the chemical's general uses; and
c. the precautions and restrictions to be observed in the manufacture, handling, storage, use and disposal of the chemical; and
d. recommendations arising from the assessment of the chemical under this Act that relate to disposing of the chemical and rendering it harmless; and
e. the procedures to be followed in the event of an emergency involving the chemical; and
f. prescribed physical and chemical data about the chemical, not being data that would reveal the chemical's composition (see Regulation 3); and
g. prescribed data relating to the health effects or the environmental effects of the chemical (see Regulation 4).

biopolymer

Means:

a. a polymer directly produced by living or once-living cells or cellular components; or
b. a synthetic equivalent of a polymer referred to in paragraph ; or
c. a derivative or modification of a polymer referred to in paragraph in which the original polymer remains substantially intact.

chargeable person (Tier 2 and Tier 3 registrants)

In relation to a registration year, means:

a. a person who proposes to introduce relevant industrial chemicals in that registration year of a value that equals or exceeds the threshold value if that person:
    i. did not introduce relevant industrial chemicals in the previous financial year; or
    ii. introduced relevant industrial chemicals in the previous financial year of a value less than the threshold value; or

b. a person who proposes to introduce relevant industrial chemicals in that registration year of any value if that person introduced relevant industrial chemicals in the previous financial year of a value that equalled or exceeded the threshold value.

chemical

Includes:

a. a chemical element, including a chemical element contained in a mixture; or
b. a compound or complex of a chemical element, including such a compound or complex contained in a mixture; or
c. a UVCB substance; or
d. a naturally-occurring chemical,

but does not include:

e. an article; or
f. a radioactive chemical; or
g. a mixture.

commercial evaluation

In relation to an industrial chemical, means testing the chemical with a view to ascertaining its potential for commercial application.

commercial evaluation permit

A permit that allows the importation and/or manufacture of a limited, specified amount of a chemical over a specified time for the purpose of commercial evaluation.

cosmetic

has the same meaning as *cosmetic product* has in the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991.

The Trade Practices Consumer Product information Standards (Cosmetics) Regulations (1991) defines a cosmetic product as 'A substance or preparation intended for placement in contact with any external part of the human body, including: the mucous membranes of the oral cavity and the teeth; with a view to: altering the odours of the body; or changing its appearance; or cleansing it; or maintaining it in good condition; or perfuming it; or protecting it.'

NICNAS registration

The application by importers and/or manufacturers in Australia to import relevant industrial chemicals for commercial purposes.

Director

The Director of NICNAS as appointed under section 90 of the Act.

disposal

In relation to a chemical, includes disposal of waste resulting from the manufacture or use of the chemical.

eligible chemical

An industrial chemical that was eligible to be submitted for inclusion on the AICS at a time during the period that began on 1 January 1977 and ended on 16 July 1990.

environment

Includes all aspects of the surroundings of humans, whether affecting them as individuals or in social groupings.

environmental effect

In relation to an industrial chemical, the effect on the environment of the importation, manufacture, handling, storage, use or disposal of the chemical.

excluded use

In relation to a chemical, means:

a. use as an agricultural chemical or a constituent of an agricultural chemical; or
b. use as a veterinary chemical or a constituent of a veterinary chemical; or
c. therapeutic use or use as an ingredient or component in the preparation or manufacture of goods for therapeutic use; or
d. use as food intended for consumption by humans or animals or a constituent of such food; or
e. use as a food additive in food referred to in paragraph .

exempt information

Information about which the Director has given a notification under section 75 of the Act, and includes information for which an application for treatment as exempt information has been made under the Act, but not finalised.

existing chemical

An industrial chemical not defined as a new chemical. This includes naturally occurring chemicals.

factory cost

In relation to the industrial chemicals manufactured by a person, means the total of:

a. the cost of labour involved in the manufacture; and

b. the cost of materials involved in the manufacture other than the cost of any relevant industrial chemical:
    i. that is used as an ingredient in the manufacturing, and
    ii. in respect of which an amount of registration charge has been paid; and
c. the factory overhead expenses

incurred by the person in respect of the manufacture of the first-mentioned chemicals.

food additive

A chemical whose inclusion in food as a food additive is permitted by the Food Standards Code [as defined for the purposes of the *Australia New Zealand Food Authority Act 1991* (Cwlth)].

foreign scheme

A chemicals notification and assessment scheme operating in a foreign country.

full assessment

The assessment of a priority existing chemical that requires that at least one of the matters in paragraphs 51(3) to 51(3)(h) of the Act be taken into account in preparing an assessment report on the chemical.

handling

In relation to a chemical, includes transporting the chemical.

hazardous chemical

a. a chemical that is included in the *List of Designated Substances [NOHSC: 10005] published in April 1999 by the National Occupational Health and Safety Commission; or*
b. a chemical that is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008] published in April *1999 by the National Occupational Health and Safety Commission.*

health effect

In relation to an industrial chemical, the effect on occupational health and safety or on public health of the importation, manufacture, handling, storage, use or disposal of the chemical.

holder

In relation to a permit or an assessment certificate, means a person in respect of whom the permit or certificate is issued.

holder of a confidence

In relation to an industrial chemical, a person who under section 17 of the Act is to be treated as the holder of a confidence about the chemical.

import

In relation to an industrial chemical, means to do an act which constitutes importation of the chemical for the purposes of the *Customs Act 1901* (Cwlth), or would constitute such importation if that Act extended to the external Territories.

importer

In relation to an industrial chemical, a person who imports or proposes to import the chemical.

incidentally-produced chemical

A chemical that is produced as a result of:

a. the exposure of another chemical to light, heat or other environmental conditions in the course of handling or storage; or
b. the occurrence of a chemical reaction during the manufacture or use of another chemical,

but not a chemical whose production has commercial value for a person manufacturing, handling, storing or using that other chemical.

industrial chemical

A chemical that has an industrial use, whether or not it also has an excluded use.

Interim Notification Scheme

The voluntary notification and assessment scheme for new industrial chemicals conducted by the former Department of the Arts, Sports, the Environment, Tourism and Territories before the commencement of NICNAS.

introduction

In relation to an industrial chemical, the importation or manufacture in Australia of the chemical.

introduction permit

A permit which allows the introduction of a new industrial chemical under section 30 of the Act before the assessment report is completed.

label

A set of information, on a container, which identifies a substance together with sufficient information so that it can be used safely. A label should contain the minimum information described in the *NOHSC National Code of Practice for the Labelling of Workplace Substances*, Australian Government Publishing Service, Canberra, 1994.

listed industrial chemical

An industrial chemical whose particulars are included in the AICS.

low volume chemical

An industrial chemical which is imported and/or manufactured in quantities which do not exceed 100 kg/year and for which a low volume permit is in force.

low volume permit

A permit which allows the importation and/or manufacture of an industrial chemical in volumes not exceeding 100 kg/year nationwide, under specified conditions.

manufacturer

In relation to an industrial chemical, a person who manufactures or proposes to manufacture the chemical in Australia.

Material Safety Data Sheet (MSDS)

In relation to a chemical or to a product or substance containing a chemical, a document that is prepared in accordance with the *NOHSC National Code of Practice for the Preparation of Material Safety Data Sheets*, Australian Government Publishing Service, Canberra, 1994.

matters to be taken into account

Matters that may be considered when assessing a priority existing chemical [subsection 51(3) of the Act]. They are:

a. the properties of the chemical;
b. any use to which the chemical is intended to be, or is reasonably likely to be, put;
c. any adverse effects on the environment or persons which the chemical has the intrinsic capacity to cause;
d. the extent to which the environment, persons in a particular occupation or the public will be exposed to the chemical;

e. any risk to the health or safety of persons who, because of their occupation, are engaged, or likely to be engaged, in the manufacture, handling, storage, use or disposal of the chemical;

f. any risk to the health or safety of likely consumers handling or using the chemical or any product containing the chemical;

g. any risk to the environment arising from the use of the chemical or from the discharge of waste products resulting from the manufacture or use of the chemical;

h. the extent to which any risk referred to in is capable of being reduced by compliance with:

    i. appropriate procedures relating to the manufacture, handling, storage, use or disposal of the chemical, or

    ii. special requirements in the packaging or labelling of the chemical; or

    iii. procedures relating to the control of, or the discharge into the environment of, the chemical or waste products resulting from the manufacture or use of the chemical; and

i. any other relevant information available to the Director.

Minister

The Minister for Health and Ageing

mixture

A physical combination of chemicals resulting from deliberate mixing of those chemicals or from a chemical reaction, but not including a UVCB substance.

monomer

A chemical, the molecules of which are, capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reactions used for a particular process of polymer formation.

naturally-occurring chemical

a. an unprocessed chemical occurring in a natural environment; or

b. a chemical occurring in a natural environment, being a substance that is extracted by:

    i. manual, mechanical or gravitational means, or

    ii. dissolution in water, or

    iii. flotation, or

    iv. a process of heating for the sole purpose of removing uncombined water,

    without chemical change in the substance.

new industrial chemical

(a) either:

(i) if the chemical is a listed industrial chemical whose introduction is subject to a condition of use under section 13—the chemical but only to the extent that the manufacturer or importer of the chemical introduces, or proposes to introduce, the chemical for any other use; or
(ii) otherwise—an industrial chemical that is not a listed industrial chemical; and

(b) in the case of a synthetic polymer—a chemical that is a new synthetic polymer;

but does not include the following:

(c) a reaction intermediate;
(d) an incidentally-produced chemical.

new monomer

A monomer not listed in the monomer section of the AICS.

new synthetic polymer

Means:

a. a polymer that includes a combination of monomers and other reactive components, each representing at least 2% by weight, being a combination not listed in the AICS; or
b. a polymer of whose weight at least 2% is attributable to a monomer or other reactive component that is not listed in the AICS as a component of a synthetic polymer.

non-hazardous chemical

a chemical in respect of which the following conditions are met:

(a) the chemical is not a hazardous chemical;
(b) the chemical is not a dangerous good;
(c) the prescribed criteria relating to the environmental effect of the chemical have been met;
(d) any other prescribed conditions have been met;
(e) the introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment.

The Director must take account of the following matters in deciding whether he or she is satisfied that the condition referred to in paragraph (e) of the definition of non-hazardous chemical is met:

(a) the proposed nature of the use of the chemical;
(b) the extent of the proposed use of the chemical;
(c) the effect of the chemical on the environment;
(d) the effect of the chemical on occupational health and safety and public health;
(e) the structure and activity of the chemical;
(f) whether, in Australia or overseas, the chemical is the subject of:
    (i) investigations initiated by a person because of concerns about a possible adverse effect on occupational health and safety, public health or the environment; or
    (ii) action taken by a person to control the use of, or access to, the chemical;
(g) any other prescribed matter.

Poisons scheduling

Chemicals that are likely to be hazardous to the public may be referred to the National Drugs and Poisons Scheduling Committee (NDPSC) for consideration. If a chemical is listed in a schedule of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), certain signal headings, warning statements and/or safety directions must be placed on the product label.

polymer

A chemical:

a. consisting of molecules that are:
    i. characterised by the sequence of one or more types of monomer units, and
    ii. distributed over a range of molecular weights whose differences in the molecular weight are primarily attributable to differences in the number of monomer units; and
b. comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; and
c. comprising less than a simple weight majority of molecules of the same molecular weight.

polymer of low concern (PLC)

a polymer that:

(a) either:

(i) has a number average molecular weight, as defined by the regulations, that is greater than 1,000; or
(ii) has a number average molecular weight, as defined by the regulations, that is less than or equal to 1,000, and has such other characteristics as are prescribed by the regulations; and

(b) has a low charge density, as so defined; and
(c) is not a hazardous chemical; and
(d) does not dissociate readily, as so defined; and
(e) under the conditions in which it is used is stable, as so defined; and
(f) has such other characteristics as are prescribed by the regulations.

preliminary assessment

The assessment of a priority existing chemical that requires that at least one of the matters in paragraphs 51(3) to 51(3) of the Act be taken into account in preparing an assessment report on the chemical.

priority existing chemical (PEC)

An industrial chemical in respect of which a declaration under section 51 of the Act is in force.

radioactive chemical

A chemical having a specific activity greater than 35 becquerels/g.

reaction intermediate

A substance that:

a. is produced in the course of a chemical reaction; and
b. has a transient existence; and
c. does not become a major component of the reaction mixture; and
d. is not removed from the reaction system.

Register

The Register of Industrial Chemical Introducers, a list of registered importers and manufacturers of relevant industrial chemicals

registration charge

A charge imposed on the registration of a chargeable person (ie above $500,000 total value of relevant industrial chemicals introduced):

a. so far as it is a duty of customs - by the Industrial Chemicals (Registration Charge - Customs) Act 1997 (Cwlth); and

b. so far as it is a duty of excise - by the Industrial Chemicals (Registration Charge - Excise) Act 1997 (Cwlth); and

c. so far as it is neither a duty of customs nor a duty of excise - by the Industrial Chemicals (Registration Charge - General) Act 1997 (Cwlth).

registration year

Starts on 1st September and finishes on 31st August the following year.

relevant industrial chemical

For the purposes of NICNAS registration, an industrial chemical:

a. that is not intended for an excluded use; and

b. that is not:

   i. a naturally-occurring chemical, or

   ii. biological material, or

   iii. an incidentally-produced chemical, or

   iv. a reaction intermediate.

sequence

In relation to a polymer molecule, means a continuous string of monomer units within the molecule that are covalently bound to one another and are uninterrupted by units other than monomer units.

site-limited chemical

A chemical which is confined to its site of manufacture solely for the purposes of further manufacture.

supplementary information statement

A statement containing, in relation to the application for an extension of an original assessment certificate to cover other introducers:

a. if there has been a significant variation in matters affecting occupational, environmental or public exposure as set out in the notification statement that accompanied the application for the original certificate or as set out in any additional information given under section 27 or section 28 of the Act in respect of the application for the original certificate, details of the variation; and

b. any new information available to the applicant about the health and environmental effects of the chemical; and

c. confirmation that the person has access to a copy of the full public assessment report about the chemical.

synthetic polymer

Any polymer other than a biopolymer.

therapeutic use

Use in, or in connection with:

a. preventing, diagnosing, curing or alleviating diseases, ailments, defects or injuries in humans; or
b. influencing, inhibiting or modifying physiological processes in humans; or
c. testing the susceptibility of humans to diseases or ailments,

and, without limiting this, includes use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics.

Cosmetics or chemicals with therapeutic claims must be entered on the Australian Register of Therapeutic Goods, through the Therapeutic Goods Administration.

threshold value

In relation to relevant industrial chemicals introduced by a person, means $500,000.

trade name product

A chemical included in the section of the AICS known as Section VIII-AICS Trade Names Annex.

UVCB substance

Means:

a. a chemical of unknown or variable composition; or
b. a complex product of a chemical reaction; or
c. biological material, other than a whole animal or a whole plant.

Value of relevant industrial chemicals imported

by a person during a particular period (whether a financial year or a registration year), means the amount, worked out to the nearest whole dollar, using the formula:

a. all of those relevant industrial chemicals; plus
b. the cost of the insurance and freight relating to those chemicals; plus
c. the customs duty payable on those chemicals.

Value of relevant industrial chemicals introduced

by a person during a particular period (whether a financial year or a registration year), means the sum of:

a. the value (if any) of the relevant industrial chemicals imported by that person during that period; and
b. the value (if any) of the relevant industrial chemicals manufactured by that person during that period.

Value of relevant industrial chemicals manufactured

by a person during a particular period (whether a financial year or a registration year), means the factory cost of manufacturing the industrial chemicals by the person during that period.

veterinary chemical product

A substance or mixture of substances that is:

a. a means of directly or indirectly:
    i. preventing, diagnosing, curing or alleviating a disease or condition in an animal or an infestation of an animal by a pest in relation to that animal; or
    ii. curing or alleviating an injury suffered by an animal; or
    iii. modifying the physiology of an animal:
        - so as to alter its natural development, productivity or reproductive capacity, or
        - so as to make it more manageable; or
b. prepared by a pharmacist or veterinary surgeon, in the course of the practice of his or her profession, to deal with a particular condition of a particular animal in a particular instance; but does not include a substance or mixture of substances of a kind that is declared by the Regulations made under Agricultural and Veterinary Chemicals Code Act 1994 (Cwlth) not to be a veterinary chemical product for the purposes of that Act.

3. Abbreviations

AAT Administrative Appeals Tribunal

ACS American Chemical Society

the Act Industrial Chemicals (Notification and Assessment) Act 1989

AGPS Australian Government Publishing Service

AICS Australian Inventory of Chemical Substances

CAD Chemical Assessment Division

CEC Commercial Evaluation Chemical (permit)

CFC Chlorofluorocarbon

the Director Director, Chemicals Notification and Assessment

EINECS European Inventory of Existing Chemical Substances

EIP Early Introduction Permit (for non-hazardous chemicals)

EOP **Controlled Use (Export Only) Permit**

GLP Good Laboratory Practice

IUPAC International Union for Pure and Applied Chemistry

$\mathbf{Log\ P_{ow}}$ n-octanol/water partition coefficient

LC_{50} Median lethal concentration

LD50 Median lethal dose

LOAEL Lowest observable adverse effect level

LVC Low Volume Chemical (permit)

mg/L milligrams per litre

the Minister Minister for Health and Ageing

MOE Margin of exposure

MSDS Material Safety Data Sheet

NAMW Number-average molecular weight

NATA National Association of Testing Authorities

NCI National Chemicals Inventories

NICNAS National Industrial Chemicals Notification and Assessment Scheme

NOAEL No observable adverse effect level

NOHSC National Occupational Health and Safety Commission

OECD Organisation for Economic Cooperation and Development

PEC Priority Existing Chemical

PLC Polymer of Low Concern

ppm parts per million

SORO Submit Once - Review Once

TGA Therapeutic Goods Administration

TSCA Toxic Substances Control Act (USA)

mm micrometre

US EPA United States Environmental Protection Agency

UVCB Chemical of unknown or variable composition, complex reaction products or biological material

4. NICNAS Fees and Charges

See the NICNAS web site for a list of New Chemicals and Registration fees and charges.

5. The *Chemical Gazette*

The *Chemical Gazette* is a special edition of the existing periodic series of the *Commonwealth Government Gazette*. It is published electronically on the first Tuesday of each month, on the NICNAS website at www.nicnas.gov.au/publications/#gazette

Occasionally, additional editions of the *Chemical Gazette* are published.

Operational information relating to NICNAS is published in the *Chemical Gazette* by way of notice or declaration by the Minister or the Director. Occasionally, information relating to other matters concerning industrial chemicals, for example, exposure standards, is published in the *Chemical Gazette* (see further below).

Companies, organisations, government departments and individuals may subscribe to an email alert for the *Chemical Gazette*.

Printed copies are available by contacting NICNAS on: 02 9577 8800.

The *Chemical Gazette* can be inspected during business hours, free of charge, at:
NICNAS
334-336 Illawarra Rd
Marrickville NSW 2204

Subscribers to the *Chemical Gazette* include a number of State Libraries and other libraries where the *Chemical Gazette* can be inspected.

The notices and/or declarations relating to NICNAS which are important and must be published in the *Chemical Gazette*.

1. Summary Assessment Report for New Chemicals

Under the Act, a summary report for a new chemical consists of:

- the name of the chemical;
- the name of each applicant;
- the address where copies of the final assessment report can be obtained by members of the public; and
- any other prescribed information.

Regulation 8 prescribes the information to be included in the summary report as follows:

a. a statement of the type of assessment carried out, that is, whether a Standard Assessment, Limited or PLC Assessment;
b. the chemical names of hazardous constituents of the chemical;

c. a summary of the occupational health and safety, public health and environmental matters contained in the assessment report;

d. the intended use of the chemical; and

e. any recommendations contained in the assessment report in relation to the chemical.

2. A Notice Calling for Information about an Existing Chemical

A notice will call for information about an existing chemical when the Director is considering whether to recommend declaration of the chemical as a PEC. The Director will request:

- specified information about a particular industrial chemical, for example, information about its health and environmental effects; and/or
- the names and quantities of industrial chemicals used by persons for a specified purpose in a specified period; and/or
- the names of industrial chemicals that are introduced by persons in specified quantities in a specified period, for example, the volumes manufactured over the previous five years.

3. Declaration of a PEC

The decision by the Minister to declare a chemical or group of chemicals as PEC(s) is announced by publication of a notice in the *Chemical Gazette*. The notice will specify, in respect of each chemical to which the notice relates:

- whether declaration applies to the chemical generally or specifically, for example, only to specific uses of the chemical;
- whether the assessment is to be a preliminary assessment or a full assessment;
- matters to be taken into account in the assessment;
- information to accompany any application for the assessment; and
- if the notice relates to more than one chemical, whether the declared chemicals are to be assessed together.

4. A Summary Assessment Report on a PEC

Under the Act, a summary report consists of:

- the name of the chemical;
- the name of each applicant;
- the address where copies of the final assessment report can be obtained by members of the public; and
- any other prescribed information.

Currently, there are no Regulations which prescribe information to be included in a summary report of a PEC.

5. Other notices and/or declarations relating to NICNAS which must be published in the Chemical Gazette.

Section in the Act	Notice or Declaration
14(1)	Inclusion of a new chemical in the AICS five years after the giving of an assessment certificate (other than an extension of an original certificate).
20(a)	Addition of information concerning chemicals added to the AICS before 17 July 1990 or between 1 March 1993 and 17 July 1993.
20(aa)	Addition of extra information about industrial chemicals already in the AICS that was obtained under section 20AB (details of trade name products).
20(b)	Correction of an error in the AICS (except the wrong inclusion of a chemical in the AICS).
20AA(1)	Removal of a chemical that has been wrongly included in the AICS.
20AB	Request for identity of chemicals making up trade name products.
21AB(2)	List of chemicals introduced under an exemption.
21J	Issue of commercial evaluation permit.
21Y	Issue of low volume permit.
21ZA(2)	List of chemicals for which a low volume permit has been issued.
30(2)	Issue of a permit to import a chemical before assessment is completed.
30A	Grant of a permit for early introduction of a non-hazardous chemical.
40(2)	Application for variation of a full public report.
40(7)	A decision on an application for variation of a full public report.
40G	Publication of a summary report, incorporating modifications.
41(2)	Equivalence of a State or Territory scheme.
41(4)	Revocation of a State or Territory scheme equivalence.
43(2)	Approval of a foreign scheme.
43(6)	Foreign scheme no longer approved.
50A(4)	A notice stating where a summary of information given under section 48 of the Act can be obtained.
54(3)	Lists of chemicals that are PECs and chemicals that have been PECs.
58(1)	A notice to seek information for assessment of a PEC.
60E(1)	A notice for variation of draft PEC assessment report.

60E(6)	A notice of a decision concerning a request for variation of draft PEC assessment report.
61(2)	Prohibition of an activity involving a PEC until assessment is completed.
65(1)	A notice to require secondary notification.
68(4)	by reference to 38 A summary assessment report after secondary notification.
69(1)	A notice to provide information for secondary notification.
71(3)	Lists of chemicals that require secondary notification or that have required, but no longer require, secondary notification.
72	A declaration that a chemical is no longer subject to secondary notification.
74(2)	List of chemicals for which assessment certificates are in force.
105(1)	Amendment of the Schedule to the Act.
106(2)	Notice requiring persons importing or exporting a particular chemical named under a specified international agreement to give information in the approved form about movements of the chemical into or out of Australia.

6. Confidentiality

EXEMPT INFORMATION

For all notification categories, including submission of additional information, claims can be made for certain data items to be regarded as exempt from publication. A notifier may consider that certain data items required in a notification statement may be commercially harmful if disclosed. The notifier must identify those data items together with full reasons substantiating the claim for exemption [subsection 75(1) of the Act].

In notification statements submitted to NICNAS, items of information subject to a claim for exemption must be clearly identified so that it is obvious to the assessor of the chemical.

Applications for exemption cannot be granted for information that falls within the scope of 'basic information' [subsection 75(2) of the Act]. The definition of basic information can be found in Appendix 2 - Definitions.

Applications for exempt information can be made for information submitted in connection with:

a. an application for a Low Volume Chemical Permit [subsection 21ZB(1) of the Act];
b. written notice to the Director of a change in circumstances or of new information, as required under the conditions of the Low Volume Chemical Permit [subsection 21ZB(2) of the Act];
c. an application for a Commercial Evaluation Permit [section 21P of the Act];
d. the notification of a new chemical (including a polymer of low concern) [section 25 of the Act];
e. the provision of further information to assist in the assessment of a new chemical [section 29 of the Act];
f. an application for early introduction of a non-hazardous chemical [section 30A of the Act];
g. an application for extension of an original assessment certificate to cover other importers or manufacturers [section 40D of the Act];
h. the notification of a new chemical which has been notified and assessed under notification law in force in a State or Territory [section 42 of the Act];
i. the notification of a new chemical which has been notified and assessed under an approved foreign scheme [section 45 of the Act];
j. the provision of information for a prospective Priority Existing Chemical (PEC) [section 50 of the Act];
k. the provision of information for a PEC [section 60 of the Act];
l. the secondary notification of a chemical [section 66 of the Act]; and

m. information given to inspectors [section 89 of the Act].

Applications should be made on Form 3 and be accompanied by the required fee ($588).

In all applications for exemption from publication, the Director weighs the public interest in publishing the information against the potential commercial harm to the notifier.

If the Director decides that the claim is justified, then those data items will be classed as exempt from publication. On the other hand, if the claim is rejected, then the Director will notify the applicant, who may appeal to the Administrative Appeals Tribunal for a review of the decision. In all cases, the applicant will receive written notice of the Director's decision.

SECURITY OF INFORMATION DURING ASSESSMENT

The dossiers of information that comprise the notification statement or permit application are only available to staff within the government agencies conducting the assessment. If assessments were to be done under contract, confidentiality agreements would be signed.

PUBLIC ACCESS TO INFORMATION

In the case of chemicals for which the summary report (or the full public report for a polymer of low concern) has been published in the *Chemical Gazette*, the full public report of the chemical is available for public inspection, from NICNAS.

DISCLOSURE OF EXEMPT INFORMATION IN SPECIAL CIRCUMSTANCES

In special circumstances, the Director may disclose certain items of exempt information about a chemical [section 79 of the Act]. This can be done:

- with the consent of the notifier and, in the case of information given under an approved foreign scheme, the corresponding foreign government; or
- without consent, in an emergency where the Director must be satisfied that any delay in disclosure could endanger the occupational health and safety of a person, public health or the environment.

In both situations, the Director must be satisfied that:

- the disclosure is to assist in the protection of occupational health and safety, public health or the environment; and
- the public interest in disclosing the exempt information outweighs the commercial interest of the applicant.

In all cases of disclosure of exempt information, the Director must give written notice to the applicant and, if necessary, the relevant foreign government [section 80 of the Act].

7. Summary of the Act

The following table provides a summary of which sections of the Act refer to the key kinds of application outlined in this book.

Exempt Chemical for Site-Limited R&D	Paragraph 21(3)(b)
Exempt Chemical for Volume-Limited R&D	Paragraph 21(6)(a)
Exempt Small Amount Chemical (cosmetic and non-cosmetic)	Subsection 21(4)
Exempt Chemical (other)	Paragraph 21(6)(b)(c)
Secondary Notification	Section 65
NICNAS Registration	Section 80
New chemicals assessments	
Commercial Evaluation Chemical	Sections 21B
Low Volume Chemical	Sections 21S
Polymers of Low Concern	Section 24A
Limited Notifications	Subsection 23
Standard Notifications	Subsection 23
Extension of Original Assessment Certificate	Section 40A
Other types of application and assessment	
Provision of a Draft Assessment Report	Regulation 15(5)
Self Assessment	Section 23A
Section 30A Early Introduction Permit	Section 30A
Section 30 Permit	Section 30
Provision of an Approved Foreign Report	Sections 44(5)
Variation of Schedule Requirements	Section 24
Exempt Information	Sections 21P, 21ZB, 25, 29, 30A, 40D, 42, 45, 60,66, 75 and 89
Variation of Assessment Report	Section 37
Variation of Full Assessment Report	Section 40
Variation of Draft PEC Assessment Report	Section 60
Listing on Confidential Section of the AICS	Sub-section 14(3)

Re-Listing on Confidential Section of the AICS	Section 19
Status of Holder of Confidence	Section 17
Priority Existing Chemical Assessment	Sub-section 55(1) and 55(1A)

8. Appeals

Many features of NICNAS depend on decisions made by the Minister for Health and Ageing or the by the Director.

The decisions listed below made by the Minister or Director under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) are appealable to the Administrative Appeals Tribunal.

Decision Under Section	**Made By**	**Subject**
14(4)	Director	A decision to include a chemical in the confidential section of the AICS five years after the giving of an assessment certificate.
17(4)	Director	A decision on whether to treat an applicant as the holder of a confidence about a chemical.
18A(2), 19(9)	Director	A decision to reject a person's reasons against the transference of a chemical from the confidential to the non-confidential section of the AICS.
20AA(6)	Director	A decision to remove a chemical wrongly included in the AICS.
20E(3)	Director	A decision that an application for listing an eligible chemical should be refused.
21H(1)	Director	A decision to refuse the application for a Commercial Evaluation Permit on the grounds that the quantity requested is not reasonably needed.
21H(2)	Director	A decision to refuse the application for a Commercial Evaluation Permit on the grounds that the period requested exceeds one year.
21L	Director	The decision to use specified conditions in a Commercial Evaluation Permit.
21U(3)	Director	A decision to refuse an application for a Low Volume Chemical Permit.
21W(3)	Director	A decision to grant a Low Volume Chemical Permit subject to specified conditions.
21W(4)	Director	A decision to impose further conditions on a Low Volume Chemical Permit or to revoke or vary conditions already imposed.
21W(6)	Director	A decision to cancel a Low Volume Chemical Permit.
24(1)	Director	A decision on waiving the requirements of the notification statement in the case of a chemical listed on a recognised international inventory of chemicals.
24(3)	Director	A decision allowing the variation of information normally

		required by the Schedule in the notification statement.
24(4)	Director	A decision on waiving the requirements of the notification statement where particular matters specified in the Schedule are irrelevant, or unnecessary, for the assessment of the chemical.
27(1)	Director	A decision to request further information about a matter relating to a requirement in the Schedule.
27(2)	Director	A decision to request further information which is additional to the requirement in the Schedule, and which is necessary to complete an assessment.
27(4)	Director	A decision that a notifier has complied with a notice to give additional information for the assessment of the chemical.
28(2)	Director	A decision to suspend consideration of the notification until the notifier supplies further new information relevant to the adequate assessment of the chemical.
30(1)	Minister	A decision to grant to a notifier a permit to introduce a chemical before the assessment certificate is given.
30(3)	Minister	A decision that information be published relating to a chemical which is subject to a permit.
30(5)	Minister	A decision on conditions specified in a permit allowing the introduction of a chemical before an assessment certificate is given.
30A(3)	Director	A decision not to grant an Early Introduction Permit.
30C(1)	Director	A decision to revoke an Early Introduction Permit.
31(3)	Minister	A decision to grant an additional 90 days in which to complete a thorough assessment and report.
37(2)(b)	Director	A decision to grant an additional 90 days in which to complete a thorough assessment and report.
40(6)	Director	A decision on varying a full public report as requested.
40F(3)(b)	Director	A decision to refuse to vary an assessment report as requested by the notifier.
44(1)(d)	Director	A decision on whether the assessment under an approved foreign scheme is relevant to Australia.
44(2)(b)	Director	A decision on adoption of a report, other information and documents given under an approved foreign scheme.
44(5)	Minister	A decision to grant an additional 90 days to complete an assessment report based on information provided under an approved foreign scheme.
51(1)	Minister	A decision to declare a PEC.
52	Director	A decision that a chemical was wrongly included in the AICS.
57(6)	Minister	A decision to extend the period of six months to 12 months

		for completion of a thorough assessment report for a PEC.
58(3)	Director	A decision concerning information to be given for the assessment of a PEC.
60E(5)	Director	A decision to refuse to vary a draft assessment report.
61(2)	Minister	A decision to prohibit a particular activity involving a declared PEC.
65(2)	Director	A decision to require a secondary notification.
67(1)	Minister	A decision to suspend an assessment certificate or introduction permit, or to prohibit continuing introduction of a chemical, on failure to comply with a secondary notification requirement.
68(6)	Minister	A decision to grant an additional period of up to 90 days in which to complete a thorough assessment and report for a chemical subject to secondary notification.
69(1)	Director	A decision to require persons who are not required to give a secondary notification of a chemical to supply information to assist in the thorough assessment of that chemical.
73(6)	Director	A decision to revoke an assessment certificate due to not being informed of a change in the holder of the certificate.
75(1)	Director	A decision to allow specific items of information to be exempt from publication.
79(a)	Director	A decision to disclose exempt information in the public interest.
80G(2)	Director	A decision to refuse an application for registration.
80K(5)	Director	A decision to refuse an application for renewal of registration.
80QA(1)	Director	A decision on assessment of a registration charge.
80QC(3)	Director	A decision in response to a reconsideration or review of an assessment.

To have a decision reviewed, you must write to the Administrative Appeals Tribunal setting out the decision to be reviewed and the reasons for requesting the review. For more information contact:

Principal Registrar
Administrative Appeals Tribunal
Level 4
Commonwealth Law Courts
Cnr Tank Street and North Quay
BRISBANE QLD 4000
Phone: (07) 3361 3000

9. Description of an Article

An item is an article [subsection 6 (2) of the Act] if it satisfies each of the following criteria:

a. An article is a manufactured item which is deliberately formed to a specific shape or design during manufacture.

b. An article has an end use function wholly or partly dependent on its shape or design.

   A solid substance which is manufactured or imported, formed to a particular shape, and which undergoes only further limited processing into a finished article, is considered to be itself an article. 'Limited processing' covers cutting, bending, surface chemical reaction, etc, but excludes processes such as pulverising, melting, pelletising, etc, where the formed shape is completely destroyed. Other items to be regarded as articles are polymer blocks, sheets, films and filaments.

c. An article undergoes no change of chemical composition during end use, except as an intrinsic part of that end use (items such as photographic film in which the chemical composition is altered as a result of use are examples of articles where the change of chemical composition is intrinsic to the intended use).

Fluids and particles are not normally considered to be articles regardless of shape or design. 'Fluids' refers to liquids (including suspensions and solutions) and gases. 'Particles' refers to any solid chemical substance or mixture of substances that is in discrete aggregations of unspecified size, which may take the form of dust, powders, dispersions, granules, lumps and flakes. Substances in a form in which the bulk properties and usefulness of the substance are dependent in part on the particle's shape are not regarded as articles.

Fluids or particles contained within a vessel serving simply to store, transport and dispense its content are considered to be chemical substances. In general, all fluids and particles, such as cleaners, solvents, fuels, glues, sealants, inks, paints and other coatings, are chemical substances if they are merely contained in some form of packaging.

The contents of containers, such as bottles, jars, cans, aerosol cans, drums, barrels, tanks, bags, tubes and sachets are chemical substances or mixtures of chemical substances.

However, for items where it is intended that the fluid or particulate contents remain in their container during normal use of the item, and that they serve an intrinsic part of the end purpose of the item, then the fluids and particles are considered to be an integral part of the article. Thus, a motor lubricant in a bottle, drum or aerosol can is a chemical substance (or a mixture of chemical substances) should be notified, but a lubricant in a motor vehicle or other piece of mechanical equipment is part of an article and should not be notified.

If a fluid or particulate substance is not considered to be an integral part of an article, the chemical substance needs to be notified, for example, inks and toners in copier, printer cartridges and typewriter ribbons.

In practice, it will only be for imported items containing fluids and particles that a decision needs to be made whether the fluid or particles constitute a chemical substance (or a constituent of a mixture or chemical substances) and therefore should be notified, or whether the fluid or particle is to be considered as an integral part of an article. The constituents of items that are locally manufactured will be present as individual chemical entities prior to packaging or assembly and therefore must be notified.

In some manufacturing processes, the chemical substance synthesised is immediately subject to physical processing to form it into an article, for example, in a process involving manufacture of a polymer resin followed by extrusion into a plastic bottle. For manufacturing processes of this type carried out in Australia, the chemical ingredients used in the manufacturing process are considered as industrial chemicals and NICNAS should be notified. However, the final resultant product being, the plastic bottle is considered to be an article.

10. Polymers of Low Concern Guidance

The material in this appendix offers greater detail on the criteria for nominating polymers of low concern (PLCs) and should be read with reference to Chapter 3 – *Which notification category?*

1. Reactive Functional Groups

The number of reactive functional groups (RFGs) in a polymer is important in determining whether it meets the new criteria. RFGs must be taken into account when considering the low molecular weight species of a polymer (see section 3 below) and in determining whether cationic polymers are PLCs (section 4 below).

A *reactive functional group* is defined as an atom or associated group of atoms in a chemical substance that is intended or can be reasonably anticipated to undergo facile chemical reaction.

RFGs are divided into three categories, *low, moderate and high concern*, to reflect the comparative reactivity of each functional group (see Table 1 below). The criterion for categorisation is more qualitative than quantitative. It is based on the presence of chemically or metabolically reactive or toxic (including ecotoxic) functional groups within the polymer. RFGs in the low concern category generally lack reactivity, or have low adverse reactivity, in a biological setting.

For human health hazard, RFGs are placed in the high concern category if there is evidence of adverse effects in humans or there is conclusive evidence of severe effects in animals. RFGs are placed in the moderate concern category if there is evidence of reactivity in a biological setting but the effects are not severe enough to place the functional group in the high concern category. Sufficient information should be available to be confident of categorisation as moderate concern. Where the reasoning behind categorisation is not clear, RFGs default to the high concern category until sufficient information becomes available. Similarly, RFGs not categorised default to the high concern category until sufficient information becomes available.

A number of functional groups are not considered to be RFGs. These include carboxylic esters, ethers, amides, urethanes, sulfones and the nitro group. This is provisional on the functional group not being modified to enhance its reactivity, eg. the dinitrophenyl ester of a carboxylic acid.

Amines are taken to be high concern RFGs. Polymers containing these RFGs are generally considered under cationic polymers.

RFGs in their respective categories are listed in the Regulations under the Act. The list will be updated when necessary by notice in the *Chemical Gazette*.

Table 1 Reactive Functional Group Categories

Low concern	Moderate concern	High concern
Carboxylic acid		Pendant acrylates and methacrylates
Aliphatic hydroxyl		Aziridines
Unconjugated olefinic considered 'ordinary'		Carbodiimides
Butenedioic acid		Halosilanes, Hydrosilanes, Alkoxysilanes[1]
Conjugated olefinic groups contained in naturally occurring fats, oils and carboxylic acids	Conjugated olefinic groups <u>not</u> contained in naturally occurring fats, oils and carboxylic acids	Hydrazines
		Isocyanates, isothio-cyanates
Blocked isocyanates (including ketoxime-blocked isocyanates)		Alpha or beta lactones
		Vinyl sulfones or analogous compounds
Thiols		*Acid halides
Unconjugated nitriles		*Acid anhydrides
		*Aldehydes
Halogens (except reactive halogen-containing groups such as benzylic or allylic halides)		*Hemiacetals
		*Methylolamides, -amines or –ureas
		*Cyanates
		*Epoxides
		*Unsubstituted positions ortho and para to phenolic hydroxyl
		*Allyl ethers
		*Imines (ketimines and

		aldimines) Partially-hydrolysed acrylamides Other reactive functional groups not in the low or moderate concern groups

[1]Alkoxysilanes with alkoxy groups greater than C2 are in Moderate Concern in US
* Denotes group is in Moderate Concern category under United States Environmental Protection Agency (US EPA) and for which information to support categorisation as 'Moderate' is unavailable to NICNAS. It is proposed that these reactive functional groups default to the high concern category pending provision of data and information by industry and/or other parties to NICNAS.

2. Functional Group Equivalent Weight (FGEW)

The concept of functional group equivalent weight (FGEW) is used to assist in determining whether the RFGs in a polymer are substantially diluted by polymeric material to allow the polymer to be a PLC.
The FGEW of a polymer is defined as the ratio of NAMW to the number of functional groups in the polymer. It is the weight of polymer that contains one formula weight of the functional group.
Low concentrations of RFGs are permissible in the polymer molecules, but the quantity is restricted by the reactivity of the particular functional group(s) in question. Guidance in calculating FGEW is provided at the end of this appendix.

3. Molecular Weight

Unless a new polymer is a polyester manufactured from the list of allowable reactants, the number average molecular weight (NAMW) of a PLC must be 1000 or greater. Under the new criteria, a PLC must also meet the low molecular weight criteria. These are described below. (Polyesters are discussed in section 9 below.)

Low Molecular Weight Species
For the purposes of the Act, the low molecular weight species in a polymer includes the oligomer content with NAMW less than 1000, where *oligomer* is defined as the low molecular weight species derived from the polymerisation reaction.

This definition is consistent with that used by the US EPA in their polymer exemption criteria. The definition means that residual monomers and other reactants are not included when determining the content of low molecular weight species.

For polymers with NAMW between 1000 and 10000, the allowable low molecular weight species (MW below 1000 and 500) has been increased from 5% and 2% respectively to 25% and 10% provided that the polymer contains:
only low concern reactive functional groups (RFGs); or
moderate concern RFGs with a combined FGEW of 1000 or more (provided no high concern groups are present); or
high concern RFGs with a combined FGEW of 5000 or more (the calculated FGEW must include moderate concern groups if present).

Example: Consider a polymer of NAMW 8000, 15% < MW 1000, 6% < MW 500 and 2 isocyanate groups at the ends of the polymer backbone. Is the polymer a PLC? First, the polymer meets the MW criteria. The FGEW is 8000/2 = 4000. As the RFGs are in the high concern category, the polymer does not meet the criterion as the FGEW is below 5000. Therefore, the polymer is not a PLC.

For polymers with NAMW 10000 or greater, the allowable low molecular weight species (MW below 1000 and 500) for these polymers will remain at 5% and 2% respectively. However, the restriction on RFGs has been removed, that is, there is no limit on the number of RFGs in a polymer with NAMW > 10000.

Example: Consider a polymer of NAMW 18000, 15% < MW 1000, 6% < MW 500 and 2 isocyanate groups at the ends of the polymer backbone. Is the polymer a PLC? First, there is no restriction on RFGs so the number of isocyanate groups does not matter. However, as the polymer does not satisfy the criterion for low MW species, the polymer is not a PLC.

4. Cationic Polymers

To be eligible as a PLC, a polymer must have a low charge, or cationic, density. Cationic polymers and polymers which are reasonably anticipated to become cationic in a natural aquatic environment are not eligible as PLCs. The main concern is the toxicity of cationic polymers towards aquatic organisms such as fish and algae.

For the purposes of the Act and this guidance, the following definitions apply:

- A polymer has a *low charge density* if it is not a cationic polymer or is not reasonably anticipated to become a cationic polymer in a natural aquatic environment (4<pH<9) or:
- the polymer is a solid material that is not soluble or dispersible in water and will only be used in the solid phase, e.g. ion exchange beads; or
- the polymer is cationic (or potentially cationic) and the combined (total) FGEW of cationic groups is 5000 or above.
  Guidance in calculating FGEW is provided at the end of this appendix.
- A *cationic polymer* is defined as a polymer that contains a nett positively-charged atom(s) or associated group(s) of atoms covalently linked to its polymer molecule. Examples are the ammonium, phosphonium and sulfonium cations.
- A *potentially cationic polymer* is defined as a polymer containing groups that are reasonably anticipated to become cationic. Examples are all amines (primary, secondary, tertiary, aromatic, etc.) and all isocyanates (which hydrolyse to form carbamic acids, then decarboxylate to form amines).
- *Reasonably anticipated* means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur, based on factors such as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in the polymerisation, the intended uses of the substance, or associated use conditions.

Example: Consider a polyamide of NAMW 7000 manufactured from equimolar amounts of ethanediamine and isophthalic acid. On average, the polymer will have one unreacted amino group at one end of the polymer chain and an unreacted

carboxylic acid group at the other end. The amino group is potentially cationic so, as FGEW is defined as the ratio of NAMW to the number of RFGs, the FGEW for the amino group is 7000/1. Therefore, the polymer meets the criteria for low charge density as the FGEW is above 5000. If the NAMW had been less than 5000 or if the polymer had two free amine groups, then the polymer would not have been eligible as a PLC.

5. Hazard classification

A polymer can only be a PLC if it is not classified as a hazardous chemical. Under the Act, each of the following is a hazardous chemical:

c. a chemical that is included in the *List if Designated Substances [NOHSC: 10005] published in April 1999 by the National Occupational Health and Safety Commission;*

d. a chemical that is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008] published in April *1999 by the National Occupational Health and Safety Commission.*

6. Elemental Criteria

A PLC must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon and sulphur. A PLC must not contain as an integral part of its composition (other than impurities) elements other than:

- carbon, hydrogen, nitrogen, oxygen, silicon and sulphur;
- sodium, magnesium, aluminium, potassium, calcium, chlorine, bromine and iodine as the monatomic counter-ions Na^+, Mg^{2+}, Al^{3+}, K^+, Ca^{2+}, Cl^-, Br^- or I^-;
- fluorine, chlorine, bromine or iodine covalently bound to carbon; or
- less than 0.2 % (by weight) of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin and zirconium.

No other elements are allowed, except as impurities. Specifically, the fluoride anion F^- is not allowed as it has a high acute toxicity.

It should be noted that this criterion refers to monatomic species only. For example, a polymer containing the ammonium counter ion may be a PLC provided it meets the other PLC criteria.

Regarding the binding of halogens to carbon, it should be noted that the perchlorate anion ClO_4^- would not be allowed, as the chlorine is not covalently bound to carbon, however, the trichloroacetate anion $CCl_3CO_2^-$ would be allowed.

7. Degradable or Unstable Polymers

A PLC must be a stable polymer. In other words, a polymer is not eligible to be PLC if it is designed or reasonably anticipated to degrade, decompose or depolymerise substantially, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so.

For the purposes of the Act and this guidance, the following definition applies:

Degradation, decomposition or depolymerisation means a type of chemical change in which a polymeric substance breaks down into simpler, smaller weight substances as

the result of (for example) oxidation, hydrolysis, heat, sunlight, attack by solvents or microbial action.

'Reasonably anticipated' is defined above in section 4.
'Substantially' is taken to mean 'considerably', 'meaningfully' or 'to a significantly large extent'. It is not intended to include the slow, natural biodegradation that occurs during, say, the weathering of paint.

Examples of polymers that would not meet this criterion include:
- polymers which are designed to be pyrolysed or burnt during their normal use;
- polymers which are explosive; and
- polymers which substantially biodegrade in the environment, for example, starch.

8. Water Absorbing Polymers

Water absorbing polymers with NAMW 10000 and greater will not qualify as PLCs.
A *water absorbing polymer* means a polymer that is capable of absorbing its own weight in water.

This criterion is for water absorbing polymers in particulate form only. It is directed towards polymers known as 'super absorbents', for example, polymers used in applications such as disposable nappies and paper towels. Based on rat inhalational data for a water-absorbing polyacrylate polymer, where lung tumours were observed in both males and females at 0.8 mg/m^3, it has been assumed that lung damage may occur from the inhalation of water absorbing polymers, as the lungs are unable to clear the inhaled particles.

Water-soluble and water dispersible polymers are not considered to be water absorbing polymers. Moreover, it is assumed that particles of these polymers are adequately cleared from the lungs after inhalation.

9. Polyesters

The definition of a polyester is as follows:
Polyester means a chemical substance that meets the definition of polymer (in the Act) and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.
Polyesters manufactured from an approved list of monomers or other reactants are eligible for notification as PLCs, provided they satisfy the other PLC criteria. This provision is independent of NAMW. The list of approved monomers and other reactants is in Table 2 below. The table, to be in the regulations, can be updated by notice in the *Chemical Gazette*.

It should be noted that a number of reactants on the list are not on AICS. Therefore, the manufacture of polyesters from these reactants could not be carried out in Australia without notification and assessment of the reactant. On the other hand, polyesters manufactured from these reactants overseas could be imported, as the reactant itself would not be introduced.

Note that polyesters manufactured from the anhydride of an acid on the polyester list, for example, succinic anhydride (butanedioic acid), are allowed, provided that there are no pendant anhydrides in the polymer.

In summary, certain polyesters will not be eligible for notification as PLCs. These include:

- biodegradable polyesters (they would not meet the degradation criterion);
- water-absorbing polyesters; and
- polyesters manufactured from any monomer or other reactant not on the list of allowable reactants, including such a reactant at less than 2%.

Table 2 List of reactants from which polyester may be made

Reactant	**CAS no.**
Monobasic Acids and Natural Oils	
Benzoic acid	65-85-0
Canola oil	120962-03-0
Coconut oil	8001-31-8*
Corn oil	8001-30-7*
Cottonseed oil	8001-29-4*
Dodecanoic acid	143-07-7
Fats and glyceridic oils, anchovy	128952-11-4*
Fats and glyceridic oils, babassu	91078-92-1*
Fats and glyceridic oils, herring	68153-06-0*
Fats and glyceridic oils, menhaden	8002-50-4*
Fats and glyceridic oils, sardine	93334-41-9*
Fats and glyceridic oils, oiticica	8016-35-1*
Fatty acids, C_{16-18} and C_{18}-unsaturated	67701-08-0*
Fatty acids, castor-oil	61789-44-4*
Fatty acids, coco	61788-47-4*
Fatty acids, dehydrated castor-oil	61789-45-5*
Fatty acids, linseed oil	68424-45-3*
Fatty acids, safflower oil	93165-34-5
Fatty acids, soya	68308-53-2*
Fatty acids, sunflower oil	84625-38-7*
Fatty acids, sunflower-oil, conjugated	68953-27-5*
Fatty acids, tall-oil	61790-12-3*
Fatty acids, tall-oil, conjugated*	
Fatty acids, vegetable oil	61788-66-7*
Glycerides, C_{16-18} and C_{18}-unsaturated	67701-30-8*
Heptanoic acid	111-14-8

Hexanoic acid	142-62-1
Hexanoic acid, 3,3,5-trimethyl-	3302-10-1
Linseed oil	8001-26-1*
Linseed oil, oxidised	68649-95-6*
Nonanoic acid	112-05-0
Oils, Cannabis*	
Oils, palm kernel	8023-79-8*
Oils, perilla	68132-21-8*
Oils, walnut	8024-09-7
Safflower oil	8001-23-8*
Soybean oil	8001-22-7*
Sunflower oil	8001-21-6*
Tung oil	8001-20-5*
Di and Tri Basic Acids:.	
1,2-Benzenedicarboxylic acid	88-99-3
1,3-Benzenedicarboxylic acid	121-91-5
1,3-Benzenedicarboxylic acid, dimethyl ester	1459-93-4
1,4-Benzenedicarboxylic acid	100-21-0
1,4-Benzenedicarboxylic acid, diethyl ester	636-09-9
1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6
1,2,4-Benzenetricarboxylic acid	528-44-9
Butanedioic acid	110-15-6
Butanedioic acid, diethyl ester	123-25-1
Butanedioic acid, dimethyl ester	106-65-0
2-Butenedioic acid (E)-	110-17-8
Decanedioic acid	111-20-6
Decanedioic acid, diethyl ester	110-40-7
Decanedioic acid, dimethyl ester	106-79-6
Dodecanedioic acid	693-23-2
Fatty acids, C18-unsaturated, dimers	61788-89-4*
Heptanedioic acid	111-16-0
Heptanedioic acid, dimethyl ester	1732-08-7
Hexanedioic acid	124-04-9
Hexanedioic acid, dimethyl ester	627-93-0

Hexanedioic acid, diethyl ester	141-28-6
Nonanedioic acid	123-99-9
Nonanedioic acid, dimethyl ester	1732-10-1
Nonanedioic acid, diethyl ester	624-17-9
Octanedioic acid	505-48-6
Octanedioic acid, dimethyl ester	1732-09-8
Pentanedioic acid	110-94-1
Pentanedioic acid, dimethyl ester	1119-40-0
Pentanedioic acid, diethyl ester	818-38-2
Undecanedioic acid	1852-04-6

Polyols

1,3-Butanediol	107-88-0
1,4-Butanediol	110-63-4
1,4-Cyclohexanedimethanol	105-08-8
1,2-Ethanediol	107-21-1
Ethanol, 2,2´-oxybis-	111-46-6
1,6-Hexanediol	629-11-8
1,3-Pentanediol, 2,2,4-trimethyl-	144-19-4
1,2-Propanediol	57-55-6
1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115-77-5
1,3-Propanediol, 2,2-dimethyl-	126-30-7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77-99-6
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl	77-85-0
1,3-Propanediol, 2-methyl	2163-42-0
1,2,3-Propanetriol	56-81-5
1,2,3-Propanetriol, homopolymer	25618-55-7
2-Propen-1-ol, polymer with ethenylbenzene	25119-62-4

Modifiers

Acetic acid, 2,2´-oxybis-	110-99-6
1-Butanol	71-36-3**
Cyclohexanol	108-93-0
Cyclohexanol, 4,4´-(1-methylethylidene) bis	80-04-6
Ethanol, 2-(2-butoxyethoxy)-	112-34-5
1-Hexanol	111-27-3

Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane.....	72318-84-4*
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-……..	13393-93-6
Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2,2′-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane].....	25036-25-3
Siloxanes and Silicones, dimethyl, diphenyl, polymers with phenyl silsesquioxanes, methoxy-terminated……..	68440-65-3*
Siloxanes and Silicones, dimethyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy-terminated……	68957-04-0*
Siloxanes and Silicones, methyl phenyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated…….	68957-06-2*
Silsesquioxanes, phenyl propyl.....	68037-90-1*

*Designates chemical substance of unknown or variable composition, complex reaction products, and biological materials (UVCB substances). The CAS Registry Numbers for UVCB substances are not used in Chemical Abstracts and its indexes.
**These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters which may be formed by reaction of these reactants.

10. Data Requirements

The data requirements for the notification of a polymer as a PLC are stipulated on Form 1-PLC, which can be found in Appendix 1. Only minor changes to the form have been made a result of the revision of the criteria. These are listed below. General guidance on PLC data requirements can be found in Appendix 12 – Schedule of data requirements.

Environmental Impact

The following wording has been included on the PLC form:
What is the environmental impact? Provide information about the release of the polymer likely to occur at the manufacture or reformulation site and during normal end use (rather than from spills etc). Qualitative or semi-quantitative estimates only are required. Where there is both a high content of low molecular weight species and a high release to water, aquatic toxicity data for fish, daphnia and/or algae may be required.

Public Health

The following wording has been included on the PLC form:
What is the likely public health exposure? Provide a brief description of any way in which the polymer could be harmful or hazardous to the health of the public at large. Where there is both a high content of low molecular weight species and the polymer is to be used as an ingredient in a cosmetic product at 1% or more, additional information, eg. toxicological data, may be required.

Attachment

How to Calculate Functional Group Equivalent Weight

Unless a functional group equivalent weight (FGEW) can be determined empirically by recognised, scientific methodology (typically titration), a worst-case estimate must be made for the FGEW. All moderate and high concern functional moieties must be taken into account when calculating FGEW. Guidance for estimating FGEW with specific methods is provided below, together with examples for each methodology. The methods described are:
end-group analysis; and
the percent charged method.

1. End Group Analysis

FGEW can be calculated by simply counting the number of RFGs and dividing into the NAMW, i.e.

$$FGEW = \frac{NAMW}{n}$$

Equation 1

where n = the number of RFGs in the monomer.

Linear Polymers

For most condensation polymers (e.g. polyesters, polyamides), the only RFGs are at the end of the chain because the other RFGs are used up in the condensation reaction. For linear polymers, where there are 2 RFGs per monomer, the FGEW is half the NAMW.

Example For a polyamide of NAMW 1500 made from ethylenediamine and adipic acid, an amine group would be expected at each end of the polymer chain. Therefore, FGEW = 1500/2 = 750.

Branched Polymers

For polymers where branching occurs, the RFGs at the end of each branched chain must be counted.

Example Consider the polymerisation of pentaerythritol (4 reactive groups) with polypropylene glycol (2 reactive groups) and an excess of isophorone diisocyanate (2 reactive groups) to give a polymer of NAMW 3000. Due to the branching of pentaerythritol and excess diisocyanate, the resultant polymer will theoretically have 6 isocyanate end groups. Therefore, FGEW = 3000/6 = 500.

2. Percent Charged Method

Some condensation and addition reactions create polymers where not all RFGs along the backbone of the polymer are consumed during the reaction, so an accurate FGEW cannot be determined by use of a simple end group analysis. In many of these cases, the calculation of FGEW may be more complex. For example, in some condensation and addition reactions, some of the RFGs along the polymer backbone are unchanged during polymerisation. Also, in some cases, the structural formula of the final polymer is not accurately known.

In these cases, FGEW can be calculated using the weight % monomer in the polymer (W) and the formula weight of the monomer (FW) as follows:

$$FGEW = \frac{100FW}{Wn}$$

Equation 2

Example For an acrylic polymer containing 7.5% acryloyl chloride monomer (FW 90.5), the FGEW of acid chloride groups in the polymer is:

$$FGEW = \frac{100 \times 90.5}{7.5 \times 1}$$

If the various RFGs in a polymer arise from multiple monomers, the following equation can be used:

$$FGEW_{comb} = \frac{1}{\frac{1}{FGEW_1} + \frac{1}{GFEW_2} + ... + \frac{1}{FGEW_n}}$$

Equation 3

Example Consider the reaction between ethanediamine (MW 60) (charged at 30%) and diglycidyl ether (MW 130) (70%) to give a polymer of NAMW 5000. The epoxides in the backbone are reacted to give an aliphatic alcohol (low concern). The amine groups remain intact, with their FGEW proportional to the charged amount of ethanediamine. As the diglycidyl ether is in excess, it can be assumed that the polymer is epoxide-terminated.

Using Equation 2, the FGEW for the amine group is (100 x 60)/(30 x 2) = 100. The FGEW for the epoxide group can be calculated using end group analysis (Equation 1), i.e. 5000/2 = 2500.
Then using Equation 3, $FGEW_{comb}$ = inverse of [1/100 + 1/2500] = 96.

Example Consider a p-cresol-formaldehyde condensation polymer which is reacted with 1.5% epichlorhydrin to give an epoxide-capped resin. As a worst-case, it is assumed that the polymer is phenol-terminated and that epoxy rings from the epichlorhydrin (MW 92.5, 1 epoxy group) are also present. A NAMW of 10000 is assumed.

Using Equation 2, the FGEW for the epoxide group is (100 x 92.5)/(1.5 x 1) = 6167. The FGEW for the phenol group can be calculated using end group analysis (Equation 1), i.e. 10000/2 = 5000.
Then using Equation 3, $FGEW_{comb}$ = inverse of [1/6167 + 1/5000] = 2762.

Example Consider the addition reaction involving the polymerisation of three acrylates, glycidyl methacrylate (10%, MW 142, 1 RFG), hydroxymethyl acrylamide (2%, MW 101, 1 RFG) and acrylic acid (88%). In this case, it can be assumed that each monomer is completely incorporated into the polymer, with the RFGs of concern being the epoxide group from glycidyl methacrylate and the hydroxymethyl amide group from the acrylamide. The carboxylic acid moiety from acrylic acid is of low concern and need not be included in FGEW calculations.

Using Equation 2, the FGEW for the epoxide group is (100 x 142)/(10 x 1) = 1420. Again using Equation 2, the FGEW for the hydroxymethyl amide group is (100 x 101)/(2 x 1) = 5050.
Then using Equation 3, $FGEW_{comb}$ = inverse of [1/1420 + 1/5050] = 1108.

11. How to obtain Chemical Abstracts Service Registry numbers (CAS)

INTRODUCTION

The Chemical Abstracts Service Registry Services furnishes CAS Registry numbers to customers either by retrieving existing CAS Registry numbers and/or assigning new CAS Registry numbers for chemical substances. This service is done by a computer search of information provided by the customer to CAS in hard copy form (for orders with less than 50 substances). If you have questions regarding this service, or need information, the CAS Registry Services Coordinator is available at ISD telephone number (1)(614) 447 3600 and ISD facsimile number (1)(614) 447 3713.

If you wish to have Chemical Abstracts Index Names or other additional substance information, such as molecular formulae, synonyms and structure diagrams, included with the CAS Registry number, please contact the CAS Registry Services Coordinator. To obtain CAS Registry numbers for your substances, the general information given below will help you determine what substance information you should include. Order forms (see the sample at the end of this Appendix) must be completed and returned with payment to the following address:

Chemical Abstracts Service
CAS Registry Services
PO Box 3012
Columbus, Ohio 43210
United States of America

INFORMATION REQUIREMENTS

Policy for the assignment of a new CAS registry number

CAS Registry Services will assign a new CAS registry number to a substance provided that:

a. The existence and chemical identity of the substance are:

   (i) documented by citation in a technical journal, other periodical, handbook, chemical manufacturer's catalogue, other publication or other information file which is readily available to the public (either gratis or at a reasonable fee) in printed, microfiche, or computer-readable form, or (ii) being reported to a governmental regulatory agency.

b. Each such request must be accompanied by the complete citation or full name of the source document/file or the name of the regulatory agency.

c. The chemical meets the chemical registration criteria established by CAS for the CAS Chemical Registry System.

d. The requesting person (or organisation) must include a written statement that they do not consider the existence and chemical identity of the substance itself

confidential, even though the interest in the substance by a specific person or organisation may be regarded as confidential.

Information to be submitted for the retrieval of an existing CAS registry number or the assignment of a new CAS registry number

For substances with well-defined, unique chemical structures, the following information must be provided:

a. chemically descriptive name which includes the locants for all substituents;
b. molecular formula; and
c. complete structural diagram

Notes:

a. If the substance is a salt, the ratios must be included.
b. If there is known stereochemistry, this must be included.

For chemical substances which cannot be uniquely defined by chemical structure, or are UVCB substances, such as complex reaction products, one of the following descriptions is required:

a. a chemically descriptive name which includes a detailed description of the reaction scheme including all starting reactants and the identification of the typical chemical composition of the product;
b. if the substance is a result of a manufacturing process or stream, then a specific description of the manufacturing process, with specific precursors, specific process terms and typical chemical composition of the product is necessary; and
c. if the substance is prepared from a natural product, for example, a resin or an oil, then the substance description should include the genus and species of the source.

CAS REGISTRY SERVICES TERMS and CONDITIONS

1. INVOICING AND PAYMENT

CAS shall mail invoice(s) for all CAS Registry Services output and related services rendered to customers. Invoiced amounts are due on receipt of the invoice and may be paid only in US dollars or UNESCO coupons. Invoices not paid within 30 days shall be assessed a 5 per cent surcharge.

2. USE AND DISTRIBUTION RESTRICTIONS

CAS Registry Services is the copyright of the American Chemical Society.

When customer's CAS Registry Services output contains synonyms or connection tables, a CAS licence is required if the customer distributes such output in computer-

readable form to third parties except in the following ways: (a) in copyrighted scientific publications when search results are incidental to the publication, and (b) in reports to a government agency which are required by law or administrative rule.

While subject to the copyright of the American Chemical Society, the following items of information are not subject to the use and distribution restrictions specified herein, provided that they are not made available to any third party in any electronic or computer-readable form: CAS Registry Numbers, CA Index Names, Molecular Formulas and Structure Diagrams.

3. LIMITATIONS AND LIABILITY.

While CAS uses its best efforts to deliver complete and accurate CAS Registry Services output, CAS does not warrant accuracy or completeness, is not responsible for errors and omissions, and is not liable for any direct, indirect or consequential damages.

CAS REGISTRY SERVICES ORDER FORM

Chemical Abstracts Service CAS Registry Services
PO Box 3012
Columbus, Ohio 43210 USA

Please complete this section for each substance for which you are requesting a CAS Registry Number.

CHEMICAL SUBSTANCE NAME(S) AND CHEMICAL SUBSTANCE DESCRIPTION: (See INFORMATION REQUIREMENTS Section 2)

If you wish the ASSIGNMENT of a new CAS Registry Number, please complete one copy of this form and include it with your order. (See INFORMATION REQUIREMENTS Section 1)

Enter the literature citation (source document) OR governmental regulatory agency on the following line:

_____

The specified substance(s) are NOT confidential. I understand that the substance(s) will reside in the CAS Chemical Registry System and will therefore be accessible to CAS and the public.

SIGNATURE_____DATE_____

NAME_____

ORGANISATION_____

ADDRESS_____

_____

TELEPHONE_____

Payment Information:

Cheque enclosed

OPTIONAL: Please charge to (tick **one):**
VISA MASTERCARD

Signature_____ Expiration Date_____

VISA or MASTER CARD account # | | | | | | | | | | | | | | | |

Please mail completed form and payment to:

Chemical Abstracts Service
Accounts Department (CAS REGISTRY SERVICES)
PO Box 3012
Columbus, OHIO 43210
USA

12. Schedule of Data Requirements

This Appendix provides guidance concerning the data necessary to submit with your application for new or existing chemical assessments. Use this to help ensure you have provided all the necessary information. The numbering in this chapter is consistent with the numbering in the Schedule to the Act.

SCHEDULE PART A

1. Identification Of Data Requirements To Be Dealt With In The Notification

Each application must identify which data is being supplied. For new chemicals, the data to be submitted for each category of application are outlined in Chapters 4, 5 and 6. Where doubt exists, contact the Director.
For PECs, data requirements are often described in terms of the Schedule. These requirements are listed by notice in the *Chemical Gazette.*

2. Summary Of Health And Environmental Effects

A summary of the occupational health and safety, public health and environmental effects of the chemical is required in all Standard Notifications and Limited Notifications. Notifiers should discuss the effects and hazards of the chemical in light of proposed recommendations for its use.
The summary should highlight the results of the tests that are used to determine the toxic effects of the chemical, including its ecotoxicity, that is, a summary of the most significant results of Part C of the Schedule. In tests where no adverse effects are observed, comments on dosage levels should be made. The summary should also highlight the physical and chemical hazards of the chemical, for example, flammability and reactivity.
The summary should highlight the toxic effects and hazards of the chemical and its impact on occupational health and safety, public health and the environment.
The summary should also address any information missing from the notification, and justify the omission(s).

3. Summary Of How The Chemical Meets The Definition Of A Hazardous Substance

Under the NOHSC Standard Control of *Workplace Hazardous Substances: National Model Regulations and National Code of Practice*, a hazardous substance is defined as:

- a substance which is listed on the NOHSC *List of Designated Hazardous Substances*; or
- a substance which has been classified as a hazardous substance by the manufacturer or importer in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria).

Under the amended NICNAS legislation, a hazardous substance is defined as a ‘hazardous chemical’.

The notifier should state whether the notified chemical is a hazardous substance or not. If the chemical is a hazardous substance, the notifier should provide a health hazard classification of the notified chemical, carried out in accordance with the NOHSC Approved Criteria. This should include the appropriate risk and safety phrases and the basis of the classification (in terms of the toxicological endpoints considered). For the purposes of notification, the health hazard classification of products containing the notified chemical should also be provided.
As a requirement for the MSDS of the notified chemical, an appropriate statement of hazardous nature should be provided. The wording to be used is either:

- Hazardous according to the criteria of National Occupational Health and Safety Commission; or
- Not classified as hazardous according to the criteria of National Occupational Health and Safety Commission.

4. Details Of Any Notification Made In Relation To The Chemical In A Country Other Than Australia

A summary of the status of the notified chemical in countries other than Australia should be provided. The information provided should include:

- name of each country;
- whether an assessment of the chemical was carried out in any of the nominated countries or, alternatively, whether the chemical is listed on one or more national inventories without being assessed;
- date of the assessment (if an assessment was carried out);
- whether a risk assessment report is available to the notifier (if an assessment was carried out); and
- whether the notifier wishes the notification package to be considered under the Foreign Schemes Program (see Section 8.2).

5. Bibliography

A complete listing of all publications referred to in the notification statement is required, including:

- references for published and unpublished studies;
- references for other information obtained from the scientific literature;
- references to standards and codes of practice;
- test methods used to generate data;
- references to other notification and assessment schemes; and
- other reports on the chemical or class of chemicals.

SCHEDULE PART B

In this section, the numbering is consistent with the numbering in the Schedule to the Act.

1. Identity Of The Substance

A complete and unambiguous identification of the chemical must be provided by completing paragraphs 1(a) to 1(g) of Part B of the Schedule. For chemicals with a Chemical Abstracts Services (CAS) number, a CAS printout should be provided. In

the case of a synthetic polymer, information listed below under paragraphs 1(a) to 1(c) should also be provided for the constituent monomer(s).

1(a) Chemical name
The chemical name(s) to be provided is that which will be used in the AICS, that is, the Chemical Abstracts (CA) Preferred Index name(s). If this is not available, then use the International Union for Pure and Applied Chemistry (IUPAC) name(s).
For substances that are not pure chemicals, that is, chemicals of unknown or variable composition, a complex product of a chemical reaction, or a biological material (UVCB), the chemical name must describe the substance as completely as possible. An example of a chemical of unknown or variable composition is fatty acids, cottonseed oil. An example of a complex product of a chemical reaction is polyethoxylated C12-20 alcohols. Typical biological materials are geranium oil and proteinase. For biopolymers, the biological source must be indicated.

1(b) Other names
Common names by which the chemical is known or identified in the scientific or technical literature are required. For example, 2-propanone is commonly known as acetone.

1(c) Marketing name of chemical
Names under which the chemical has been, or will be, marketed are required. This will include trade names.

1(d) CAS number
Each new chemical has its own unique number assigned to it by the Chemical Abstracts Service (CAS). The number, known as the CAS number, can be obtained by reference to the procedure in Appendix 11 - *How to obtain Chemical Abstracts Service registry numbers.*
If a CAS number has not been allocated to the chemical, then the notifier should state when an application has been made.

1(e) Molecular and structural formulae
Provide a molecular formula that gives the identity and number of atoms of each element in the molecule, for example, C6H6 for benzene, H2SO4 for sulphuric acid.
Provide a structural formula that indicates the location of atoms, ions or groups and the nature of bonds joining them, for example, acetic acid.
For polymers, the molecular and structural formulae of the constituent monomers, and their appropriate ratios, should be provided.

1(f) Molecular weight
The gram-molecular weight of the chemical is to be provided. For polymers, both the number-average molecular weight and the weight average molecular weight should be provided (see Part D in this Chapter).

1(g) Spectral data
Copies of spectra, for example, from infra-red spectroscopy, nuclear magnetic resonance spectroscopy, mass spectroscopy and ultraviolet-visible spectrophotometry, are required to confirm the structural formula. Principal wavelengths and/or other significant data should be indicated. Analytical details, such as the solvent used or the

infrared matrix used, for example, nujol mull or potassium bromide pellet, should also be provided.

For biological materials that are derived from plants (herbs), confirmation of the identity of the herb is required. Due to the variability within classes and species of herbs, an authenticated certificate of analysis should be provided. Internationally, herbs can be identified at Kew Gardens, London, United Kingdom. In Australia, herbs can be identified at the New South Wales Herbarium in Sydney.

Similarly, confirmation of the identity of biological materials derived from animals and gene technology is required.

2. Composition Of The Chemical

2(a) Purity
The degree of purity of the chemical (as a weight percentage) is to be provided. For chemicals containing water, this percentage shall be given for the dried substance, unless water is an integral part of its composition.

2(b) Toxic or hazardous impurities
The identity and the weight percentage of all known (or reasonably anticipated) impurities (including isomers and by-products) of a hazardous or toxic nature shall be provided, together with details of their toxic and hazardous properties. This section includes impurities which are classified as dangerous goods and substances listed on the Poisons Schedule. For impurities that are classified as hazardous substances in accordance with the NOHSC Approved Criteria, the risk phrases should be indicated.

Where possible, all impurities should be identified by their CAS number and Chemical Abstracts Preferred Name Index name. If this is not available, then the IUPAC name or common chemical name should be provided.

2(c) Non-hazardous impurities
For all non-hazardous impurities present at 1% by weight or more, the identity and weight percentage is to be provided.

2(d) Additives/adjuvants
The maximum weight percentage of all chemicals incorporated into the main chemical substance is required.
Chemical substances such as stabilisers, inhibitors and modifiers should be included. All additives/adjuvants should be identified by their CAS number, Chemical Abstracts Preferred Name Index name, common name and name under which the chemical is marketed.

3. Information On Use

All proposed uses of the chemical are required, for example, solvent, dyestuff, adhesive, plasticiser or detergent. For each use, the approximate percentage of total manufacture or import should be indicated. The information should be given in descending order of importance. The industry where the chemical is to be used should

be identified, for example, the paper and pulp industry. The fields of use and methods of application should be described, for example, a spray-on paint stripper in the painting industry. For all forms of the notified chemical, including final end-use products, the concentration of notified chemical in the mixture or product must be provided. This information is critical for the risk assessment. Information provided for use should be as complete as possible to enable a proper assessment of the notified chemical to be carried out.

4. precis of appearance

The appearance of the chemical shall be described in terms of colour and form, for example, brown, viscous liquid or grey powder. Its physical state at 20°C and 101.3 kPa (ambient conditions) is required.
The odour, including odour threshold, and volatility of the substance should also be provided. For example, toluene is a liquid of low volatility with a characteristic aromatic odour, and an odour threshold at approximately 10 ppm v/v.

5. Estimated Manufacture Or Import Volume

Specify whether the chemical is to be manufactured in Australia or imported, and the amount in range of tonnes per year (1-10, 10-100, 100-1000, 1000-10000 or greater than 10000) for each of the first five years. Estimated quantities should be those of the notified chemical, not of the product or formulation.

6. Occupational Health And Safety

6(a) Occupational exposure data

The data to be included must provide a comprehensive description of occupational exposure factors so that an adequate occupational health and safety assessment can be carried out. In the case of importers who do not use the chemical, the relevant items of information should be obtained from the user. For new chemicals that have been in use overseas, relevant occupational exposure information, for example, monitoring data for a similar use, should be submitted if available from overseas sources. The following is a set of information that is to be submitted. Any other information that is relevant to occupational exposure should also be included.

6(a)(i) Number and category of workers

An estimate of the maximum total number and category of workers likely to be exposed to the chemical or any product treated with the chemical is required, for example, those employed in maintenance tasks associated with the chemical, or those employed in packaging and storing the chemical. Include all workers involved from the manufacturing process or importation onwards, and also those involved in storage, handling, transportation and disposal of the chemical. Though some of this information may be imprecise, for example, in the case of product development, estimates should be provided.

6(a)(ii) Nature of work done

To adequately assess the occupational health and safety hazards of the chemical, some indication of the nature of the work carried out, or to be carried out, is required for each type of worker exposed to the chemical. For each of the worker categories,

briefly describe the nature of work carried out with the chemical. State the maximum duration of exposure for each category in hours per day and days per year and the frequency of exposure. Include activities requiring protective clothing and equipment, and indicate the physical form(s) of the chemical during exposure, for example, hot liquid or fine powder.

6(a)(iii) Safety procedures to be observed when handling the chemical
Information is required on methods and procedures to minimise or prevent worker exposure. Principles and procedures for the effective control of chemicals in the workplace are detailed in the NOHSC standard *Control of Workplace Hazardous Substances: National Model Regulations and National Code of Practice.*
While the standard has been written for the control of hazardous substances, the principles apply just as well to chemicals not classified as hazardous.

The prevention of worker exposure to a particular chemical can be achieved by working through the following hierarchy of control measures:

- isolation of the process or operation;
- engineering controls, including local exhaust ventilation for vapours, gases or particulates;
- adoption of safe work practices, including changes to work methods; and
- the provision and use of suitable approved personal protective equipment where other measures have not been effective.

A description of the *isolation procedures and engineering controls* used, or to be used, in minimising worker exposure to the chemical is required. This may include:

- isolation of a hazardous operation by removal to a remote area of the workplace;
- modifications to the working environment, for example, ventilation or fume extraction;
- enclosure, for example, spray painting within booths; and
- preventive maintenance Schedules designed to maintain plant, equipment and extraction systems to a high standard.

A description of the *safe work practices* to be observed by workers in handling the chemical is required. These include:

- precautions during routine handling of the chemical;
- precautions during storage and transport of the chemical;
- precautions in handling spills;
- good housekeeping; and
- introduction of procedures to reduce the duration and frequency of exposure for employees.

Specific information on *protective clothing and equipment* necessary during both routine and non-routine tasks is required.

- The types of respiratory equipment required should be specified in accordance with Australian Standards AS 1716 *Respiratory Protective Devices* and AS 1715 *Selection, Use and Maintenance of Respiratory Protective Devices* or equivalent internationally acceptable standards.
- The type of protective clothing required should be stipulated, for example, gloves, eye protection and/or footwear. This information should be specific,

for example, flame-proof cotton overalls. Impervious gloves are not sufficient, whereas nitrile gloves would be. The relevant Australian Standards (or equivalent) should be consulted, for example, AS 2161.2 *Occupational Protective Gloves Part 2: General Requirements, AS 1336 Eye Protection in the Industrial Environment,* and AS 3765.1 *Clothing for Protection against Hazardous Chemicals Part 1: Protection against General or Specific Chemicals.*

Australian and International Standards are updated from time to time, so notifiers should check that they consult the most recent versions of each standard.

6(a)(iv) Education and training

A brief description of the core training and education given to employees to become proficient in safe working practices is required. This should include a section on the training required to introduce the new chemical into the workplace. For importers who may not use the chemical, some indication of the proposed core training and education program should be obtained from the user. The information should include:

- instruction on health and safety hazards of the chemical, including the routes of entry into the body;
- instruction in the correct use of all protective equipment required during handling of the chemical;
- instruction in the correct use of relevant plant and equipment;
- instructions for emergency situations;
- information on labelling of the chemical; and
- availability of the MSDS.

The duration and frequency of training periods should be indicated.

6(a)(v) Prevalence of work-related Injuries and diseases related to workers exposed to the chemical

For chemicals already in use, any effect on the occupational health of workers exposed to the chemical may be known before introduction of the chemical into Australia. The type, frequency and severity of all work-related injuries and diseases resulting from worker exposure to the notified chemical are required, for example, incidence of health effect or disease and total work time lost. Where available, details on the duration, frequency and levels of exposure of workers to the chemical should be indicated. Exposure to other chemicals or other relevant factors should also be mentioned.

If workers exposed to the chemical have experienced adverse health effects, then these should be fully described in the notification under paragraph 6(b) of Part B of the Schedule, Health Conditions. Guidance for information in paragraph 6(b) of Part B of the Schedule is detailed below.

6(a)(vi) Other occupational hazards

Other information on possible occupational hazards not referred to elsewhere in paragraph 6(a) of Part B of the Schedule should be provided. In particular, information on conditions that may tend to increase the hazard of the chemical is required. This information may include such items as:

- adverse working conditions, for example, heat or cold;
- any work in confined spaces;
- potential exposure to other hazardous substances;

- possibility of reaction, for example, with other substances or with water; and
- any other interaction, for example, interaction of chemicals and heat.

6(b) Health conditions

Information to be submitted with respect to health conditions will usually only be available for chemicals already in use, for example, chemicals used in a foreign country. The notification statement should include a list of any health conditions that have been reported or are known to the notifier. The list must include health conditions that indicate that the chemical should not be used.

This should include all health conditions such as asthma, broken skin, dermatitis, or therapeutic or recreational drug use or abuse, for example, anti-hypertensive agents, alcohol or tobacco.

The notification statement should report any evidence of specific health conditions associated with the chemical that might suggest that it should not be used without special precautions. For example, exposure to the chemical may cause severe dermatitis.

The notification statement should list any health conditions that could reasonably be expected to occur for the notified chemical, for example, by analogy with structurally similar chemicals, or analogues.

Any health conditions aggravated by the chemical should be mentioned, for example, exposure to the chemical may increase the incidence of asthma in susceptible workers.

6(c) Occupational health monitoring

Occupational health monitoring should include details of both the atmospheric monitoring and biological monitoring procedures to be adopted in giving some measure of worker exposure to the chemical. For chemicals already in use, methodology may be obtained from international sources. For new chemicals, methodology may be developed by consideration of existing methodology for structurally similar existing chemicals. Applicants should provide information on existing or proposed exposure limits and any known methods of atmospheric or biological monitoring of the notified chemical.

If no monitoring procedures are proposed, then this should be justified in terms of the health and safety hazards of the chemical and extent of worker exposure to the chemical.

For importers who may not use the chemical, some indication of proposed monitoring procedures should be obtained from the user.

6(c)(i) Atmospheric monitoring

Information is required on the type(s) of atmospheric monitoring proposed, for example:

- personal monitoring, where the time-weighted average concentration of actual worker exposure to the chemical is indicated;

- automatic continuous monitoring, where peak level concentrations and time-weighted average concentrations of the chemical in the work areas are indicated;
- fixed-point monitoring, where time-weighted average concentrations of the chemical over a set period, for example, an eight-hour shift, are indicated for a fixed location in the work area; and
- grab sampling, where instantaneous concentrations of the chemical are indicated.

Details on sampling techniques and sampling equipment should be included. For example, passive monitor badges may be used for personal monitoring. A brief description of the analytical method(s) used should be provided, together with the principal technique specified, for example, gas chromatographic or gravimetric analysis. Details of the type of instrumentation used in the method should also be included.

6(c)(ii) Biological monitoring

Biological monitoring involves the quantitative measurement of the chemical or its metabolite in the appropriate body tissue, fluid or excretion product, for example, in blood, urine or expired air.

Information should be provided on the test(s) to be used, the program of activities, the relevant collection procedures and the analytical methods and instrumentation.

6(d) Observations on human exposure

Information held, or reasonably obtainable, by the notifier on studies or observations of the effects of the chemical on humans is required. In particular, observations of health problems or adverse symptoms in humans exposed to the chemical are required. This may include information on specific incidents, for example, acute exposure resulting from an accidental spillage. Information on any epidemiological studies on workers who have been exposed to the chemical is required. Where possible, any health conditions (either positive or negative) should be related to exposure levels.

7. Environmental Impact

An assessment of the environmental impact of the chemical is to be provided. Information on the following should be included in the notification statement:

- manufacturing process;
- release to the environment for each use, including that from any manufacturing, reformulation, repackaging and end use;
- storage and transport; and
- disposal.

Information supplied in this section should be complementary to that detailed in paragraph 13 of Part B of the Schedule. In the case of importers who may not use the chemical, information on environmental impact should be obtained from the user.

7(a) Manufacturing process

Information on the manufacturing process is not required for chemicals manufactured outside Australia. However, information is required on the formulation process for

imported chemicals if they are reformulated or repackaged in Australia, for example, into products for industrial or domestic use.

7(a)(i) Identity of the site(s) where the chemical will be manufactured or reformulated

The location(s) of each industrial site (manufacturing, processing or other operation) controlled by the notifier is required. The location of sites where repacking and/or reformulation of the chemical is carried out is also required.

7(a)(ii) Process description

For each operation controlled by the notifier, the process description should include:

- a diagram of the major unit operation steps and chemical conversions;
- the identity and entry points of all feedstocks, including reactants, solvents and catalysts; and
- the location of the points of release of the chemical to the environment.

7(a)(iii) Release of chemicals at each site

For each release point identified in the preceding subsection, the following information is required:

- an estimate of the amount and concentration of chemical released directly to the environment or into control technology (in kg/day);
- the media (air, soil or water) to which the chemical is released;
- a description of any control technology used to limit release; and
- the destination(s) of releases to water.

7(b) Release to the environment for each use

For each recommended specific use or application identified in paragraph 3 of Part B of the Schedule, the information provided should include the estimated number of sites for each use, broad process descriptions and descriptions of situations in which environmental release of the chemical may occur, including through equipment cleaning, for example:

- to ambient air, for example, through smoke stack emissions, car exhaust fumes, incineration gases, aerosols and fugitive refrigerant gases;
- in water, for example, natural waterways or ground water, including release to waste water treatment facilities; and
- to the surrounding land, for example, through overspray of paints, general wear and tear and deposition.

The quantity, concentration and media of release for each situation are required.

7(c) Transport and storage

The safe storage requirements, for example, location, temperature or incompatibility, should be defined for the chemical. The chemical's classification under the *Australian Code for the Transport of Dangerous Goods by Road and Rail* is also required.

A description of all intended storage facilities is required, including size, type and capacity of containers and potential for environmental exposure. A description of all intended transport between storage facilities should be provided, including quantity to be transported, mode of transport and potential for environmental exposure. Technical details on storage and transport should also be included in the MSDS(see paragraph 12 of Part B of the Schedule).

7(d) Disposal
A full description of all disposal procedures is required, including for all contaminated packaging, including:

- route of disposal, for example, landfill or incineration;
- quantities to be disposed of by each route, including residues in contaminated packaging (where applicable and not addressed in paragraphs 7(a) and 7(b) of Part B of the Schedule); and
- identity and hazards of any degradation products resulting from disposal.

If disposal needs to be in accordance with government regulation, this should be stated.

8. Public Health

Exposure of the general public to industrial chemicals may occur in three ways. Firstly, there may be exposure during industrial use as a result of contamination of air, water or food. Secondly, there may be exposure as a result of an industrial accident. Thirdly, there may be exposure from domestic use. The notifier must provide a description of the potential public health implications of the chemical in the light of the toxicological findings and the expected public health exposure.
The following information submitted in other parts of the Schedule should be taken into account when providing the description of public health implications, with the items listed below cross-referenced under the appropriate heading in the notification statement:

- description of proposed uses (as specified in paragraph 3 of Part B of the Schedule);
- identity and percentage of any impurities and their toxicological significance (paragraph 2 of Part B of the Schedule);
- physico-chemical properties (paragraph 9 of Part B of the Schedule);
- information about the site of manufacture or reformulation in Australia and the release of the chemical into the environment at that site (paragraph 7(a) of Part B of the Schedule);
- for each use of the chemical, information about its release into the environment, including the quantity, concentration and frequency of release (paragraph 7(b) of Part B of the Schedule);
- conditions of safe storage (paragraph 7(c) of Part B of the Schedule);
- disposal procedures (paragraph 7(d) of Part B of the Schedule);
- consequences of, and emergency procedures associated with, accidental spillage (paragraph 13(b) of Part B of the Schedule);
- the results of toxicity tests in animals (Part C of the Schedule); and
- information arising from human exposure to the chemical, including symptoms of exposure, poisoning reports, clinical observations and epidemiological studies (paragraph 6(d) of Part B of the Schedule).

The studies provided in a Standard Notification statement (as per items listed in the Schedule) are generally sufficient to enable assessment of public health hazards associated with single or infrequent human exposure, such as may occur in accidental situations. Unless appropriate additional information is provided, they are generally not sufficient to allow an assessment of public health risks where widespread or long-term exposure is likely. For example, distribution in domestic products, regular

exhausting of a chemical into the atmosphere resulting in deposition on edible plants or water catchments, contamination of waterways by an accidental spill or release of the chemical in a manner which may lead to incorporation in the food chain. For these reasons, the Director may require additional information on these aspects if significant public exposure is likely.

9. Physico-Chemical Data

In general, all physical and chemical property data should specify:

- the grade and nature of the chemical tested, including its purity (if the chemical is in a mixture, this should be noted for all data provided);
- the testing authority or organisation providing the data (where applicable);and
- the physical conditions used for all test data, for example, temperature or pressure.

Where the notifier performs measurements, the OECD *Guidelines for the Testing of Chemicals* may be helpful. The numbers in parenthesis after each test are the method numbers in the guidelines, for example, TG102 in subsection 9(a) in Part B of the Schedule refers to Test Guideline number 102. The standard of testing to obtain data should conform to the *principles of good laboratory practice*. Notifiers may refer to the OECD Principles of Good Laboratory Practice for information on this matter.

9(a) Melting point/boiling point (TG 102, TG 103 or equivalent)
The melting point or boiling point is to be provided. However, for non-pure chemicals a temperature range may be more appropriate, or for some chemicals the freezing point is more appropriate than the melting point.

9(b) Specific gravity/density (TG 109 or equivalent)
The density (in kg/m3) is required for all chemicals. For gases, the specific gravity (air = 1) is also required, as this will assist in indicating any tendency of the chemical to settle or disperse when discharged at high concentrations into the atmosphere. For liquids, both the liquid and vapour densities should be provided.

9(c) Vapour pressure (TG 104 or equivalent)
The vapour pressure of the chemical is to be provided expressed as kilopascals (kPa) at 25°C.
Any effect on the measurement by impurities should be stated. Vapour pressure is important for estimating the chemical's potential for inhalation exposure and for determining the application route(s) for toxicity testing.
Vapour pressure is environmentally relevant because it helps to estimate the chemical's distribution between the environmental compartments, that is, the phase transitions between soil and air, soil and water, and (with water solubility) water and air. It can help to predict atmospheric concentrations.

9(d) Water solubility (TG 105 or equivalent, TG 120 for polymers)
The saturation mass concentration of the chemical in water is required (in g/L at 20°C). The method of measurement should be indicated. If the substance is insoluble in water, the detection limit of the analytical method used should be indicated, and any water accommodated fraction of the chemical determined. Water solubility is significant environmentally because:

• it largely determines the mobility of the chemical within and between the air, soil and water compartments;
• it may be important in determining appropriate emergency services responses;
• water-soluble chemicals gain ready access to humans and other living organisms; and
• it has large effects on the potential for bioaccumulation.

9(e) Hydrolysis as a function of pH (TG 111 or equivalent)
This parameter is to be provided for water-soluble chemicals only (water solubility greater than 10-3 mole/L). The degree of hydrolysis at 25°C is required at pH values normally found in the environment (pH 4-9) and under more acidic conditions (pH 1-2) for physiological purposes. Hydrolysis is one of the main modes of abiotic degradation of substances in the environment.

9(f) Partition coefficient (n-octanol/water) (TG 107 or equivalent, TG 117)
This parameter is to be provided only for (pure) water-soluble chemicals which do not dissociate or associate, and which are not surface-active. It is expressed as log Pow, at 20oC.
The partition coefficient of a substance between water and a lipophilic solvent (n-octanol) can indicate its potential for skin absorption, or can be used to estimate the chemical's bioaccumulation potential in aquatic organisms. Relationships exist between this parameter and bioaccumulation in fish.

9(g) Adsorption and desorption (TG 106 or equivalent)
Information on adsorption and desorption should be provided, with results expressed in terms of the adsorption and desorption of the chemical in/from standard soils under standard test conditions. This data is necessary for the evaluation of the tendency of chemicals to migrate into the air, water and soil or sediment compartments of the environment. Adsorption and desorption processes also have an effect on the transport of chemicals and on their bioavailability.

9(h) Dissociation constant (TG 112 or equivalent)
The dissociation constant (in pKa) is required for all chemicals that dissociate in water.
The method of determination should be stated. The extent of dissociation of a chemical in water governs the forms that it will take in the aquatic environment. Knowledge of the dissociation constant, together with the pH of the systems in which a chemical is likely to be found, makes it possible to estimate the extent to which dissociated and undissociated forms will be present.

9(i) Particle size (distribution)/fibre length (TG 110 or equivalent)
The mean particle size and particle size range of the substance is required (for solids only). In particular, the respirable fraction (1-10 ∝m) should be indicated. For fibrous substances, the fibre length and length range is required instead. Particle size is one factor which influences the distribution and mass transport of insoluble and non-volatile particles in water, air and, in some cases, the upper soil layer. Furthermore, the tendency of a chemical to settle and penetrate biological tissue, for example, inhalation characteristics, depends on particle size.

9(j) Flashpoint (open cup/closed cup)
The flash point (in °C) of the chemical is required, with its method of determination (open or closed cup method).

9(k) Flammability limits (%) (explosive limits)
The degree of flammability is required, that is:

- pyrophoric;
- highly flammable;
- flammable;
- combustible; or
- not flammable.

The upper and lower percentage limits of flammability in air are required. These limits indicate the percentage concentrations of flammable vapour in air at which a flame can be propagated or an explosion will occur.

The distinction between flammable and combustible should not be overlooked. For example, sodium chloride, carbon tetrachloride and carbon dioxide are noncombustible and non-flammable, but sugar, cellulose and ammonia are combustible but non-flammable. Details on the nature and identity of toxic and hazardous combustion products are required.

9(l) Auto ignition temperature
The minimum temperature (in °C) for auto ignition should be provided. Auto ignition is the minimum temperature required to initiate or cause self-sustained combustion in any substance in the absence of a high-temperature ignition source, such as a spark or flame.

9(m) Explosive properties
Information on the chemical's potential to detonate as a result of heat, shock or friction, is required. Details on the nature and identity of hazardous explosion products should be provided.

9(n) Reactivity
Any information about the stability and reactivity of the chemical is required, including:

- oxidising properties;
- incompatibility with other substances;
- conditions contributing to instability; and
- full information on the decomposition products and their hazards.

Use of calculated data
The provision of estimated values for physico-chemical parameters derived from Quantitative Structure Activity Relationships (QSARs) is not encouraged and will only be accepted as a last resort after all other efforts to obtain data, including from the literature, have been exhausted.

The QSAR procedures involve the use of empirical relationships between the n-octanol/water partition coefficient (log Pow) and parameters such as water solubility and soil absorption/desorption coefficients that have been established for certain broad chemical classes. The use of this method, however, involves inherent statistical

undertainties and, moreover, its applicability depends on the avilability of reliable values for log Pow. The use of QSAR estimated data is inappropriate if the unknown compound contains cationic or anionic groups [or has the potential to become charged in the environmental pH range (4>pH<9)], and particularly so if the material is expected to possess surfactant properties.

The limitations of QSAR estimates and the scientific caution required in their interpretation and use have been well documented by Kaiser *et al* (Kaiser K. L. E., Deardon J. C., Klein W. and Schulz T. W.; "A note to users of ECOSAR"; *Water Quality Research Journal of Canada*, **34(1)**, pp 179-182, 1999). In some cases the inherent instability of a compound may preclude accurate experimental determination of certain properties, and in such cases QSAR
estimates may be acceptable.

10. Methods Of Detection And Determination

A listing of the analytical methods used for the detection and determination (assay) of the chemical is required. Where standard methods are used, the appropriate bibliographical references should be stated. Otherwise, a description of the method(s) should be given such that a competent analytical chemist could repeat the measurements without further aid.

11. Label

A copy of the proposed label(s) for the notified chemical and all products containing the notified chemical shall be compiled in accordance with the NOHSC *National Code of Practice for the Labeling of Workplace Substances*, and included in the notification statement.

12. Material Safety Data Sheet

MSDS provide information needed to allow the safe handling of substances. They are used by employers to ensure that employees have ready access to information on substances used at work. In each notification statement, a copy of the proposed MSDS for the chemical must be provided. MSDS are required for all chemicals notified under NICNAS, not just hazardous chemicals. Where the chemical is available commercially from the notifier in other products, for example, as an ingredient in a polymer mixture, then MSDS for those products must also be submitted. Where the chemical exists in more than one form in the notifier's workplace, for example, as an ingredient in a solvent mixture, then MSDS for those products must also be submitted. All MSDS should be compiled in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets*. An original that can serve as a camera-ready copy for publication with the full public report should be included.

13. Emergency Procedures

Information on emergency procedures should include the UN Number, proposed Dangerous Goods Class(es) and the Hazchem Code. This information will be

determined using the classification in the *Australian Code for the Transport of Dangerous Goods by Road and Rail.*

13(a) Occupational emergency procedures
A full description of procedures employed to render the chemical harmless in the workplace is required. This should include environmental emergencies, for example, spillage or release of the chemical in the workplace, and personnel emergencies, for example, inhalation of leaking vapours by workers.

13(b) Environmental emergency procedures
A full description of procedures employed to render the chemical harmless outside the workplace is required. This should include procedures for managing:

- workplace emergencies affecting the public at large, for example, a gas release affecting nearby residents;
- transport emergencies; and
- emergencies at storage facilities outside the workplace.

This information should include the possibility of:

- recovery;
- containment;
- neutralisation; and
- destruction, for example, incineration.

SCHEDULE PART C

In this section, the numbering is consistent with the numbering in the Schedule to the Act.

INTRODUCTION

Part C of the Schedule specifies the health and environmental effects data that must be submitted as part of a Standard Notification statement. Complete study reports must be provided. All data should specify:

- the organisation responsible for the test; and
- whether standard protocols and good laboratory practice were followed.

The numbers in parenthesis after each test are the method numbers used in the OECD *Guidelines for the Testing of Chemicals*. Ideally, toxicity tests should be carried out in accordance with these or equivalent guidelines. It should be noted that this *Handbook for Notifiers* is not intended to provide detailed instructions on test procedures, and notifiers are referred to appropriate sources for comprehensive information on test procedures.

ACUTE TOXICITY DATA

Information on the acute toxicity of the chemical will give a measure of the toxic effects following short term exposure of the substance, and may indicate its specific toxic effects and possible mode of action. The tests undertaken should be relevant to the physical properties of the chemical and take into consideration the way in which the chemical is to be used.

LD50 values are not mandatory requirements and procedures such as the limit test are acceptable.

(a) Acute oral toxicity (TG 401 or equivalent)

Acute oral toxicity testing provides information on the health hazards likely to arise from a short-term exposure by the oral route. The results may provide information on the chemical's mode of toxic action.

The data required includes:

- some quantitative measure of toxicity with an indication of accuracy;
- test animal used, indicating number, species/strain and sex;
- the nature of the dosed material, for example, solution or suspension (details of the vehicle used (if any) should be provided);
- method; and
- results of testing, including:
  - tabulation of response data by number, sex and dose level,
  - toxic effects seen, time of onset and duration,
  - time of death after dosing,
  - slope of dose-mortality curve, where possible, and
  - effects on the organs, for example, gross findings at autopsy and histological data.

(b) Acute dermal toxicity (TG 402 or equivalent)

Acute dermal toxicity testing provides information on the health hazards likely to arise from a short-term exposure to the skin. The results may provide information on dermal absorption and the chemical's mode of toxic action by this route.

The data required includes:

- some quantitative measure of toxicity with some indication of accuracy;
- test animal used, indicating number, species/strain and sex;
- the nature of the dosed material, for example, solution or suspension (details of the vehicle used (if any) should be provided);
- method; and
- results of testing, including:
  - tabulation of response data by number, sex and dose level,
  - toxic effects seen, time of onset and duration,
  - time of death after dosing,
  - slope of dose-mortality curve, where possible, and
  - effects on the organs, for example, gross findings at autopsy and histological data.

(c) Acute inhalation toxicity (TG 403 or equivalent)

The acute inhalation toxicity of the chemical, such as a gas, volatile substance or aerosol/particulate, provides information on health hazards likely to arise from short-term exposure by inhalation. The results may provide additional information on the chemical's mode of toxic action.

The data required includes:

- some quantitative measure of toxicity with some indication of accuracy;
- test animal used, indicating number, species/strain and sex;
- nature of dosed material, with particle size if aerosol or particulate;
- method; and
- results of testing, including:

- tabulation of response data by number, sex and dose level,
- toxic effects seen, time of onset and duration,
- time of death after dosing,
- slope of dose-mortality curve, where possible, and
- effects on the organs, for example, gross findings at autopsy and histological data.

IRRITATION/CORROSION

Information derived from irritation testing serves to indicate the possible existence of hazards likely to arise from exposure of the skin, eyes and mucous membranes to the chemical. Chemicals that have predictable corrosive potential based on physico-chemical properties, such as strong acidity or alkalinity, are often not tested in animals for irritation.

(d) Skin irritation (TG 404 or equivalent)

A finding of dermal (skin) irritation by the chemical on the skin of mammals indicates the existence of possible hazards likely to arise from exposure of the human skin to the chemical.

The dermal irritation assessment should be made in conjunction with an assessment of the nature, intensity and reversibility of the observed response. The data required includes:

- test animal used, indicating number, species/strain and sex;
- method;
- form of the dose; and
- results of testing, including:
  - tabulation of response data by number, sex and dose level for each observation time period, for example, 30-60 minutes, 24, 48 and 72 hours after patch removal, and
  - description of any lesions observed, together with the onset time and recovery period.

(e) Eye irritation (TG 405 or equivalent)

Results of animal eye irritation studies can help to predict possible hazards likely to arise from exposure of human eyes and associated mucous membranes. An assessment of the severity of acute eye irritation is required. Evaluation should be made in conjunction with an assessment of the nature and reversibility of the response observed. The data provided should include:

- test animal used, indicating number, species/strain and sex;
- method;
- physical nature and, where applicable, concentration and pH value for the test substance; and
- results of testing, including:
  - tabulation of response data by number and sex at each observation time, for example, 1, 24, 48 and 72 hours, and
  - description of the degree and nature of irritation/corrosion on the cornea, iris and conjunctiva, with time onset, severity and recovery period.

SENSITISATION

(f)(i) Skin sensitisation (TG 406 or equivalent)

The potential of a chemical to provoke a skin sensitisation reaction (dermal sensitisation or allergic contact dermatitis) can help to predict the possible hazard to a human population that is repeatedly exposed to the chemical. In animal studies, the two preferable methods have been the Magnusson and Kligman Guinea-Pig Maximisation Test, which use an adjuvant, and the Buehler Test, also in guinea pigs, but without an adjuvant. More recently, mouse models for assessing sensitisation potential have been developed, namely the ear-swelling test and the local lymph node assay. Both assays can detect moderate to severe sensitisers.

For animal studies, the data provided should include:

- test animal used, indicating number, species/strain and sex;
- method; and
- results of testing, including:
  - tabulation of response data by number, sex and age of treated and control animals
  - dose level administered at each stage, and
  - whether irritation occurred during the induction stages and any histological abnormality at the conclusion of the test.

For some chemicals, human patch tests may have been conducted. If so, the study and results should be provided.

(f)(ii) Respiratory sensitisation

No standard OECD guidelines are available for the determination of the respiratory sensitising potential of chemicals in animals. If non-standard studies are available, they should be submitted. Similarly, any human evidence regarding this effect should be provided.

(g) Repeated dose toxicity

Repeated dose toxicity data provides information on possible health hazards likely to arise from repeated exposures over a limited period of time. The basic study used for repeated dose toxicity is normally the 14-day or 28-day oral study (TG 407 or equivalent). This method may provide information on neurological effects, immunological effects and reproductive organ toxicity. Where toxicity arising from dermal absorption has been observed in acute toxicity studies, and human skin contact is likely during use of the chemical, a 14-day to 28-day repeated dose dermal toxicity study (TG 410 or equivalent) should be conducted to provide information on possible health hazards likely to arise from repeated skin contact. Similarly, where toxicity arising from inhalation has been observed in acute toxicity studies, and inhalation by humans is likely during use of the chemical, a 14-day to 28-day repeated dose inhalation toxicity study (TG 412 or equivalent) should be conducted to provide information on possible health hazards likely to arise from repeated inhalation.

Data from each study should include:

- test animal used, indicating number, species/strain and sex;
- dosing vehicle, if any;
- route and frequency of administration;
- method;
- results of testing, including:

- tabulation of toxic response data by number, sex and dose,
- description of effects observed on the animal and its organs, including clinical biochemistry and pathology investigations (include signs of toxicity, their time and onset of duration, whether the effects were reversible, and necropsy and histological findings), and
- discussion of the results and conclusions of the study.

GENETIC TOXICOLOGY

The primary function of genotoxic testing is to investigate the potential of the chemical to induce mutations in the human genome and the potential for any mutations to be transmitted through the germ cells to future generations. The battery of tests should include:

- a test which demonstrates the chemical's ability to induce point mutations in established microbial systems; and
- a test that demonstrates any production by the chemical of chromosome damage in mammalian cells grown *in vitro.*

There are a number of tests in each group that may be selected. Notifiers are referred to the OECD *Guidelines on Genetic Toxicology Testing and Guidance on the Selection and Application of Assays* for a listing of tests that may be used. Equivalent or appropriate tests from other recognised protocols can also be used. The selection of tests to be used in the battery will depend on:

- the nature of the chemical;
- the extent of its eventual distribution and use;
- data from other toxicological tests and toxicokinetic studies; and
- the available technical expertise.

(h) Induction of point mutations (TG 471, TG 472 or equivalent)
A test designed to demonstrate the induction of point mutations (base-pair change and frame shift mutations) in established microbial test systems is required, with and without the use of appropriate metabolic activation systems. Suggested methods include TG 471 *Salmonella typhimurium* Reverse Mutation Assay and TG 472 *Escherichia coli* Reverse Mutation Assay.

(i) Induction of germ cell damage (TG 478 or equivalent)
A test designed to detect the induction of germ cell damage *in vivo* is required. A suggested method is test method TG 478 the Dominant Lethal Test in the Rat or Mouse.

(j) Chromosome damage (TG 473, TG 474, TG 479 or equivalent)
A test designed to demonstrate the production of chromosome damage in appropriate mammalian cells grown *in vitro* is required, with and without the use of appropriate metabolic activation systems. Suggested methods include TG 473 *In vitro* Mammalian Cytogenetic Test, TG 474 Micronucleus Test and TG 479 *In vitro* Chromatid Exchange Assay.

ECOTOXICITY DATA

Information on the ecotoxicity of the chemical is required to give a measure of the short-term toxic effects on biotic systems. The data provided should specify:

- organisation responsible for the test;
- whether standard protocols and good laboratory practice were followed; and
- number of animals or plants used.

Results calculated from measured/actual concentrations are strongly preferred over results calculated from nominal concentrations. The use of QSAR generated data for fish, *Daphnia* and algal toxicity is not encouraged and will only be accepted as a last resort. The limitations of this approach have been documented by Kaiser *et al* (Kaiser, K.L.E.: Deardon, J.C.; Klein, W.; and Schultz, T.W.; 'A Note to the Users of ECOSAR'; Water Quality Research Journal of Canada, **34(1)**, pp 179-182, 1999).

(k) Fish, acute toxicity test (TG 203 or equivalent)

An assessment of the acute toxicity of the chemical to fish is made after continuous exposure of the fish to a series of concentrations of the chemical in water over a period of four days. Mortalities and any abnormal responses are recorded over this period. The data required includes:

- measure of toxicity, for example, LC50 (in mg/L), with confidence limits;
- number and species of fish used;
- duration of exposure;
- no-effect level (in mg/L);
- method; and
- results of testing, including:
  - tabulation of mortality against concentration according to observation time, and
  - concentration-mortality curve at end of test.

(l) Daphnia, acute immobilisation test and reproduction test (TG 202 or equivalent)

An assessment of the toxicity of the chemical to aquatic invertebrates is made by the exposure of daphnids to a series of concentrations of the chemical in water. The test comprises two phases:

- acute phase, which gives:
  - 24 hour EC50 value,
  - highest concentration causing no immobilisation, and
  - lower concentration causing 100 % immobilisation; and
- reproduction phase, which gives:
  - EC50 (immobilisation) values over period of 1-14 days,
  - no observed effect concentration (in mg/L), and
  - other information based on reproduction observations.

The data provided should include:

- number and species of *Daphnia* used;
- duration of exposure;
- concentrations used;
- description of the methods used; and
- tabulation of concentration-response time results.

It should be noted that a *Daphnia sp* reproduction test is a Schedule item and therefore should be provided, especially when acute toxicity and exposure to the aquatic compartment are both high. In the absence of this part of the test, a variation to the data requirements should be submitted along with supporting scientific argument to fully justify the omission, for example, limited aquatic exposure.

(m) Algal growth inhibition test (TG 201 or equivalent)
An assessment of the potential effects of the chemical on the natural environment is made by exposing algae to a series of concentrations over at least three days. Algae growth is determined after each day, and the algae concentration per mL is calculated for each time and concentration. An assessment can be based on the 72 hour EC50 value and the growth concentration curves.
The data provided should include:

- test organisms used, for example, origin, strain and method of cultivation;
- test conditions used, including concentrations used and duration of test; and
- results of testing, including:
  - EC50 value,
  - no observed effect concentration,
  - assessment of time-effect relationship,
  - cell concentrations and concentration-effect relationship, and
  - other observed effects.

BIODEGRADATION

An assessment of the potential of the chemical to biodegrade in the environment is required. Therefore, test results for ready biodegradability should be provided. The method used and the body responsible for the test should be indicated.

(n) Ready biodegradability (%) (TG 301A-F or equivalent)
As assessment of the ability of the chemical to rapidly biodegrade in the environment is made by studying the biodegradation of the chemical in aqueous solutions over a period of up to 28 days.

The data provided should include full details of the method used in the test and tabulation of the time-effect results. For some chemicals not readily biodegradable, the inherent and ultimate biodegradability (TG 302A-C or equivalent) of the chemical may be required.

NOTE: Although not a scheduled item, it is increasingly common that biodegradation data obtained under anaerobic conditions is available. If it is available, this data should be provided in notification dossiers, particularly if the notified material is likely to become associated with aquatic sediments. Similarly, data on biodegradation in seawater should also be provided if available.

(o) Bioaccumulation
An assessment of the potential of the chemical to bioaccumulate in the environment, both aquatic and terrestrial, is required. A full bioaccumulation test is not a Schedule requirement, however, results should be provided if available.

The assessment should take into consideration:

- partition coefficient for n-octanol/water;
- fat solubility;
- water solubility; and
- ready biodegradability.

If the chemical has a low partition coefficient and/or is readily biodegradable, then no bioaccumulation testing is required. Notifiers are referred to the OECD *Testing Guidelines on Degradation and Accumulation* for further information.

SCHEDULE PART D

Part D refers to Polymers. In this section, the numbering is consistent with the numbering in the Schedule to the Act.

IDENTITY AND COMPOSITION OF THE POLYMER

Information given in this section must characterise the polymer as closely as possible. The information should be complementary to that given under paragraphs 1 and 2 of Part B of the Schedule, where details of the complete polymer mixture, that is, the polymer and its additives/adjuvants, are provided. All monomers and other reactants should be identified according to the guidelines in section 1 of Part B of the Schedule.

1. Weight-percentage of ingredients

The maximum weight-percentage of each monomer and all other reactants used to manufacture the polymer is required. Include all substances used in the manufacture of the polymer and which become part of the polymer composition. Reactants include chain transfer and cross-linking agents, modifying groups and other end groups incorporated into the polymer. Also include post-reacting agents used in the manufacture of post-reacted polymers.

The weight-percentage of reactant must be based on the dry weight of polymer.

2. Number-average molecular weight of the polymer

If more than one molecular weight composition of the polymer is to be manufactured, then the number-average molecular weight of the lowest molecular weight composition is required. The weight average molecular weight and an indication of the molecular weight

distribution (polydispersity) should also be provided. The method used to determine the molecular weight, for example, size exclusion chromatography, and the organisation conducting the test, should be stated. A report of the analysis must be included in the notification statement.

3. Maximum weight-percentage of residual monomer(s) and all other reactants

The maximum weight-percentages of all residual monomers and other reactants (as listed in paragraph 1 of Part D of the Schedule) at the completion of manufacture or at the time of importation are required. The method used to determine the concentrations of reactants, for example, gas chromatography, and the organisation conducting the test, should be stated. A report of the analysis should be included in the notification statement.

4. Low molecular weight polymer

The maximum weight percentage of the low molecular weight fraction of the polymer is required, that is, the fraction with molecular weight below 1,000 daltons and the fraction with the molecular weight below 500 daltons. The method used to determine the low molecular weight fractions and the organisation conducting the test should be stated. A report of the analysis should also be included in the notification statement. The low molecular weight fractions are usually determined in the one analysis with the weight-average and number-average molecular weights (see paragraph 2 of Part D of the Schedule).

5. Degradation products
Information on all products resulting from the degradation, decomposition or depolymerisation of the polymer is required, including identification of the products. Details should include the conditions under which degradation, decomposition or depolymerisation take place. The rate and mode of degradation, decomposition or depolymerisation should be provided, together with the likely proportion of products formed. In particular, information on all dangerous and hazardous products should be provided.
Information on the degradation products likely to be produced during or after the disposal of the polymer should be included.

6. Loss of monomers, other reactants, additives and impurities
Information on the natural loss of monomers, reactants, additives and impurities from the polymer is required in order to assess health and environmental effects during use of the polymer. This data should include:

- loss by volatility, for example, monomer;
- loss by exudation, for example, additive; and
- loss by leaching, for example, by water or oil.

The conditions under which such loss may occur should be indicated.

DATA REQUIREMENTS FOR POLYMERS OF LOW CONCERN

Form 1-PLC specifies the information required for the notification statement for Polymers of Low Concern (PLC) (see Appendix 1 - *Forms*.) It may be necessary to attach supporting data if the space on the form is insufficient. Notifiers need not submit raw data, such as toxicological studies with their Form1-PLC. However, such data should be easily accessible to the notifier in case further information is required for assessment. The information to be provided on or with Form 1-PLC is stipulated below.

(a) Chemical name of the polymer
The exact chemical name, as described in paragraph 1(a) of Part B of the Schedule is required. The chemical name to be provided is the Chemical Abstracts (CA) Preferred Index name or the International Union for Pure and Applied Chemistry (IUPAC) name of the polymer. An assessment certificate cannot be issued unless NICNAS is informed of the identity of the polymer. If the identity is considered confidential, an application for the Data Requirements

(b) Marketing or other name(s)

Include all the alternative chemical names by which the polymer is known and all trade or marketing names for the polymer.

(c) Chemical Abstracts Service (CAS) number
The CAS number, as described in paragraph 1(d) of Part B of the Schedule is required. If a CAS number has not been assigned to the chemical, this should be indicated on the form.

(d) Justification for 'low concern' classification
The notifier must demonstrate that the polymer meets the criteria for a PLC so, in most circumstances, all of the Yes boxes on Form 1-PLC should be ticked. If the notifier believes that, for example, the notified polymer does not meet one of the criteria yet the polymer should be regarded as a PLC, then the relevant No box should be ticked and information and data to support the application should be provided.

(e) Molecular formula
The molecular formula should be provided in the form (monomer 1)a.(monomer 2)b....(monomer m)n.

(f) Structural formula
A structural representation of the polymer indicating the location of atoms, ions or groups and the nature of the bonds joining them must be provided. If space is insufficient, attach a separate sheet. If the polymer is random and cannot be represented, this should be stated, and the structure of monomer components provided.

(g) Means of identification
A list of the spectral data available to confirm the identity and structural formula of the notified polymer must be provided. For example, the list could include infrared, nuclear magnetic resonance, ultraviolet-visible and/or mass spectroscopy data (see paragraph 1(g) of Part B of the Schedule). A copy of at least one example of spectral data should accompany Form 1-PLC.

(h) Number-average molecular weight
The number-average molecular weight must be provided, as described in paragraph 2 of Part D of the Schedule in this Chapter. A copy of the analysis should accompany Form 1-PLC.

(i) Weight percentage of molecules with molecular weight less than 1000 daltons and less than 500 daltons
The percentages of low molecular weight species below 1000 daltons and 500 daltons must be provided. As described in paragraph 4 of Part D of the Schedule, normally this information can be determined from the gel permeation chromatographic measurement of the number-average molecular weight.

(j) Charge density
The notifier must demonstrate that the polymer meets the PLC criteria for low charge density. The questions on charge density and cationic potential on Form 1-PLC must be answered and, if the polymer contains any charged groups, a calculation of the charge density must be provided. The charge density should be provided in terms of

the number of charges per 1000 daltons molecular weight, or the equivalent weight of charged groups, which is the ratio of the number-average molecular weight to the number of charged groups in the polymer. Comments on the potential for ionisation in the pH range (4-9 inclusive) likely to be encountered in the environment should be included.

(k) List of polymer constituents
The correct chemical name, CAS number and the weight percentage of each of the polymer constituents (monomers and other reactants) must be provided. All test data must be supported by methodology. Compliance with currently accepted principles of good laboratory practice is preferred and should be stated if it applies. All information submitted should be referenced wherever possible.

(l) Residual monomer content
The identity and weight percentage of all residual monomers and other reactants must be provided. A copy of the analysis should accompany Form 1-PLC. Notifiers should note that a PLC must satisfy the criteria for low molecular weight species. Low molecular weight species include monomers and other reactants and low molecular weight oligomers.

(m) Water solubility
The water solubility in mg/L must be provided. Notifiers should specify whether the figure quoted is a test result or an estimate. For test results, a copy of the analysis should accompany Form 1-PLC.

(n) Particle size distribution
For polymers that are solids, the mean particle size and the particle size distribution must be provided, including the percentage of particles in the respirable and inspirable ranges. A copy of the analysis should accompany Form 1-PLC.

(o) Stability of the polymer
Notifiers must comment on the potential for the polymer to break down by hydrolysis, thermal degradation, photodegradation, depolymerisation or otherwise, under processing and normal conditions of use.

(p) Residual reactive functional groups
The presence and identity of reactive functional groups that are intended to, or are reasonably likely to, undergo further reaction must be specified. If no such groups are present, this should be stated.

(q) Intended use(s)
As described in paragraph 3 of Part B of the Schedule, all intended uses of the polymer must be provided. For example, the polymer may be component in a paint mixture for outdoor use, or an industrial plastic for the preparation of components for the automotive industry.

(r) Appearance of the polymer
A description of the physical state and colour of the polymer at 20°C and 101.3 kPa (ambient conditions) must be provided (as described in paragraph 4 of Part B of the Schedule).

(s) Estimated manufacture or import volume
The approximate intended volumes of import and/or manufacture must be provided for the polymer during each of the first five years (as described in section 5 of Part B of the Schedule in this Chapter). The estimates should distinguish between the notified polymer and any imported or manufactured products containing the polymer.

(t) Site of manufacture or reformulation
Notifiers must include a list of the Australian sites where the polymer or formulations involving the polymer are to be manufactured. If the polymer is imported in a product, notifiers should advise whether, and where, the polymer is packaged or reformulated prior to further transport and use.

(u) Physico-chemical properties
Data on certain physico-chemical properties are required. These data items are melting point, density, flammability limits, auto ignition temperature, explosive properties and reactivity, for example, oxidation potential. Guidance on these properties can be found in paragraph 9 of Part B of the Schedule.

(v) Occupational health and safety data
The information to be provided on occupational health and safety is similar to that specified for most other categories of notification. The information can be provided in summary form on Form 1-PLC. However, it is likely that insufficient space will be available on the form and information will need to be appended. The submission should address occupational health and safety issues at all stages of the polymer's manufacture, formulation and end-use. Processes should be described in sufficient detail for the assessor to determine the route, extent and significance of possible exposure and the effectiveness of the proposed control measures. The information to be provided is itemised on Form 1-PLC. However, notifiers should consult paragraph 6 of Part B of the Schedule for guidance.

(w) Environmental Impact
The information required on environmental impact can be provided in summary form on Form 1-PLC. It is possible that insufficient space will be available on the form and information will need to be appended. Release of the polymer to the environment is required for all stages of the polymer's manufacture, formulation and end-use. Processes should be described in sufficient detail for the assessor to determine the extent and significance of possible environmental exposure. Storage and disposal of the polymer should be considered. Where there is both a high content of low molecular weight species as well as a high release to water, aquatic toxicity for fish, daphnia and/or algae may be required. Notifiers should consult paragraph 7 of Part B of the Schedule in this Chapter for further guidance.

(x) Public Health
The information to be provided on public health is similar to that required for most other categories of notification. The information can be provided in summary form on Form 1-PLC. However, in some cases, additional information will need to be appended. The submission should consider possible exposure to the public at large at all stages of the polymer's manufacture, formulation and end-use. Where there is both a high content of low molecular weight species and the polymer is to be used as an

ingredient in a cosmetic product at 1% or more, additional information, e.g. toxicological data, may be required. Notifiers should consult paragraph 8 of Part B of the Schedule for further guidance.

(y) Label

A copy of the proposed label(s) for the notified polymer and all products containing the polymer shall be compiled in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* and submitted with Form 1-PLC.

(z) Material Safety Data Sheet

A copy of the proposed MSDS for the notified polymer and all products containing the polymer shall be compiled in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)] and submitted with Form 1-PLC.

13. AICS Online Training

Guidance for Searching AICS online

AICS online is the list of chemicals on the non-confidential section of the Australian Inventory of Chemical Substances (AICS) that can be searched via the Internet. This list is updated every fortnight.

Suggested strategy of Searching

AICS online can be searched using the following three chemical identifiers:

- **CAS Number**
  This is the easiest and fastest method to search AICS online. We recommend that you try to find the CAS number first if the chemical name you have is not on AICS. There are several useful Internet sites to help find CAS numbers.

- **Chemical Name**
  The second most useful method for searching AICS is by chemical name. However chemicals are known by many names and these may not be listed on AICS. If the chemical name you have is not found on AICS, then we recommend that you try and find other names for the chemical. There are several useful Internet sites to find other chemical names.

- **Molecular Formula**
  Search by molecular formula is least effective and recommended to be used in combination with chemical name search. Few chemicals on AICS have molecular formulas.

Internet sites

There are several Internet sites that are helpful identifying CAS numbers or chemical names:

- **Chemical information**
- **Internet search engines**

Search strategies for specific group of chemicals

Further guidance is provided for the following groups of chemicals:

- **Polymers**
- **Cosmetics**

Confidential AICS search

CAS Number Search

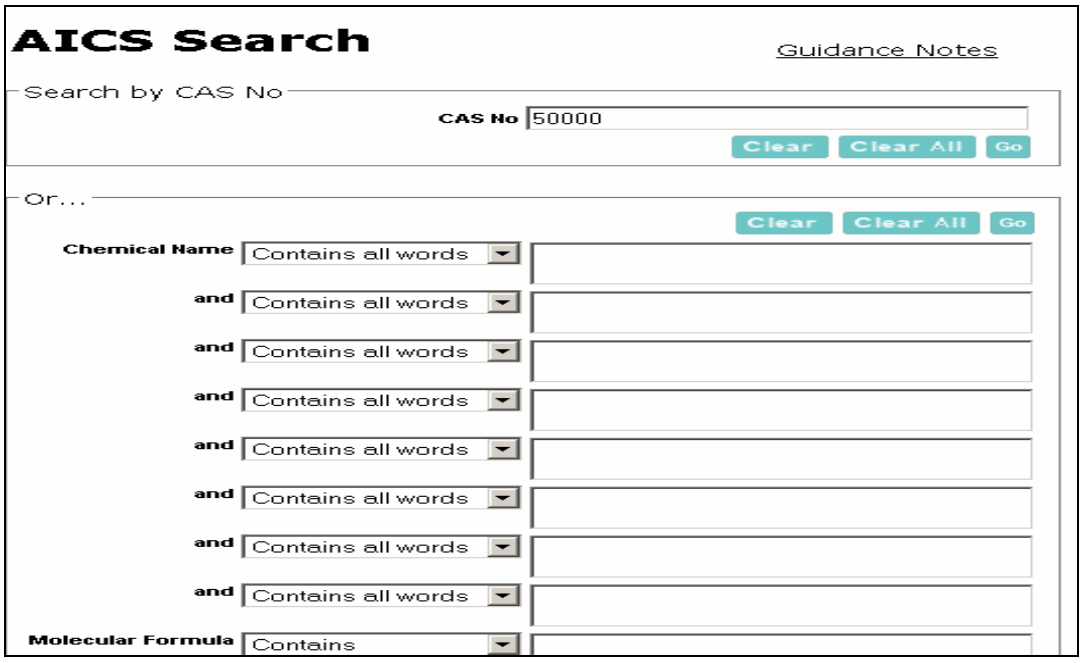
The CAS Number is a unique number assigned to a substance when it is entered into the Chemical Abstracts Service (CAS) REGISTRY database. More information on CAS is available at http://www.cas.org/EO/regsys.html and http://www.nicnas.gov.au/publications/pdf/handbook/appendix11.pdf.

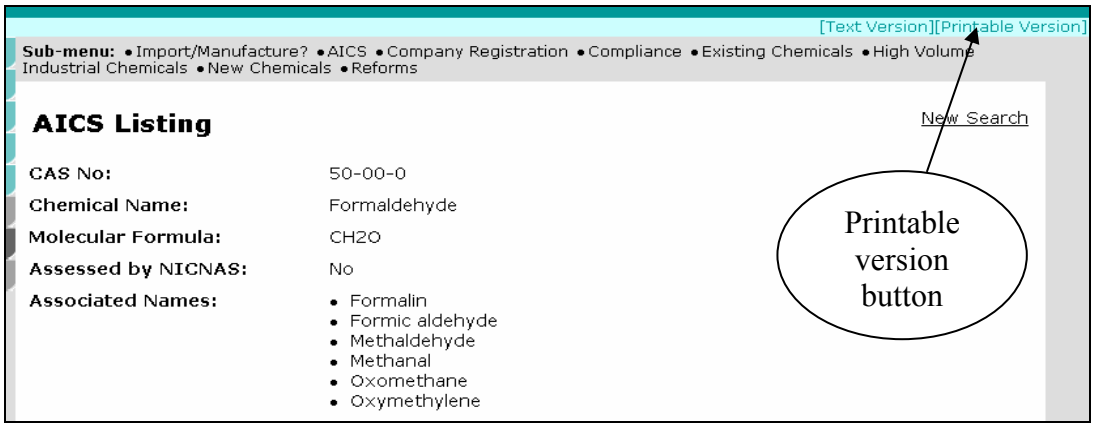
Because each CAS number is a unique identifying number, in contrast to chemical or associated names for which there may be multiple names in use for a chemical, searching the AICS using CAS number is the easiest and least ambiguous method of identifying whether chemicals are listed or not.

The format of CAS number is three blocks of numbers separated by dashes i.e. XXX-XX-X. The first block can be between 2 and 6 digits. The second block has only 2 digits and the last block is always a single digit. Any preceding zeros in the first block need to be discarded. For example, the CAS number for formaldehyde is 50-00-0.

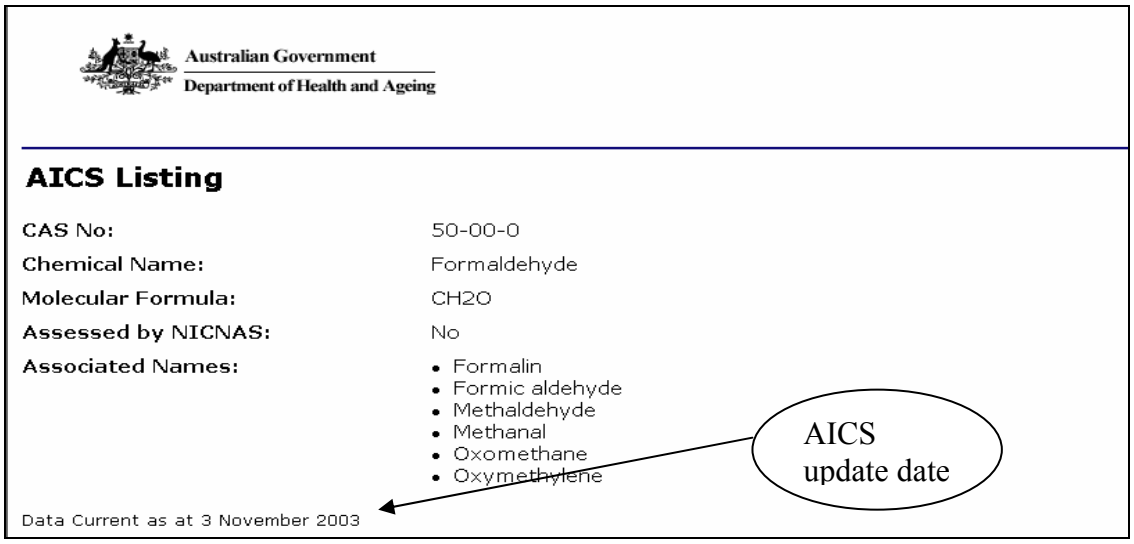
If the entered CAS number matches a CAS number listed on AICS exactly, details of the chemical will be displayed on the screen. The result of a search using a CAS number is limited to only a single chemical. If CAS number entered is not the correct format (eg. too few or many numbers), an alert message will be displayed. The CAS number search field will not accept "wild card" searches.

As an example, to search for formaldehyde, the CAS number (50-00-0 or 50000) can be entered into the search field and the search commenced by hitting Go. If no dashes are included, the system will add them to the last three digits. Below are screenshots of before and after searching for '50000'.





To print the results of the chemical search, click on the printable version. This will open the search result in a window suitable for printing (below).



If there are no hits for the CAS number then a negative search screen will appear stating "No results found".

Chemical Name Search

Chemicals are listed under 'Chemical Name' with their CAS approved name. Chemicals are more commonly known by names other than their CAS approved name. Only some of these associated names or synonyms are also included on AICS. Both of these names can be searched by using the "Chemical Name Search" method.

In the example above, formaldehyde has six listed associated names on AICS. However, it has several more associated names, such as "formal" which are not listed on AICS. Therefore, if "formal" is entered for the search, a negative result will occur even though formaldehyde is listed.

The search engine for chemical name search has been set up to search for name fragments. A fragment is defined as a word, with a 'space' or 'bracket' or '–' or 'number' separating the next word.

Please note that the chemical names are in different formats on AICS (eg. extra space, bracket or sequence) and a negative result may occur if the correct format is not used. Given below are some examples for simple chemicals with different name formats:

1. Methylethyl ketone is listed (for CAS 78-93-3) whereas ethylmethyl ketone and methyl ethyl ketone are not listed, though they represent the same chemical.
2. Isopropylbenzene is listed (for CAS No. 98-82-8) whereas searching on isopropyl benzene gives no result, though the chemical is the same.
3. Sodium sulfate (7757-82-6) is more commonly known as sodium sulphate. Sulfate is the CAS approved name format.

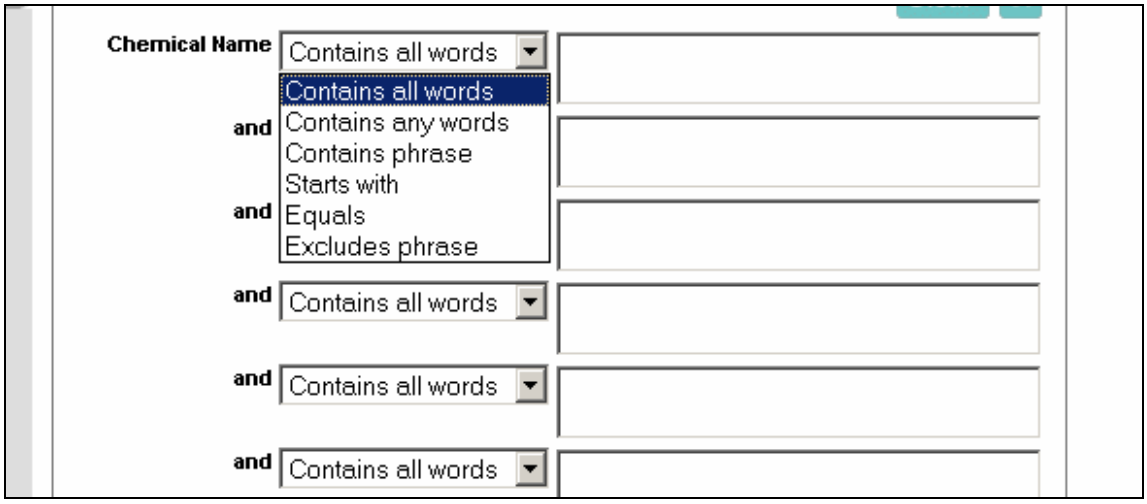
If you do not have the CAS number or correct chemical name, you should ensure that you have sufficient associated names to enable a comprehensive AICS search. Associated chemical names or synonyms can be obtained through Internet sources or other published documents.

AICS does not list trade names or International Nomenclature of Cosmetic Ingredients (INCI) names and so searching cannot be conducted for these names.

Chemical names and molecular formula searches can be enhanced by the use of the wildcard"*". This can be used in different search options.

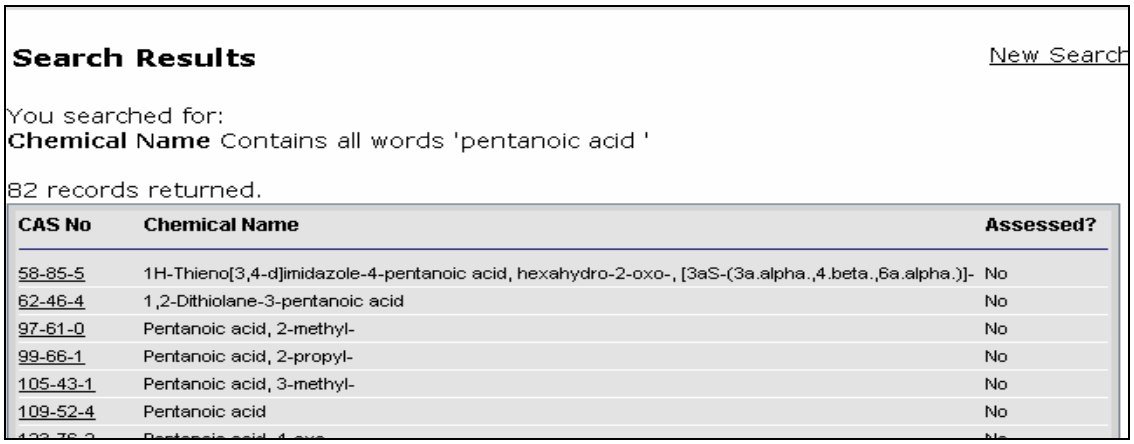
Search results are limited to 200 hits for any search. If there are more than 200 hits, the search engine returns a request to refine the search. Chemical name searches can be refined using the operator phrases available as drop down menus.

There are several options for Chemical Name Search:



(a) Contains all words: The search will be conducted on all words entered on the line. The sequence or any preceding characters (including wildcards) are ignored.

Wildcard option, "*", can be used at the end of words for search. This is the best option if a chemical name is long and has many components (eg polymers). For example, if 'pentanoic acid' is entered on the search field, the search engine will break the name into two fragments, 'pentanoic' and 'acid' and search for chemical names on AICS that contain both the fragments. There are about 82 records on AICS that contain both the fragments.



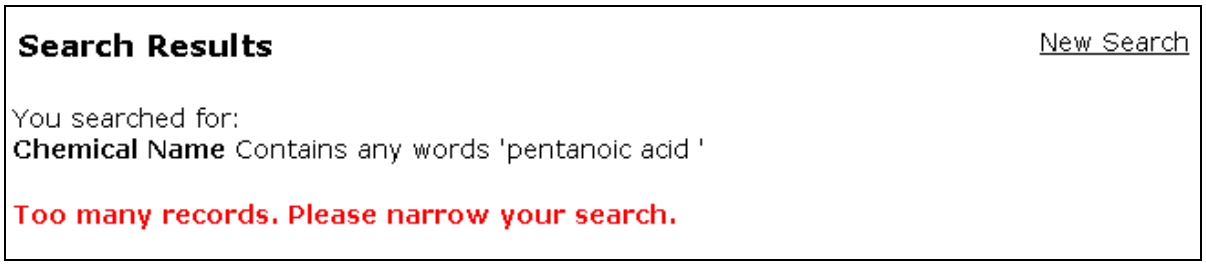
Search Results New Search

You searched for:
Chemical Name Contains all words 'pentanoic acid '

82 records returned.

CAS No	Chemical Name	Assessed?
58-85-5	1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3aS-(3a.alpha.,4.beta.,6a.alpha.)]-	No
62-46-4	1,2-Dithiolane-3-pentanoic acid	No
97-61-0	Pentanoic acid, 2-methyl-	No
99-66-1	Pentanoic acid, 2-propyl-	No
105-43-1	Pentanoic acid, 3-methyl-	No
109-52-4	Pentanoic acid	No

(b) Contains any words: This will search for any word entered on the line. This option has to be used in combination with other options as it may lead to large number of hits. For example, if 'pentanoic acid' is searched using this option, too many hits occur. This is because the search engine is trying to find if either of the fragments 'pentanoic' or 'acid' is listed in the chemical names on AICS.



Search Results New Search

You searched for:
Chemical Name Contains any words 'pentanoic acid '

Too many records. Please narrow your search.

(c) Contains phrase: This will search for any phrase entered. The sequence of the phrase items is maintained during the search. This option needs to be used with caution as it may result in a negative result if the sequence on AICS does not match the sequence of the search phrase.

For example, if 'pentanoic acid' is searched using contains phrase option, 82 records are returned, however, if the sequence is reversed and 'acid pentanoic' is searched for no results are returned.

Search Results New Search

You searched for:
Chemical Name Contains phrase 'pentanoic acid'

82 records returned.

CAS No	Chemical Name	Assessed?
58-85-5	1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3aS-(3a.alpha.,4.beta.,6a.alpha.)]-	No
62-46-4	1,2-Dithiolane-3-pentanoic acid	No
97-61-0	Pentanoic acid, 2-methyl-	No
99-66-1	Pentanoic acid, 2-propyl-	No
105-43-1	Pentanoic acid, 3-methyl-	No
109-52-4	Pentanoic acid	No
123-76-2	Pentanoic acid, 4-oxo-	No
126-00-1	4,4-Bis(4-hydroxyphenyl)pentanoic acid	No

Search Results New Search

You searched for:
Chemical Name Contains phrase 'acid pentanoic'

No results returned.

(d) Starts with: This will search for any chemical name starting with the name entered. Here wild card,"*", can be used at either side of the word for searches. This is the best option when using wildcard.

For example, if 'pentanoic acid' is searched, all chemicals where pentanoic acid is the first part of the name are displayed.

Search Results New Search

You searched for:
Chemical Name Starts with 'pentanoic acid'

79 records returned.

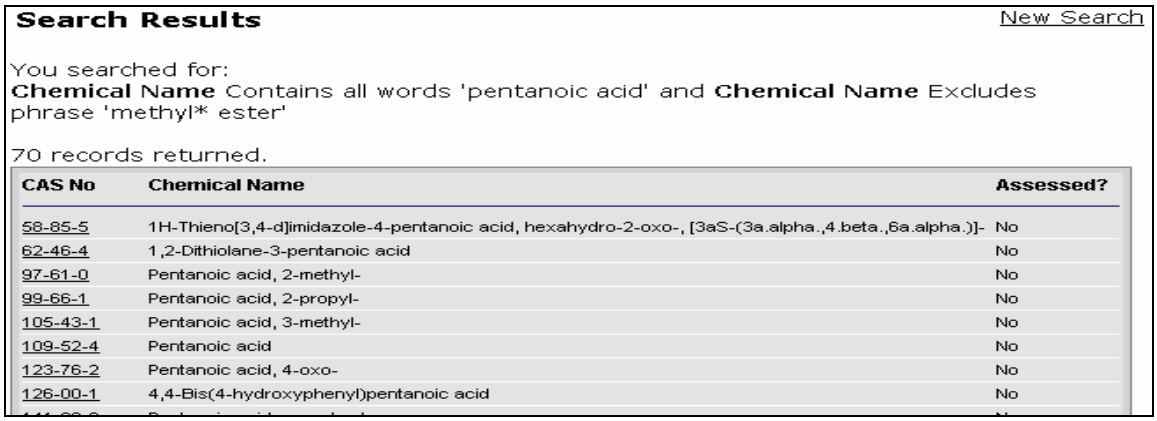
CAS No	Chemical Name	Assessed?
97-61-0	Pentanoic acid, 2-methyl-	No
99-66-1	Pentanoic acid, 2-propyl-	No
105-43-1	Pentanoic acid, 3-methyl-	No
109-52-4	Pentanoic acid	No
123-76-2	Pentanoic acid, 4-oxo-	No

(e) Equals: This search matches the exact chemical name. In this option, spaces, brackets, commas, dashes are important and unless these are entered correctly the chemical will not be matched. Wildcard cannot be used with this option. It is useful when searching for individual chemical names (eg benzene, water etc)

(f) Excludes phrase: This option will exclude any phrase/word entered. It should be noted that sequence is important in any phrase option. If you want to exclude only individual words, use this option on separate lines. This is useful to narrow down search results.

For example, to narrow down the search results for 'pentanoic acid' from 82 (using 'contains all words' option) to manageable numbers, excludes phrase may be used. First identify the words/ phrases in the list that you do not want in your results by scrolling down. Once these are identified, type the words on different search lines and use the option 'excludes phrase'.

Results when exclude terms are on same line:



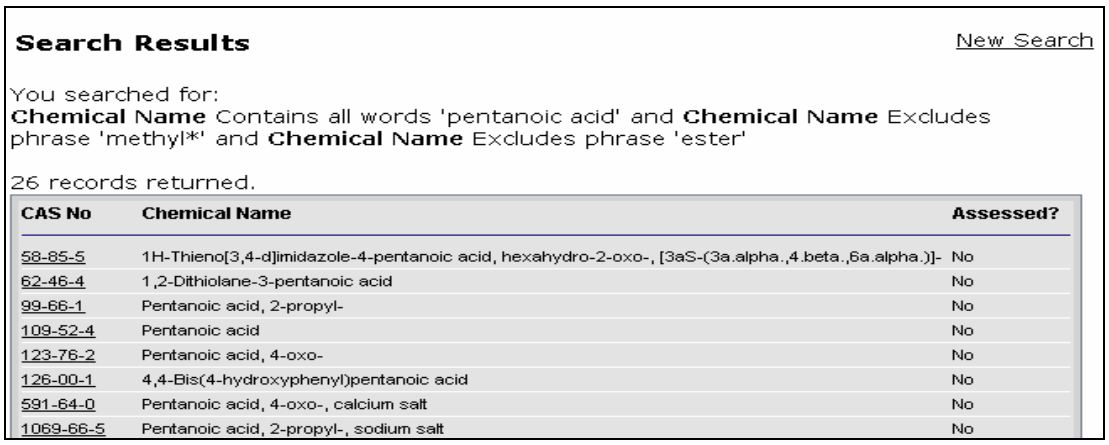
Search Results New Search

You searched for:
Chemical Name Contains all words 'pentanoic acid' and **Chemical Name** Excludes phrase 'methyl* ester'

70 records returned.

CAS No	Chemical Name	Assessed?
58-85-5	1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3aS-(3a.alpha.,4.beta.,6a.alpha.)]-	No
62-46-4	1,2-Dithiolane-3-pentanoic acid	No
97-61-0	Pentanoic acid, 2-methyl-	No
99-66-1	Pentanoic acid, 2-propyl-	No
105-43-1	Pentanoic acid, 3-methyl-	No
109-52-4	Pentanoic acid	No
123-76-2	Pentanoic acid, 4-oxo-	No
126-00-1	4,4-Bis(4-hydroxyphenyl)pentanoic acid	No

Results when exclude terms are on different search lines:



Search Results New Search

You searched for:
Chemical Name Contains all words 'pentanoic acid' and **Chemical Name** Excludes phrase 'methyl*' and **Chemical Name** Excludes phrase 'ester'

26 records returned.

CAS No	Chemical Name	Assessed?
58-85-5	1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3aS-(3a.alpha.,4.beta.,6a.alpha.)]-	No
62-46-4	1,2-Dithiolane-3-pentanoic acid	No
99-66-1	Pentanoic acid, 2-propyl-	No
109-52-4	Pentanoic acid	No
123-76-2	Pentanoic acid, 4-oxo-	No
126-00-1	4,4-Bis(4-hydroxyphenyl)pentanoic acid	No
591-64-0	Pentanoic acid, 4-oxo-, calcium salt	No
1069-66-5	Pentanoic acid, 2-propyl-, sodium salt	No

Any combination of the above operator phrases can be used to do the search.

Molecular Formula Search

Molecular formula information on AICS is limited to only a few chemicals. We recommend you use this option to assist only in narrowing chemical name searches.

The search options are:

Contains: This will search for phrase entered on the line. The sequence of phrase is maintained during the search. This option needs to be used with caution as it may result in negative result if the sequence on AICS does not match the search phrase. Wildcard, "*", can be used in the search if the sequence is not known.

Starts with: This will search for molecular formula starting with the phrase entered. Wildcard, "*", is useful to get more hits and can be used in the start or end of phrase.

Equals: This search matches the exact molecular formula. This option is useful when molecular formula is known. Wildcard is not useful in this option.

Excludes phrase: This option will exclude any phrase/word entered.

Internet sites

Chemical information databases

Given below are some links that may be useful to find chemical information. It should be noted that information on these links may not be accurate.

- US TSCA search page http://msds.pdc.cornell.edu/tscasrch.asp

  The US TSCA inventory can be searched on this site to obtain chemical identity information that can be used to search AICS.

- EU Existing chemicals page http://ecb.jrc.it/existing-chemicals/

  The EU Existing chemical inventory, EINECS, can be searched on this site by using chemical name or EINECS numbers. This site is particularly useful to identify CAS number when an EINECS number is available.

- EU cosmetics chemicals list
  http://europa.eu.int/comm/food/fs/sc/sccp/out123cm_en.pdf

  Information on cosmetic ingredients and their chemical identities are available on this site.

- International Nomenclature for cosmetic ingredients (INCI)
  http://pharmacos.eudra.org/F3/inci/index.htm

  Information on cosmetic ingredients and their chemical identities are available on this site.

- National Library of Medicine (US)
  http://chem2.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

  This site lists chemicals and available toxicity information. It is particularly useful as it lists chemicals which are not on major inventories.

- MSDS-Search
  http://www.msdssearch.com/BackgroundN.htm#USEFUL%20LINKS

  The links on this site can be used to find other sites where the chemical identities can be searched.

Internet search engines

Any Internet search engine (Yahoo, Ninemsm, Google etc) can also be used to find if information on chemical name and CAS number.

Search results can be narrowed down using the advanced search options (contains phrase, exactly etc). An easier way is to add additional search terms. For instance if you are searching for a chemical name only and get more than 2000 hits, just add the term ‘CAS number’ and redo the search. This will show the site hits where both the ‘chemical name’ and ‘CAS number’ are on the web site.

Search strategies for specific group of chemicals

Polymers

Searching for polymers by name can be difficult as the names are long and chemical names are sometimes in different formats. Given below are a few hints on how to search for polymers on AICS.

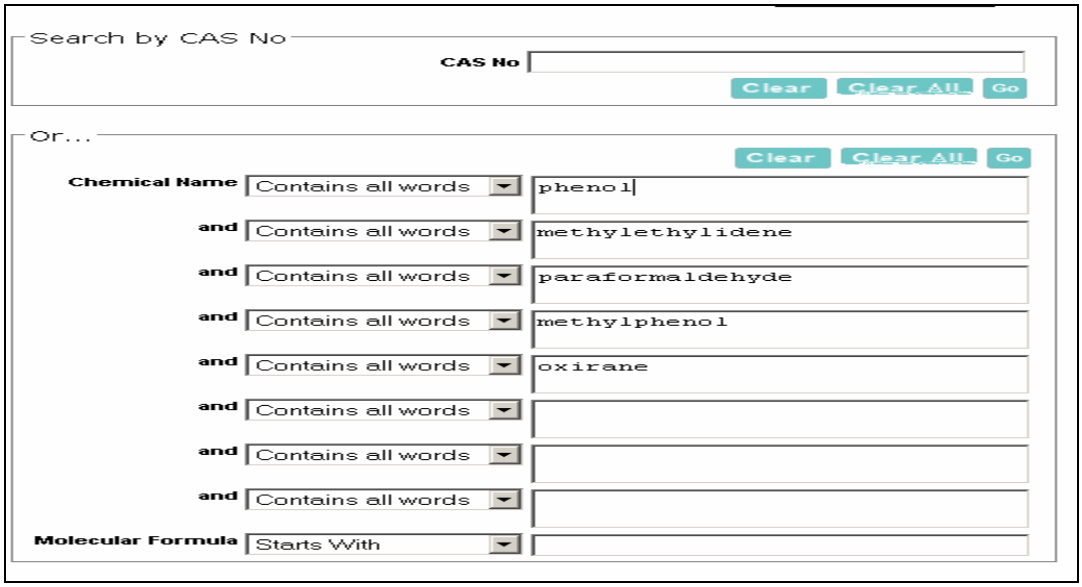
Clearly, because of the complexity of polymer names, searching for polymers on AICS using the CASRN is the best option. However, if no CASRN is available, it is best to break the chemical name into keyword fragments and search for a combination of these fragments to find the polymer. An example of a polymer chemical name search is below:

Example 1:
Polymer to be searched:
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane, polymer with paraformaldehyde, 3-methylphenol, 2-methylphenol and 4-methylphenol

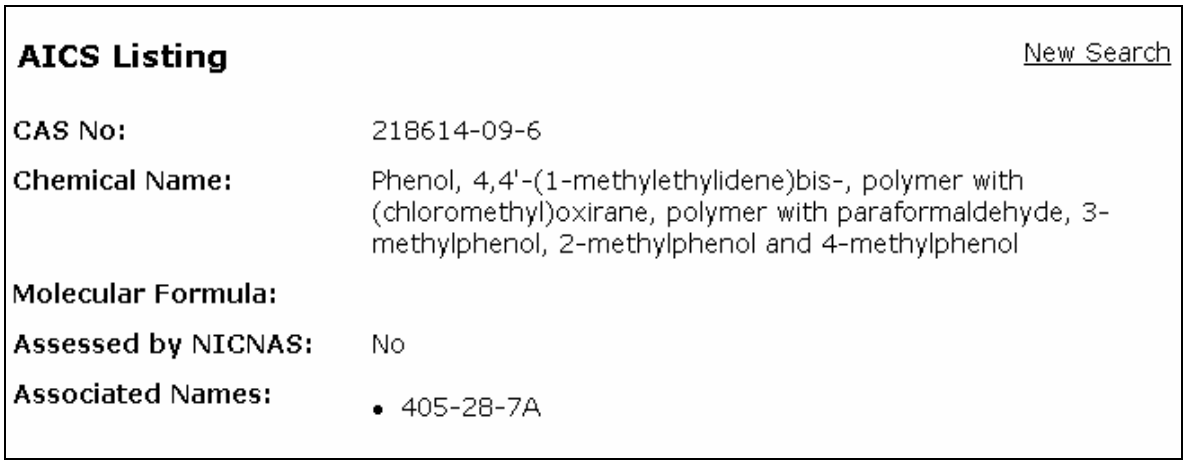
This polymer name can be broken down into the following keyword fragments:

Phenol
Methylethylidene
Chloromethyl
Oxirane
Paraformaldehyde
Methylphenol

Choose the search operator “Contains all words” and input the fragments on the same line or different lines. Click Go to search for the polymer.



If there is more than one hit for the name combination, then all the search results will be displayed. In this case only one chemical name was found on AICS and it will be displayed as follows:



Example 2:
This example demonstrates a search sequence for a polymer where the supplied chemical name is different to the name listed on AICS.

Polymer to be searched:
Acrylic acid, polymer with acrylonitrile, butyl acrylate and styrene

If the above polymer is searched for the keyword fragments acrylic acid, acrylonitrile, butyl acrylate and styrene, the search will return as negative.

However, if synonyms for each keyword fragment can be identified using AICS or other sources, these can be used for the AICS search.

Synonym for acrylic acid on AICS is:
2-propenoic acid;

Synonyms for butyl acrylate on AICS are:

2-Propenoic acid, butyl ester
Acrylic acid, butyl ester
Butyl 2-propenoate
n-Butyl acrylate

Synonyms for acrylonitrile on AICS are:
2-Propenenitrile
Cyanoethylene

Synonyms for styrene on AICS are:
Benzene, ethenyl-
Ethenylbenzene
Vinylbenzene

A combination of the above synonyms can be used for the search as shown below:

You searched for:
Chemical Name Contains all words 'propenoic acid' and **Chemical Name** Contains all words 'butyl 2-propenoate' and **Chemical Name** Contains all words 'propenenitrile' and **Chemical Name** Contains all words 'ethenylbenzene'

17 records returned.

CAS No	Chemical Name	Assessed?
25586-25-8	2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and 2-propenenitrile	No
25852-38-4	2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene and 2-propenenitrile	No
29129-78-0	2-Propenoic acid, 2-methyl-, polymer with butyl 2-propenoate, ethenylbenzene and 2-propenenitrile	No
31360-56-2	2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene, 2-propenamide and 2-propenenitrile	Yes
31392-42-4	2-Propenoic acid, 2-methyl-, polymer with butyl 2-propenoate, ethenylbenzene, methyl 2-methyl-2-propenoate and 2-propenenitrile	No
56343-89-6	2-Propenoic acid, 2-methyl-, polymer with butyl 2-propenoate, ethenylbenzene, 2-hydroxyethyl 2-methyl-2-propenoate and 2-propenenitrile	No
56507-08-5	2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene, N-(hydroxymethyl)-2-propenamide and 2-propenenitrile	No
65622-95-9	2-Propenoic acid, 2-methyl-, polymer with N-(butoxymethyl)-2-propenamide, butyl 2-propenoate, ethenylbenzene and 2-propenenitrile	No
68412-42-0	2-Propenoic acid, 2-methyl-, polymer with butyl 2-propenoate, ethenylbenzene, formaldehyde and 2-propenenitrile, butyl ester	No
69572-23-2	2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and 2-propenenitrile, ammonium salt	No
102082-99-5	2-Propenoic acid, butyl ester, polymer with ethenylbenzene,N-(hydroxymethyl)-2-methyl-2-propenamide, methyl 2-propenoate and 2-propenenitrile	No
104339-54-0	2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene, N-(methoxymethyl)-2-methyl-2-propenamide and 2-propenenitrile	No
108151-20-8	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with butyl 2-propenoate, ethenylbenzene, methyloxirane and 2-propenenitrile, acetate (salt), graft	No

Several possible candidate polymers may be returned. The correct polymer can be identified manually from the list by clicking on the CAS number (see below).

AICS Listing New Search

CAS No: 25586-25-8

Chemical Name:
2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and 2-propenenitrile

Molecular Formula: (C8H8.C7H12O2.C3H4O2.C3H3N)x

Assessed: No

Associated Names:
- Ethenylbenzene, 2-propenoic acid, butyl 2-propenoate, 2-propenenitrile polymer

Clearly, it is important to consider synonyms when conducting chemical name searches.

Cosmetics

Cosmetic chemicals are known by their more common industry trade names eg. INCI. As most of these trade names are not on AICS, searching with these terms will generally yield negative results. The strategies to find cosmetic ingredients are:

1. Contact your supplier to get correct chemical details or ask them to check the chemicals.
2. Use Internet resources to find chemical information and use it to search AICS. Please note that information on these links may not be accurate.

Example:
Stearamide DEA

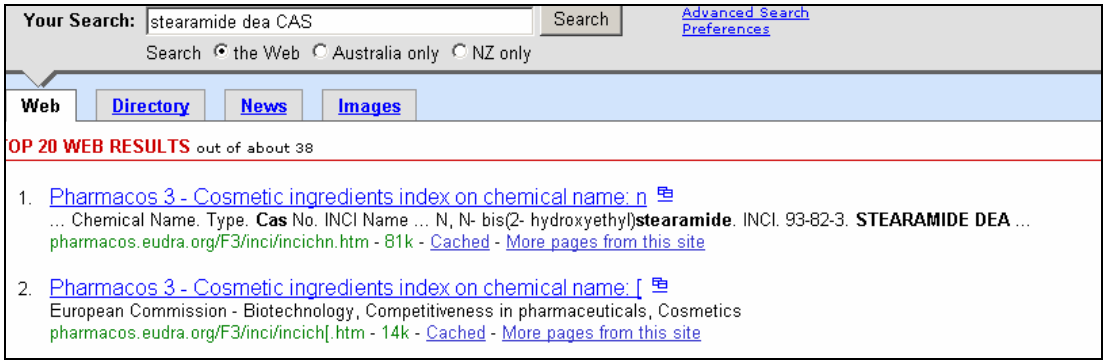
If this term is searched on AICS, no results are obtained.

Search Results New Search

You searched for:
Chemical Name Contains all words 'Stearamide DEA'

No results returned.

However from Internet searching the CAS number can be found.



The CAS number for this chemical is 93-82-3 and using this information AICS can be searched.

AICS Listing New Search

CAS No:	93-82-3
Chemical Name:	Octadecanamide, N,N-bis(2-hydroxyethyl)-
Molecular Formula:	C22H45NO3
Assessed by NICNAS:	No
Associated Names:	

Confidential AICS Search

If there is no match on the chemical name or CAS number, the chemical may be listed in the confidential section of AICS. This section cannot be searched via the web. For NICNAS to conduct a search of the confidential section of the AICS, written submission of a *bona fide* intention to manufacture or import the chemical must be submitted to NICNAS. Click here to view confidential search requirements.

14. Controlled Use Exposure Criteria and Scenarios for Controlled Use Permit

Controlled Use Exposure Criteria

To be eligible for a controlled use permit, the information provided in Form 1-CUP should demonstrate that each of the exposure criteria for public exposure, occupational exposure and environmental exposure is met.

Public exposure criteria

The principal criterion for public exposure is that there are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance.

The chemical should not be present in products available to the public, except in an article where the chemical or polymer is fixed into the article matrix and is not available for exposure. If the release of the chemical or breakdown product is at sufficient rate to lead to accumulation in the environment (considering the environmental fate properties of the chemical or breakdown product) resulting in potential exposure of humans to elevated levels of the chemical, then, the chemical would not meet the criteria for the controlled use permit.

Examples of the types of uses that fall outside the scope of the controlled use permit (CUP) are ink in ink-jet cartridges, detergents and personal care products and engine lubricants where "DIY" operations may occur.

Occupational exposure

The principal criterion for occupational exposure is that any worker exposure that is likely to occur will be adequately controlled through use of engineering controls, work practices and personal protective equipment.

Examples of engineering controls and work practices which are considered appropriate are included in the two exposure scenarios which have been developed (see below). The control measures specified in these scenarios may be generally applicable to industrial use only scenarios. It is preferred that Industry work with NICNAS to develop additional exposure scenarios (see development of additional scenarios below).

The controlled use permit is only suitable where the identity and practices of the down-stream user are known.

Environmental exposure

The criteria for environmental criteria are:

- There must be no ambient release to surface water resulting in concentrations of the chemical above 1 µg/L (1 ppb); and

- There must be no ambient release to air above 1 µg/m^3 average annual concentration; and
- There must be no release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Releases to Surface Water
This criterion covers all controlled point-source releases to surface water (both marine and freshwater) throughout the lifecycle of the chemical in Australia. The maximum Predicted Environmental Concentration in water (PECwater) after secondary or tertiary wastewater treatment arising from any controlled point-source release can be calculated using the following formula:

$$\mathbf{PEC_{water} = (Q \times 1000) \div F}$$

Where,

PEC_{water} = **P**redicted **E**nvironmental **C**oncentration in **water** in µg/L;
Q = Daily **Q**uantity of chemical released from site in kg/day; and
F = Daily receiving stream **F**low in ML/day.

Non point-source (dispersive) releases of chemicals, such as those associated with the release after use of detergents and personal care chemicals (shampoos, cosmetics, etc) are not considered to be controlled and therefore fall outside the scope of the CUP.

Releases to Air

This criterion covers all releases to air throughout the lifecycle of the chemical in Australia. The maximum Annual Average Concentration in air (AACair) from all releases to air throughout the lifecycle of the chemical in Australia can be calculated using the following formula:

$$\mathbf{AAC_{air} = Q \times N \times 9.68 \times 10^{-6}}$$

Where,

AAC_{air} = **A**nnual **A**verage **C**oncentration in **air** in µg/m^3;
Q = Daily **Q**uantity of chemical released from site in kg/day; and
N = **N**umber of release days per year in days.

Sufficient detail should be provided to demonstrate that significant releases to air will be restricted by proposed physical controls for chemicals that:

1. are gases at any point in the chemical's lifecycle; OR
2. have a vapour pressure ≥ 0.01 Pa at 20 – 25°C

Releases to Land

This criterion covers all releases to land, including landfill, throughout the lifecycle of the chemical in Australia. To meet this criterion, the chemical must have negligible potential for migration to groundwater from releases to land or landfill. Negligible potential can be assumed if the following conditions are satisfied:

1. no uncontrolled releases to land; AND
2. the chemical's log10 Adsorption/Desorption Coefficient (log10 KOC) ≥ 4; and

3. migration to groundwater is precluded throughout the lifecycle of the chemical in Australia by the chemical's inherent properties or by management conditions.

Data for Adsorption/Desorption Coefficient for the notified chemical or accepted close analogue can be either measured or estimated by an appropriate, validated model.

"No uncontrolled release" precludes, for example, chemicals incorporated into rubber tyres, which by the very nature of their use will be released to land in an uncontrolled manner through abrasion of the tyre from normal "wear and tear". Similarly, uncontained spray drift from outdoor spray application will also fail the "no uncontrolled release" condition. A final example of types of use which are considered to fall outside the scope of the CUP is for chemicals used as engine lubricants where "DIY" operations may occur (e.g. changing oil/filters).

Release of chemicals to land associated with biosolids (sludge removed from STPs) is considered to be a controlled release. However, the chemical must still meet the other conditions associated with this criterion.

Finally, while release to regulated landfill, for the sake of this condition, is considered to be a controlled release, the chemical must still meet the other conditions associated with this criterion.

Exposure Scenarios

Two controlled use exposure scenarios have been developed in consultation with Industry. Typically a chemical being used as described in these scenarios will meet the exposure criteria set out above (exceptions may occur where a chemical has particular physicochemical characteristics, for example, the chemical is highly volatile, the chemical is persistent). The specific criteria, for example calculation of the releases to surface water, should still be demonstrated in the information provided in Form 1-CUP.

The scenarios are set out as performance criteria. Specific controls are discussed against each of the performance criteria where information is available to NICNAS. The listed control measures are bulleted. Listed control measures are considered to meet the performance criteria as suitable controls under the CUP category. Control measures other than those listed may also meet the performance criteria, and the permit application should describe how each unlisted control meets the performance criteria.

Personal protective equipment (PPE) is generally not specified as part of the controls, as the granting of a CUP is normally dependent on the existence of suitable engineering controls. However PPE should always be used as an additional protection measure, according to the guidance in the OASCC Code of Practice, and the use should be specified in the application. PPE use for cleaning and maintenance tasks must be described in relation to the likely risks of these operations.

Scenario 1. Containment and controlled reformulation (Reformulation of a Plastic Additive.)

This scenario is for chemicals which are not manufactured in Australia, and the only handling is to reformulate them into plastic articles, whether via masterbatch or directly. Chemicals which are added to the plastics will normally have the following functions: fillers; plasticisers; antioxidants; coupling agents; colourants; UV & other weathering stabilizers; polymeric impact modifiers; anti-static agents; flame retardants; and preservatives. Processing additives such as curing agents; blowing agents; heat stabilizers; slip promoters; lubricants; and viscosity aids may also meet this scenario.

Public exposure

The only products that will be available to the public are finished moulded plastic articles. Therefore, unless release of the chemical or breakdown product from the plastic article is at sufficient rate to lead to accumulation in the environment (considering the environmental fate properties of the chemical or breakdown product), resulting in potential exposure of humans to elevated levels of the chemical, it is considered that the chemical is sufficiently immobilised by incorporation into the article and the criteria for public exposure are met.

Potential for public exposure is only possible in the event of release of the chemical after a transport incident or inappropriate handling. The following performance criteria should be in met with regards to transport, storage and packaging:

The chemical should be packaged in dangerous goods-approved packaging or in robust packaging suitable for protection and retention of the contents.

- Additives are transported and stored in robust polyethylene-lined heavy duty woven polypropylene bags or Flexible Intermediate Bulk Containers (FIBCs).

The chemical should be transported by road or rail as dangerous goods according to the Australian Code for Transport of Dangerous Goods by Road and Rail, if appropriate, or transported by recognised industrial chemicals transport operators.

The chemical should be stored in dangerous goods stores that are approved under States and Territories legislation, or stored in general industrial chemicals stores controlled by experienced stores operators and in a location to prevent damage to packaging and release to drains, sewer or soil.

Occupational exposure

Potential occupational exposure involves several stages – transport and storage, weighing and transferring to a mixing vessel, mixing and extrusion, handling the

finished polymer or masterbatch, and disposal and cleaning. Exposure scenarios are mostly for dermal exposure or exposure to vapours or dusts.

Transport and storage criteria are outlined above.

Handling operations when packaging is opened for access to the new chemical must be carried out in designated areas by trained operators who have had specific training relating to the new chemical or to products containing the new chemical. All operators are to be trained in the appropriate operational procedures and precautions.

- The contents will not be liberated until the bag is opened for addition of the contents to a pre-mix container (hopper) or a low or high speed mixer. For large containers automated unloading would be expected.

All dust or vapour generating processes such as mixing, grinding and heating should be enclosed, while transfer processes should generally be performed under local exhaust ventilation (LEV).

- Mixing, grinding, extrusion and/or moulding are enclosed.

In particular, the possible volatilisation of the additive during the extrusion process should be addressed either by demonstrating that the vapour pressure remains low at the relevant temperature or by detailing vapour control measures.

- Melting and extrusion or moulding is enclosed and fumes and/or vapours are controlled by exhaust ventilation

Dust exposure during transfer, weighing and disposal of packaging must be addressed by demonstrating enclosure of the process, sufficient use of LEV, or use of the chemical in a non-dusting form, such as masterbatch pellets or waxy solids.

- Chemical is used in non-dusting form or masterbatch
- For bulk quantities, mechanical systems are used for unloading and weighing, for example, by loss in weight feeder or distribution is automated through enclosed transfer systems
- Weighing and addition to mixers is conducted under suitably designed LEV which has been properly installed, tested and maintained.

Precleaning (where the situation permits) and PPE should be described for cleaning and maintenance operations.

Handling finished articles or masterbatch is considered to be qualitatively the same process as use of the finished article by the public, and therefore does not require specific controls.

Environmental exposure

There should be no intentional release of the new chemical to the aquatic, air or terrestrial environmental compartments.

Residual chemical retained in packaging should be disposed of with the empty packaging to regulated landfill. The chemical must have negligible potential for migration to groundwater from releases to land or landfill.

Waste chemical generated during setting of initial extrusion specifications or from off-specification material and from cleaning/purging at the end of production runs extrusion processes should be a minor proportion of the introduced substance. Quantities of waste chemical may arise from spillage prior to blending, when captured in dust/ vapour extraction filter or from waste extruded preparations that are not able to be recycled.

All production and cleaning waste should be recycled where possible or collected and consigned to regulated landfill. The chemical must have negligible potential for migration to groundwater from releases to land or landfill.

The moulded articles at the end of their life should either be recycled or released to regulated landfill sites. The chemical must have negligible potential for migration to groundwater from releases to land or landfill.

Environmental exposure only possible in the event of release of the chemical after a transport incident. Transport and storage controls are outlined above.

Scenario 2. Site-Limited and Closed System (Enclosed Use and Complete

Consumption)

This scenario is for the use of a chemical as a chemical industry feedstock, where the use of the chemical results in its conversion to a different chemical or polymer prior to its release from the industrial environment. The scenario is specified to be for importation, but is relevant also for on site production of an intermediate. The scenario does not address the chemical or polymer produced from the feedstock or intermediate. This is separately subject to NICNAS requirements.

Public exposure

Public exposure is controlled by the “complete” consumption within the chemical conversion process prior to any public exposure to the products of this process. The residual level of the chemical in any product available to the public must be specified.

Potential for public exposure is only possible in the event of release of the chemical after a transport incident or inappropriate handling. The following controls should be in place with regards to transport, storage and packaging:

The chemical should be packaged in dangerous goods-approved packaging or in robust packaging suitable for protection and retention of the contents.

The chemical should be transported by road or rail as dangerous goods according to

the Australian Code for Transport of Dangerous Goods by Road and Rail, if appropriate, or transported by recognised industrial chemicals transport operators.

The chemical should be stored in dangerous goods stores that are approved under States and Territories legislation, or stored in general industrial chemicals stores controlled by experienced stores operators and in a location to prevent damage to packaging and release to drains, sewer or soil.

Occupational Exposure

Potential occupational exposure is limited by the use of an enclosed process, which accounts for weighing and transferring to a reaction vessel, at which point the chemical ceases to exist. Exposure scenarios are mostly for dermal exposure or exposure to vapours or dusts during transfer from the imported containers to the enclosed pipework system attached to the reactor, and maintenance and cleaning.

Handling operations when packaging is opened for access to the new chemical must be carried out in designated areas by trained operators who have had specific training relating to the new chemical or to products containing the new chemical. All operators are to be trained in the appropriate operational procedures and precautions.

The chemical should remain within an enclosed pipework system for its entire life cycle within a factory, with weighing by load cell or volumetric metering. Potential exposure apart from maintenance and cleaning should be limited to transfer operations, and these should be conducted using protective transfer mechanisms, particularly low dead volume couplings. If drum spears are used, suitable control of exposure during drum changing should be demonstrated.

- When transferring liquids, prevention of hazardous substances in the gas phase is addressed by:
    - Transfer in enclosed systems or in systems that can be equalised
    - Using gas displacement devices for pumping
    - Extracting vapours at the point of escape and
    - Providing good general ventilation.
- Liquid transfer should involve control processes such as:
    - Emptying into a calibrated vessel
    - Emptying through volumetric meters
    - Running drain lines to installed scales.
- To avoid liquid escape during transfer, chemical pumps conform to appropriate international standards and piping connections employ dry break couplings. Design considerations should take account of shortening the distance of transfer to and from storage containers.

Solid transfer may be accepted under this scenario, but the presence of engineering controls to ensure enclosure of the process needs to be demonstrated. Manual unloading under LEV does not meet the criteria.

- Solid transfer to the reactor does not involve manual unloading and the presence of engineering controls to ensure enclosure of the process needs to be

demonstrated. In addition a low dust or no dust form of the solid should be employed.

Reactors should be enclosed.

- The action of pressure relief devices should not threaten personnel and splash deflectors must be used. The quantity and nature of the substances present may make it necessary to conduct releases to the atmosphere or to provide scrubbers, flare systems or blowdown tanks. Seal systems installed on shafts of pumps, drives, mixers and stirrers should accord with the reaction mix. Seal systems must be tested regularly and leaks fixed.

Sampling systems must be designed to minimise exposure.

- Sampling of the reactor should be conducted with the following design points in mind:
  - The sample should be withdrawn at a point in the plant where the pressure and temperature are as low as possible
  - The cross-sectional area of the sampling device should be as low as possible
  - Sampling devices should be designed such that a malfunction does not result in release of large quantities of reactor contents
  - The inevitable pre-sample liquid must be returned to the closed system
- When the sample is transferred into the sample container, splashing, vapourisation, dripping, overflowing, and escape of hot liquids must be prevented. Steps must be implemented to prevent static charging and consideration should be given to sampling with vacuum for taking samples with no pre-sample flow.

Precleaning (where the situation permits) and PPE should be described for cleaning and maintenance operations.

Transport and storage controls are outlined above.

Environmental exposure

There should be no intentional release of the new chemical to the aquatic, air or terrestrial environmental compartments.

Residual chemical retained in packaging should be disposed of with the empty packaging to regulated landfill. The chemical must have negligible potential for migration to groundwater from releases to land or landfill.

Quantities of the new chemical spilled or remaining from batch production should be collected and placed into sealable containers for reuse or disposal. The new chemical should be totally consumed during production.

All production and cleaning waste collected for disposal should be sent to a regulated landfill. The chemical must have negligible potential for migration to groundwater from releases to land or landfill.

Development of additional scenarios

The above sets of proposed controls address the two specific scenarios which have been developed. These represent two examples of chemicals with site limited industrial use only, coupled with sufficient levels of engineering controls to minimise worker exposure.

The control measures specified in these scenarios may be generally applicable to industrial use only scenarios, and it is possible to devise additional scenarios either based on the controls specified above or other scenarios that may be proposed by industry for consideration to develop further scenarios. If a company would like NICNAS to consider developing a new scenario, a request should be made in writing, detailing the new scenario. Assistance in obtaining site visits for NICNAS staff would be helpful.

15. Structural Alerts for permit categories

These structural alerts have been developed for use by notifiers in determining whether a substance meets the hazard criteria established for the:

- low volume permit category (for volumes > 100 kg); and
- controlled use permit.

The structural alerts are classes of chemicals, functional groups or substructures that are linked to a particular endpoint. The absence of a structural alert does not mean that a chemical is non-hazardous or is not of concern for a particular end-point (unless defined by an exclusion/boundary). Chemicals with a structural alert for corrosion are considered to have the potential to cause both skin and eye irritation.

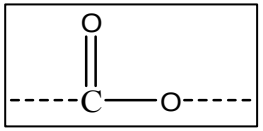
The structural alerts have been compiled from references used internationally e.g. the US EPA categories of concern and those commonly used by NICNAS. These alerts have been grouped as follows:

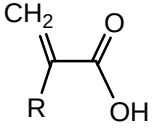
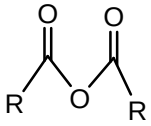
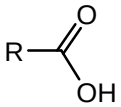
C	Structure contains only C, H, (O)	Table 1
CHal	Structure contains only C, H, (O) and Halogen atoms	Table 2
CN	Structure contains only C, H, (O) and N atoms	Table 3
CNHal	Structure contains only C, H, (O), N and Halogen atoms	Table 4
CNS and CNSHal	Structure contains only C, H, (O), N and S atoms or Structure contains only C, H, (O), N, S and Halogen atoms	Table 5
CS and CSHal	Structure contains only C, H, (O), and S atoms or Structure contains only C, H, (O), S and Halogen atoms	Table 6
CSi and CSiHal	Structure contains only C, H, (O), and Si atoms or Structure contains only C, H, (O), Si and Halogen atoms	Table 7
Other	Structure contains atoms other than C, H, N, O, S, Si and Halogen atoms	Table 8

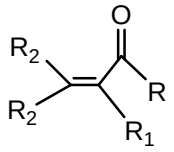
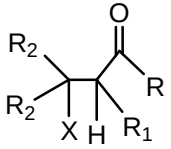
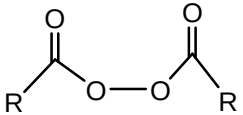
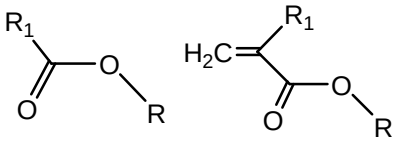
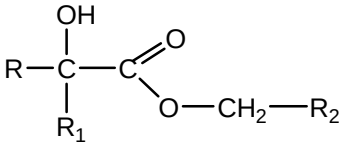
In determining whether a chemical contains a structural alert, it may be necessary to consult more than one table, if different substructures of the chemical would be covered by different tables.

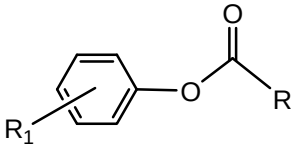
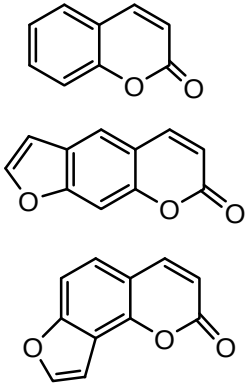
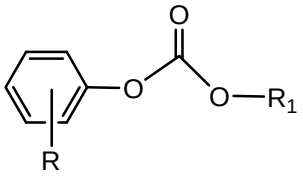
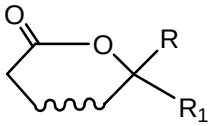
Boundaries and exclusions for the structural alerts have been included in the tables. Specific physicochemical exclusion rules for corrosion and skin/eye irritation have been included at the end of each table. These have been externally developed and validated. Those shown during validation to have limited predictive value or found to be not properly defined have not been included.

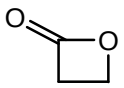
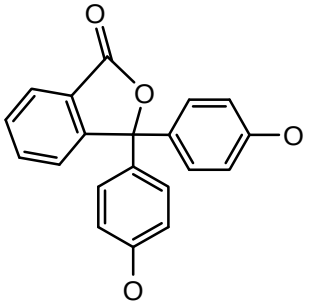
Table 1- C – Structure contains only C, H, (O)

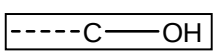
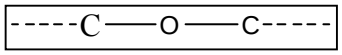


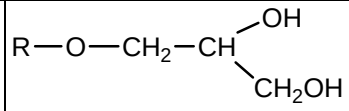
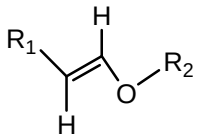
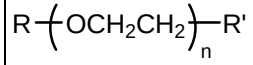
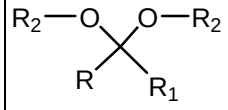
Category	Structure	Boundaries	Endpoints	Comment	Reference
(meth)acrylic acids	 R = H or CH_3	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
Acid anhydrides	 R = any	Structures with a carboxylic acid anhydride equivalent weight of ≥5,000 are presumed not to pose a hazard under any conditions. Typically, concerns for health effects are confined to those species with molecular weights <1,000. Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation, Sensitisation, Reproductive and Developmental toxicity	concern for potential pulmonary sensitisation	1, 2, 3, 6
Aliphatic acids	 R = aliphatic chain no other subgroups	C1-C7 – Corrosion C7-C14 eye irritation >C20 – only slight eye irritant Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion, eye irritation		2,5

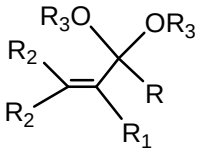
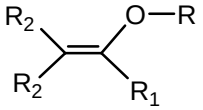
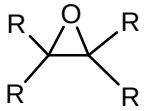
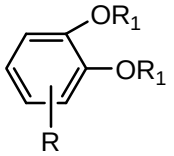
Alpha-, beta-unsaturated esters and precursors	 Precursors  R = O (not OH) R_1 = not a heteroatom R_2 = not aryl (unless R = H) X = good leaving group	For Carcinogenicity R2 not C>5 or aromatic	Carcinogenicity Sensitisation	See also esters	3,4
Diacyl peroxides	 R = any	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation, Sensitisation, potential carcinogenicity		2, 3, 6
Esters (incl. Acrylic and methacrylic esters)	 R and R_1 = alkyl, arylalkyl or aryl group	Physicochemical exclusion rules apply for corrosion/irritation.	Skin irritation		2
Aliphatic alpha hydroxyesters	 R, R_2 = aliphatic chain R_1 = H or aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Eye irritation		5

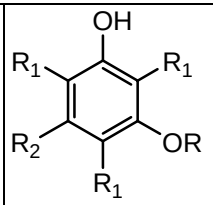
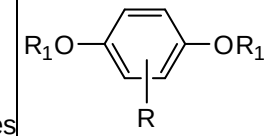
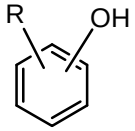
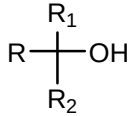
Phenyl esters	 R = alkyl, aryl R_1 =any	Physicochemical exclusion rules apply for corrosion/irritation.	Skin irritation, Sensitisation		2, 3
Coumarins and Furocoumarins			Carcinogenicty		4
Phenyl carbonates	 R = any R_1 = alkyl, aryl		Sensitisation		3
Lactones	 R, R_1 = H, alkyl, arylalkyl or aryl group	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2

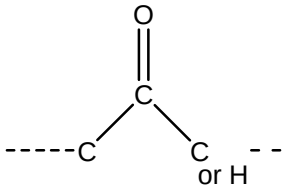
Propiolactone		Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Corrosion/Skin irritation		2,4
Phenolphthaleins			Carcinogenicity		6
Vinyl esters	A carboxylic acid ester with at least one vinyl group (CH_2=CH-) attached to an organic acid radical (RCOO-).		Carcinogenicity, Neurotoxicity, Reproductive toxicity	See also esters	6

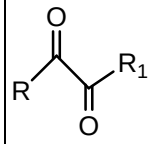
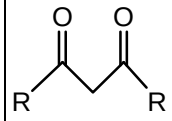
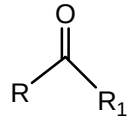
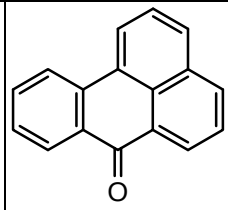
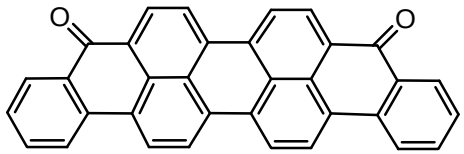
 and 

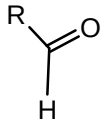
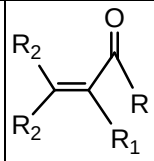
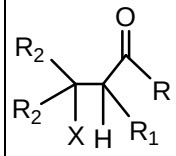
Category	Structure	Boundaries	Endpoints	Comment	Reference
Aliphatic glycerol monoethers	 R = aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	serious eye damage		5
Alpha, beta-unsaturated aliphatic alkoxy group	 R_1 = any aliphatic carbon R_2 = aliphatic or aromatic carbon		Carcinogenicity		4
Ethylene glycol ethers	 n = 1, 2, 3 R = AlkylC7 or less or phenol or alkyl substituted phenyl R' = H or alkyl C7 or less or any group that can be chemically or metabolically removed to yield a glycol ether	Physicochemical exclusion rules apply for corrosion/irritation.	Skin irritation, systemic toxicity, developmental/reproductive toxicity	Concern for hemolysis, bone-marrow damage, and leukopenia of both lymphocytes and granulocytes; direct and indirect kidney damage; liver damage, immunotoxicity, and central nervous system (CNS) depression.	2, 6
precursors of aldehydes and ketones	 R, R_1 = alkyl, aryl R_2 = any		Sensitisation		3

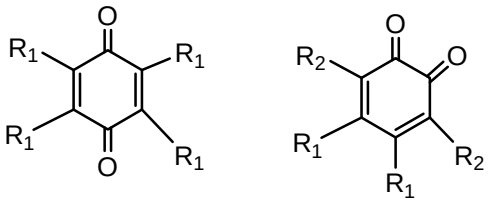
Precursors of alpha, beta-unsaturated aldehydes, esters and ketones	 R = H, C, O R_1 = not a heteroatom R_2 = not aryl (unless R = H) R_3 = any	For Carcinogenicity, R1 and R2 not C>5 or aromatic	Carcinogenicity, Sensitisation		3,4
Enol precursors of aldehydes and ketones	 R, R_2 = any R_1 = not a heteroatom		Sensitisation		3
Epoxides	 For sensitisation and Corrosion/Irritation R = H, alkyl, aryl, aryl akyl else R = any	Structures with epoxy equivalent weights of ≥5000 are presumed not to pose a hazard under any conditions. Carcinogenicity and reprodcutive toxicity concerns are confined to those species with molecular weights <1,000. Carcinogenicity and reprodcutive toxicity concerns are restricted to species with molecular weights <500 if exposure is limited to the dermal route. Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Reproductive toxicity, Corrosion/Skin irritation, Sensitisation		1,2,3,4,6
Catechols and o-alkyl precursors	 R = any R_1 = H, alkyl	For sensitisation: CN at ortho or para removes activity, R groups on both oxygens remove activity	Carcinogenicity, Sensitisation		1, 3, 9

resorcinols and o-alkyl precursors	 R_1, R_2 = H, OH, any carbon or O alkyl. One R_1 must be H. R = H, methyl, ethyl	CN at ortho or para removes activity, R groups on both oxygens remove activity	Sensitisation		1
hydroquinones and O-alkyl precursors	 R = any R_1 = H, alkyl	CN at ortho or para removes activity, R groups on both oxygens remove activity	Sensitisation		1,3
Phenols		Physicochemical exclusion rules apply for corrosion/irritation	Corrosion/Skin irritation		2
Aliphatic monoalcohols	 R = aliphatic chain $R_{1,2}$ = H or aliphatic chain	C3-C11 – serious damage to eyes C12-14 – eye irritation >C15 – only slight eye irritation Physicochemical exclusion rules apply for corrosion/irritation	Eye irritation/serious eye damage		5

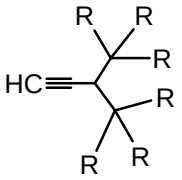
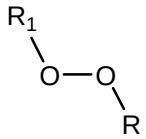


Category	Structure	Boundaries	Endpoints	Comment	Reference
1,2-Dicarbonyls	 R = alkyl, aryl R_1 = H, alkyl, aryl		Sensitisation	See also aldehydes and ketones	3
1,3-diketones	 R = alkyl, aryl		Sensitisation		3
Ketones	 R, R_1 = alkyl, aryl	Physicochemical exclusion rules apply for corrosion/irritation.	Skin irritation, sensitisation		2,3
Benzanthrone derivatives	 Benzanthrone  Violanthrone	Physicochemical exclusion rules apply for corrosion/irritation.	Skin irritation	These dyes may be irritants. Lipophilic dyes containing different functional groups e.g. halogens, amino, imino,	2

				phenolic, thiol, make the molecule more electrophilic, leading to higher reactivity.	
Aldehydes	 R = any type of carbon atom linked to any other atom	Physicochemical exclusion rules apply for corrosion/irritation	Carcinogenicity, Corrosion/Skin irritation, sensitisation		1, 2,3,4
Alpha-, beta-unsaturated aldehydes and ketones	 R = H, C R_1 = not a heteroatom R_2 = not aryl (unless R = H)	For Carcinogenicity, R2 not C>5 or aromatic	Carcinogenicity, Sensitisation		3,4
Precursors of alpha, beta-unsaturated aldehydes and ketones	 R = H, C R_1 = not a heteroatom R_2 = not aryl (unless R = H) X = good leaving group	For Carcinogenicity, R2 not C>5 or aromatic	Carcinogenicity, Sensitisation		3,4

Ortho-quinones and paraquinones	 R_1, R_2 = H, OH, any carbon or O-alkyl. One R_1 position must be H.	For sensitisation/Corrosion: CN at ortho or para removes sensitisation/irritation activity Physicochemical exclusion rules apply for corrosion/irritation	Carcinogenicity, Corrosion/ Skin Irritation, Sensitisation		1, 2, 3,4

Miscellaneous

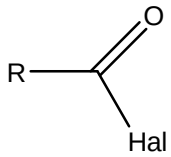
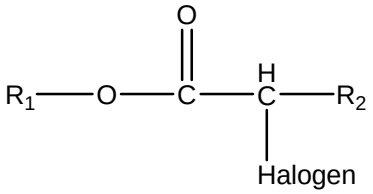
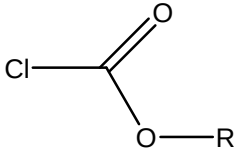
Category	Structure	Boundaries	Endpoints	Comment	Reference
Alpha alkyne	 R can be any kind of group	Physicochemical exclusion rules apply for corrosion/irritation	Skin irritation		2
peroxide (hydro/alkyl)	 R = H or alkyl chain R_1 = C-any	Physicochemical exclusion rules apply for corrosion/irritation	Skin irritation, potential carcinogenicity		2, 6
Polycyclic aromatic hydrocarbons	Three or more fused rings, not heteroaromatic e.g. pyrene, tetracene.		Carcinogenicity		4

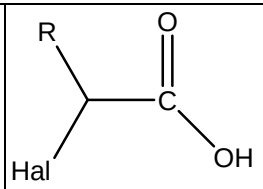
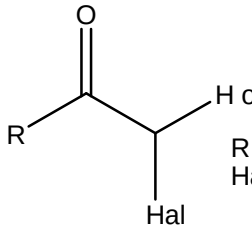
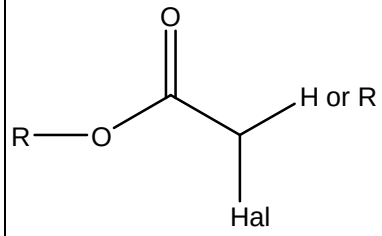
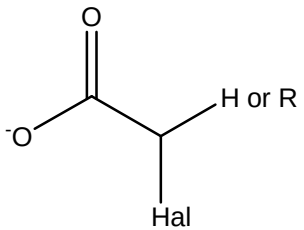
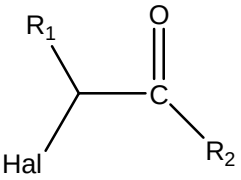
Physicochemical exclusion rules for corrosion and skin/eye irritation for C chemicals[7,8]

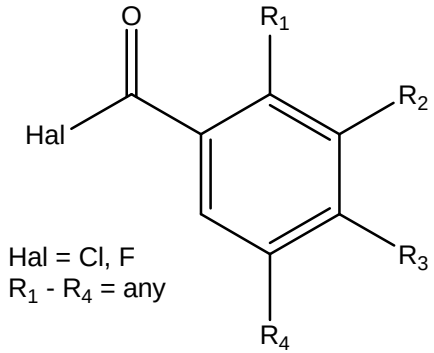
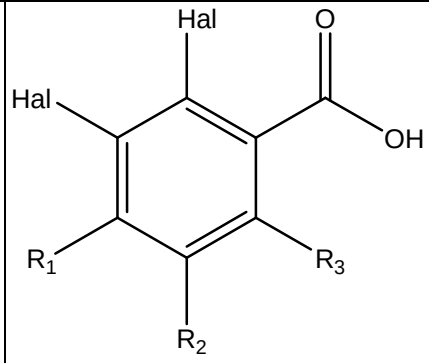
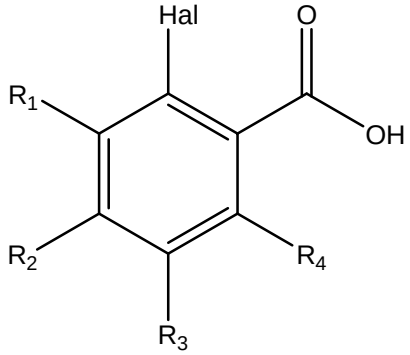
If molecular weight >350, then not classified as R34, R35,
If molecular weight >380, then not classified as R34, R35, R41 or R36

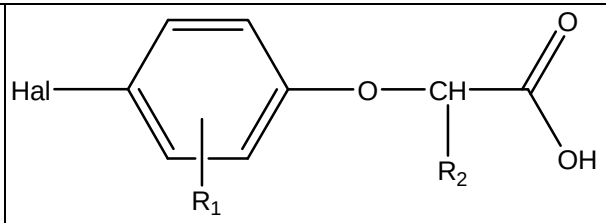
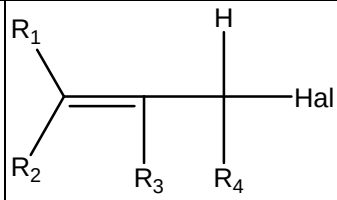
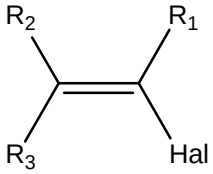
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41 or R36
If aqueous solubility <0.0001 g/L, then not classified as R34, R35, R41 or R36

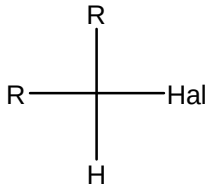
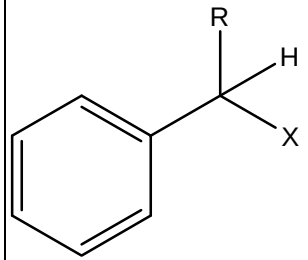
Table 2 - CHal - Structure contains only C, H, (O) and Halogen atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
Acyl halides		Irritation/corrosion: R = alkyl, arylalkyl, or aryl Sensitisation: R = any Hal = F, Cl, Br Carcinogenicity: R = any group except OH, SH Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin Irritation, Sensitisation, Carcinogenicity		1,2,3,4
Aliphatic alpha-halogen esters	 R_1, R_2 = any, but not containing N atoms	Physicochemical exclusion rules apply for corrosion/irritation.	Skin Irritation		2
Aliphatic esters of chloro formic acid	 R = aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Serious eye damage		5

Aliphatic halogenated saturated acids	 R = aliphatic chain Hal = Cl, Br	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin Irritation		2
alpha-Carbonyl halogen compounds (alpha-halocarbonyls)	 R = alkyl, aryl Hal = Cl, Br  		Sensitisation	Primary halides are more reactive than secondary halides. Bromides are more reactive than chlorides.	1
Alpha-halogenated aldehydes/ketones	 R_1, R_2 = H, alkyl, arylalkyl or aryl group	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin Irritation		2
Substituted benzoic acid halogenides		Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion	Some benzoic acid halogenides hydrolyse immediately when getting in contact with water, the resulting acid may cause only mild skin irritation	2, 5

	 Hal = Cl, F R_1 - R_4 = any				
Substituted di-halogen-benzoic acids	 R_1, R_2, R_3 = alkyl (aliphatic chain) or Halogen	Physicochemical exclusion rules apply for corrosion/irritation.	Skin Irritation, serious eye damage		2,5
Halogen benzoic acids	 R_1, R_2, R_3, R_4 = H, aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Serious eye damage		5

Halogen benzenes with substituents containing carboxylic acid groups	 R_1 = H or halogen R_2 = aliphatic chain Hal = F, Cl or Br	Physicochemical exclusion rules apply for corrosion/irritation.	Serious eye damage		5
Allyl halides	 R_1 - R_4 = H, alkyl, arylalkyl or aryl Hal = F, Cl or Br	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin Irritation		2
Monohaloalkene	 R_1, R_2 (or R_3) = H or alkyl R_3 (or R_2) = any atom/group (except halogens)		Carcinogenicity		4

alpha-haloalkanes; halogenated alkanes	 For sensitisation: R = alkyl, aryl Hal = Cl, Br, I For irritation: R= aliphatic Hal = F, Cl, Br For carcinogenicity:  R = any atom/group Hal = Cl, Br, I	Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Sensitisation, Skin Irritation		1, 2, 3,4
(Poly)Halogented Cycloalkanes	Any cycloalkane skeleton with three or more halogens directly bound to the same ring		Carcinogenicity	Nongenotoxic	4
Benzyl halides	 R = alkyl, arylalkyl or aryl group X = halogen	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin Irritation		2

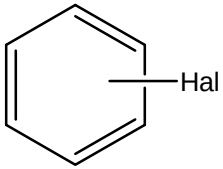
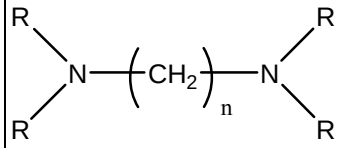
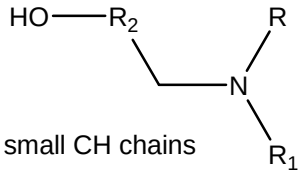
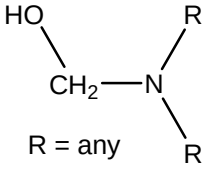
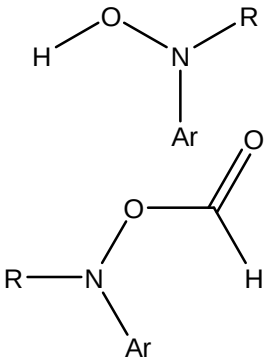
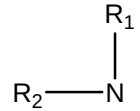
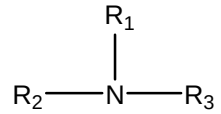
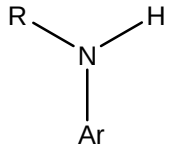
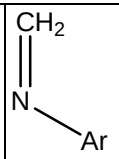
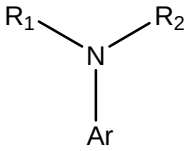
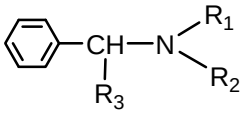
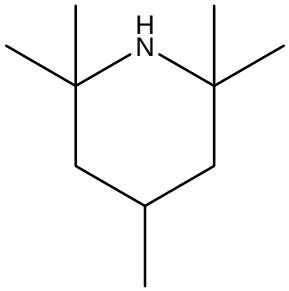
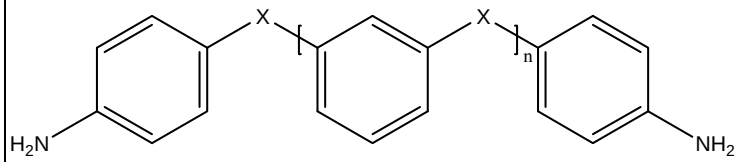
Halogenated benzene		Chemicals with two halogens in ortho or meta are excluded Chemicals with three or more hydroxyl groups are excluded	Carcinogenicity	Nongenotoxic	4
Halogenated PAH	Ar——Hal Ar = naphthalene, biphenyl, diphenyl		Carcinogenicity	Nongenotoxic	4

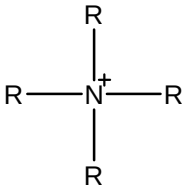
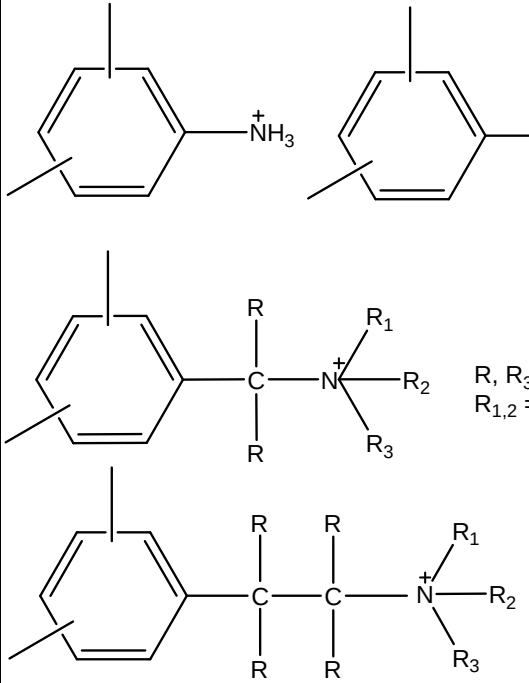
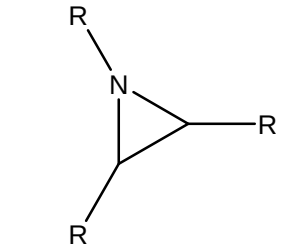
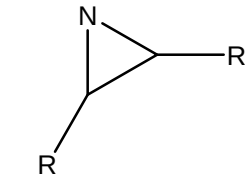
Table 3 - CN – Structure contains only C, H, (O) and N atoms

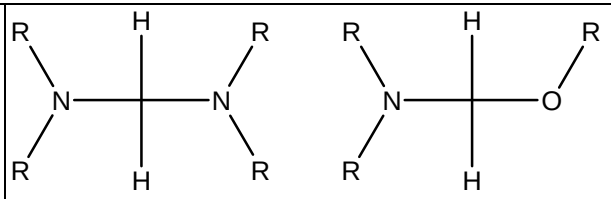
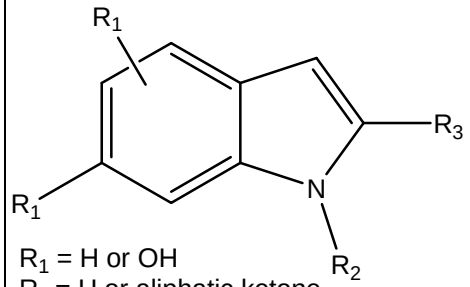
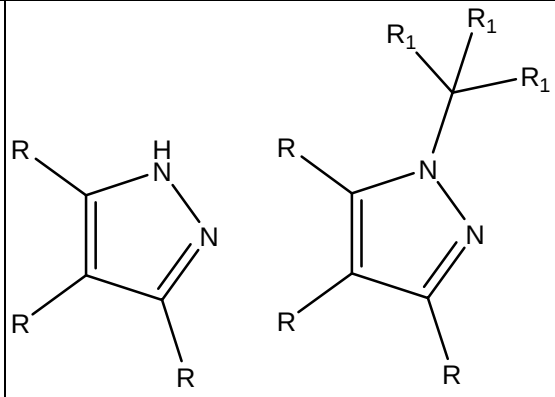
Category	Structure	Boundaries	Endpoints	Comment	Reference
1,2-Diamines	 n = 2 to 6 R = H or alkyl	Up to three R groups can be alkyl, but with four alkyl groups the chemical is inactive.	Sensitisation	See also primary, secondary, tertiary aliphatic amines.	1, 3
Alkylalkanol-amines	 R - R_2 are small CH chains	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
N-methylol derivatives	 R = any		Carcinogenicity		4
Aromatic hydroxyl amine and its derived esters	 Ar = any aromatic/heteroaromatic ring R = any atom/group	Chemicals with ortho-disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the amino group are excluded.	Carcinogenicity		4

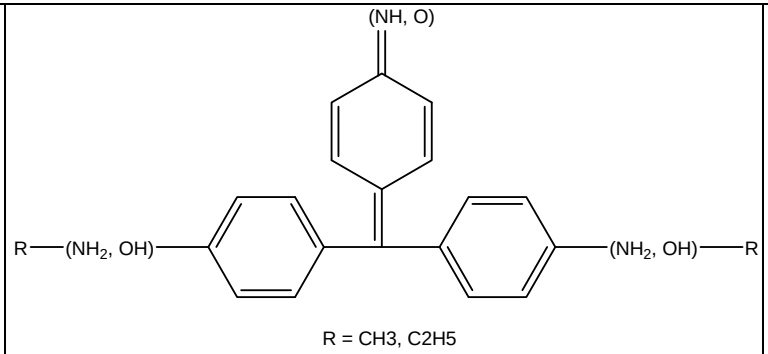
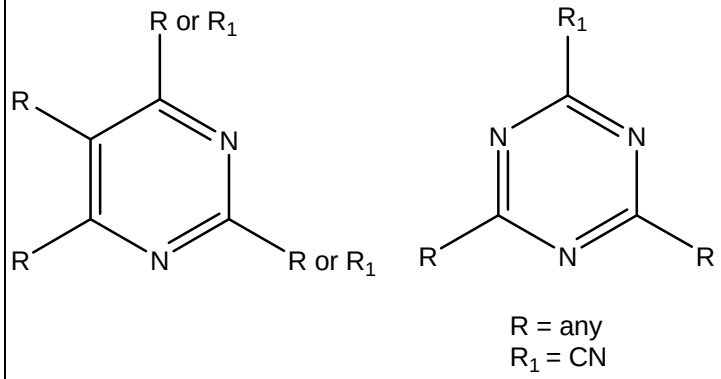
Primary and secondary aliphatic amines	 Primary, secondary R_1 and R_2 = H and/or aliphatic chain or non-aromatic ring	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
Tertiary aliphatic amines	 R_1 - R_3 = aliphatic chain and one of them needs to be small	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2
Aromatic primary and secondary amines		For Carcinogenicity: R=H, methyl, ethyl Ar = any aromatic/heteroaromatic ring For carcinogenicity: Chemicals with ortho-disubstitution, or with an ortho carboxylic acid substituent are excluded For carcinogenicity: Chemicals with a sulfonic acid group on the same ring of the amino group are excluded. For irritation: Ar = sub/unsubstituted benzene ring R = H or aliphatic chain For sensitisation: Ar = sub/unsubstituted benzene ring R = H, alkyl, or aryl Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Skin irritation, Sensitisation		2,3,4

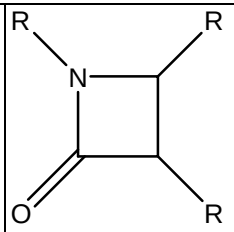
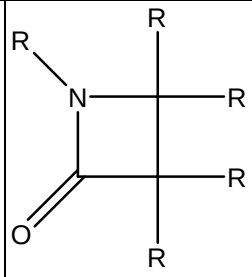
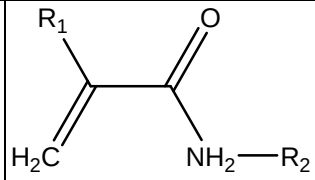
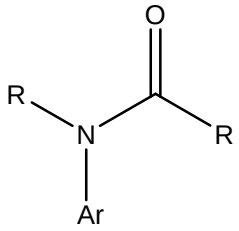
Precursor aromatic amine	 Ar = any aromatic/heteroaromatic ring		Carcinogenicity		4
Tertiary aromatic amine		For carcinogenicity R1= methyl, ethyl R2=methyl, ethyl Ar = any aromatic/heteroaromatic ring Chemicals with ortho-disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the amino group are excluded. For irritation: Ar = sub/unsubstituted benzene ring R = H or aliphatic chain	Skin Irritation, Carcinogenicity		2, 4
Derivatives of alpha amino benzene	 R_1 = H or aliphatic chain $R_{2,3}$ = any	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5

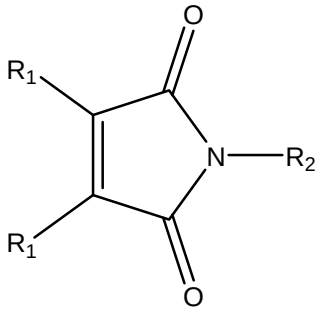
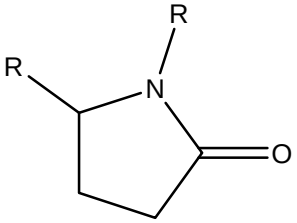
Hindered amines	Not well defined, though typically it will contain two or more hindered amine functional groups. An example structure is shown below:  		Systemic Toxicity	Concerns for the immune system, liver, blood, the male reproductive system, and the G.I. tract. Where dermal uptake is limited due to MW these are mainly of concern if there is significant inhalation exposure. Also see primary and secondary amines	6
Dianilines	 X= C,N, O or S n ≥ 0	The chemical must have at least two phenyl rings with a bridging carbon, oxygen, nitrogen, or sulfur Each terminal phenyl ring must have a primary amino group (or a group that can be readily metabolized to a primary amino group) either meta- or para- to the bridging atom Compounds with one or more additional phenyl ring(s), with or without ring substituents, and one or more bridging atoms are also included in the category.	Carcinogenicity, Systemic toxicity	Systemic toxicity concern regarding retinopathy and reproductive organs. The compounds of greatest concern are those having X = C, N, or O and n = 0 or 1.	6

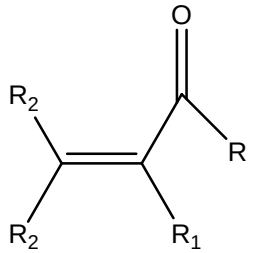
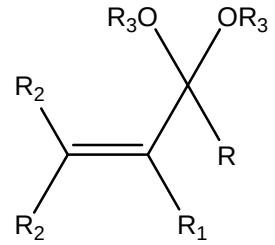
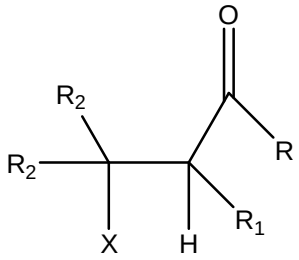
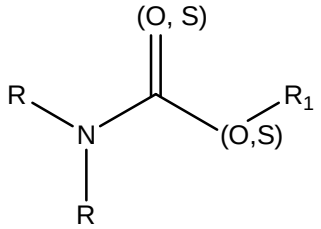
Quaternary organic ammonium compounds		For corrosion, R = any, however one R group should be small. For sensitisation, R = aryl or alkyl.	Corrosion, Sensitisation		2,3,5
Quaternary aromatic ammonium salts	 R, R_3 = any $R_{1,2}$ = H or aliphatic chain		Serious damage to eyes/Eye irritation		5
Aziridines	 For carcinogenicity, R = any atom/group  For irritation/corrosion, R = H or alkyl	Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Corrosion/Skin irritation		2,4

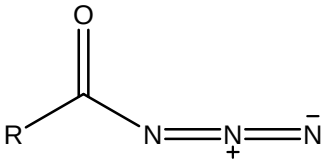
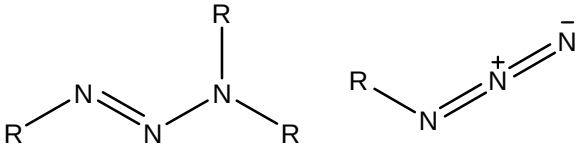
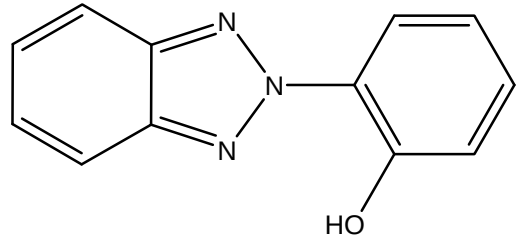
Formaldehyde donors			Sensitisation		3
Substituted indoles	 R_1 = H or OH R_2 = H or aliphatic ketone R_3 = any	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5
Substituted pyrazole	 R = H, NH_2 or aliphatic chain R_1 = any	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5
Heterocyclic polycyclic aromatic hydrocarbons	Three or more fused rings, heteroaromatic		Carcinogenicity		4

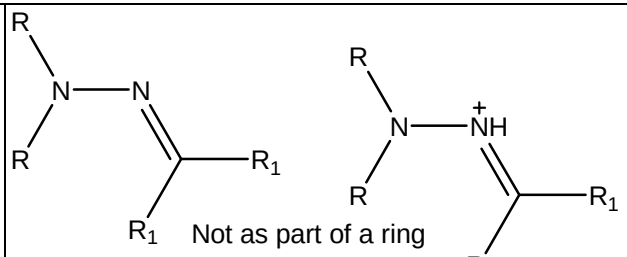
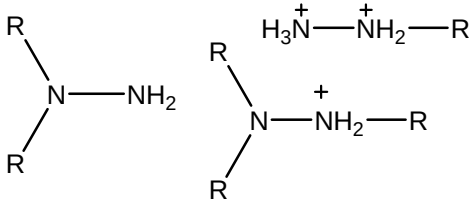
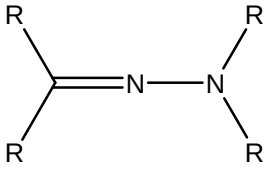
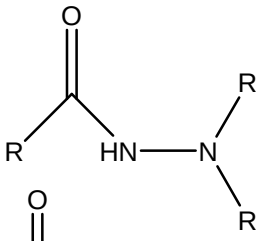
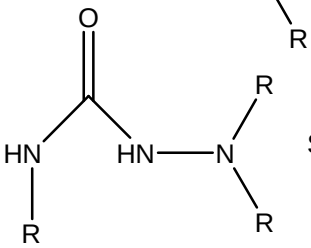
Triarylmethane pigments		Dyes substituted with solubilizing groups such as carboxylic acid, sulfonic acid, or halogens, are not included. Pigments that have essentially negligible water solubility (<1ppb) and therefore, little or no bioavailability, are also not included.	Carcinogenicity, reproductive and developmental toxicity		6
Activated N-heterocycles			Sensitisation		1

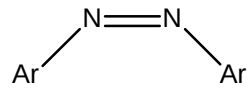
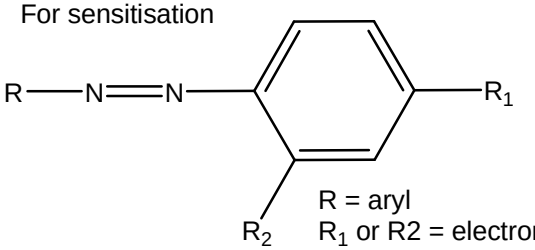
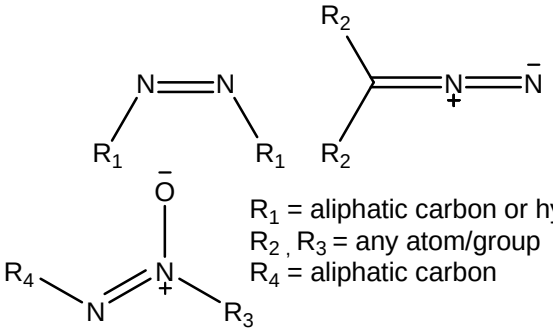
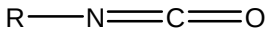
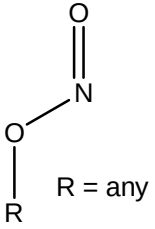
Alpha-lactams	 R = C-any		Sensitisation		1
Beta-lactams	 R = any		Sensitisation		3
Acrylamides	 R_1 = H or CH_3 R_2 = any	Structures with an acrylamide equivalent weight of ≥5,000 are presumed not to pose a hazard under any conditions. Typically, concerns are confined to those species with molecular weights <1,000 whenever inhalation (or environmental) exposure is expected, and to species <500 when dermal, but not inhalation, exposure to humans is expected.	Carcinogenicity, Mutagenicity, reproductive and developmental toxicity		6
Aromatic N-acyl amide		Chemicals with ortho-disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the nitro group are excluded.	Carcinogenicity		4

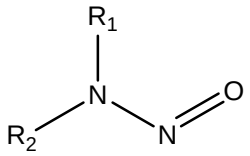
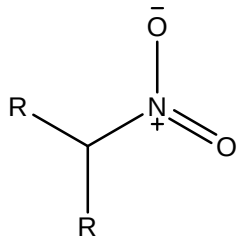
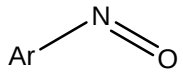
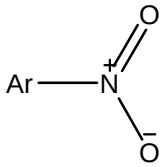
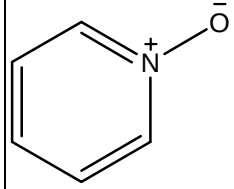
Acid imides	 R_1 = any but not part of aromatic ring R_2 = H or any carbon		Sensitisation		1
Pyrrolidones	 R = H or aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5

Alpha-, beta-unsaturated amides and precursors	 Precursors   R = N R_1 = not a heteroatom R_2 = not aryl R_3 = any X = good leaving group	For Carcinogenicity (not precursors), R1 and R2 not C>5 or aromatic	Carcinogenicity Sensitisation		3,4
Alkyl carbamate	 R = aliphatic carbon or hydrogen R1 = aliphatic carbon		Carcinogenicity		4

Acid azides	 R = any		Carcinogenicity, Sensitisation		3,4
Azides and triazenes	 R = any		Carcinogenicity		4
Benzotriazole-hindered phenols	 Any molecular structure containing this substructure		Systemic toxicity, Reproductive toxicty, Sensitisation	Concerns regarding hematology; weight and histopathology of lymphoid organs (spleen, thymus, and bone marrow); cellularity of the bone marrow, thymus, and spleen; and histopathology of the liver, kidney, heart, and all endocrine glands. Health effects may vary depending on the nature of the ring substituents.	6

Hydrazines, hydrazonium salts and precursors	 Not as part of a ring   Hydrazone  Hydrazide  Semi carbazide	Physicochemical exclusion rules apply for corrosion/irritation. For irritation/corrosion/ sensitisation, R = H or any type of carbon atom linked to any other atom, except that R is not –C(=O)-R. R1 = any. For semicarbazide and irritation/corrosion, R = H, alkyl, arylalkyl or aryl	Corrosion/Skin irritation, sensitisation, carcinogenicity, systemic toxicity	Concerns for carcinogenicity and chronic effects to liver, kidney, and blood	1,2,4,6

Aromatic azo compound	For carcinogenicity  Ar = any aromatic/heteroaromatic For sensitisation  R = aryl R_1 or R2 = electron donating	For carcinogenicity: Chemicals with a sulfonic acid group on both rings linked to the diazo group are excluded	Sensitisation, Carcinogenicity		3,4
Aliphatic azo and azoxy	 R_1 = aliphatic carbon or hydrogen R_2 , R_3 = any atom/group R_4 = aliphatic carbon		Carcinogenicity		4
Isocyanates		For corrosion: R = aliphatic	Carcinogenicity, Corrosion, Sensitisation	Concern for skin and respiratory sensitisation	1,2,3,4
Alkyl nitrite	 R = any		Carcinogenicity		4

Alkyl and aryl N-nitroso	 R_1 = aliphatic or aromatic carbon R_2 = any atom/group		Carcinogenicity		4
Aliphatic N-nitro	 R = aliphatic carbon or hydrogen		Carcinogenicity		4
Aromatic nitroso	 Ar = any aromatic/heteroaromatic ring		Carcinogenicity		4
Nitro-aromatic	 Ar = any aromatic/heteroaromatic ring	Chemicals with ortho-disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the nitro group are excluded.	Carcinogenicity		4
Aromatic ring N-oxide			Carcinogenicity		4

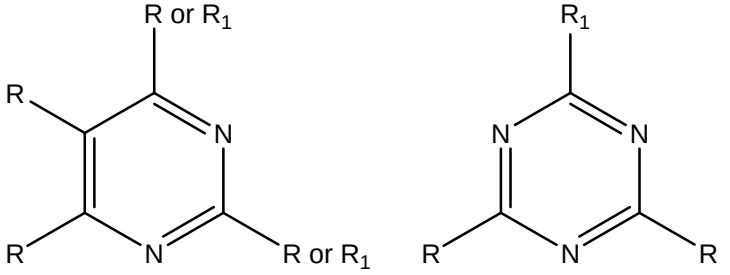
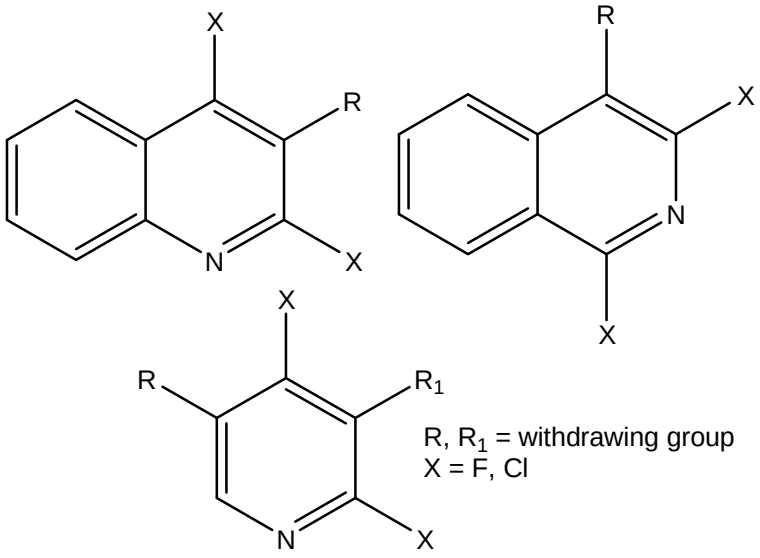
Physicochemical exclusion rules for corrosion and skin/eye irritation for CN chemicals[7,8]

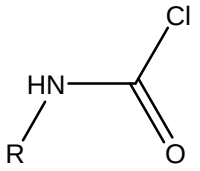
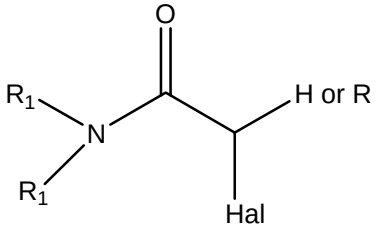
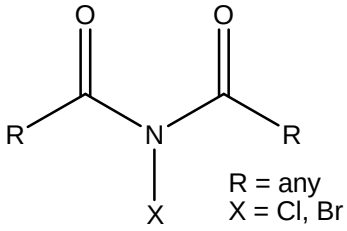
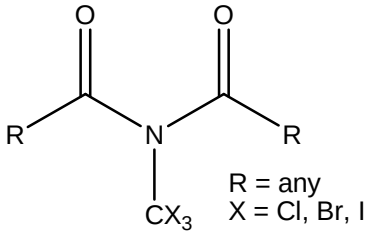
If molecular weight > 290, then not classified as R34, R35
If molecular weight > 540, then not classified as R34, R35 or R38

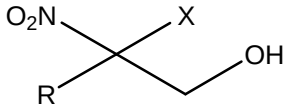
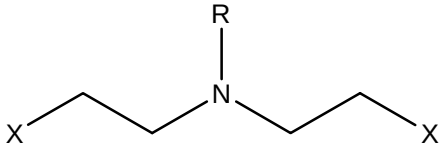
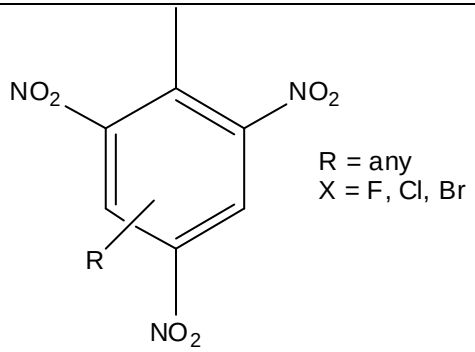
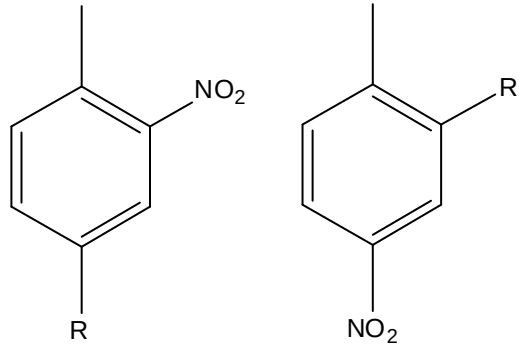
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 4.5, then not classified as R34, R35
If log Kow > 5.5, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41, R38 or R36

If aqueous solubility < 0.01g/L, then not classified as R34 or R35
If aqueous solubility < 0.0001 g/L then not classified as R34, R35 or R38

Table 4 - CNHal - Structure contains only C, H, (O), N and Halogen atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
Activated N-heterocycles	 R = any R_1 = F, Cl	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation, Sensitisation		1,2, 3
Activated halo-pyridines, quinolines, and isoquinolines	 R, R_1 = withdrawing group X = F, Cl		Sensitisation		3

Alpha-carbamoyl halogen compounds (a-halo-carbomoyl)	 R = alklyl, aryl	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2
alpha-Carbonyl halogen compounds (alpha-halocarbonyls)	 R = alklyl, aryl R_1 = C-any Hal = Cl, Br		Sensitisation		1
N-Haloimides	 R = any X = Cl, Br		Sensitisation		3
N-trihalomethyl imides	 R = any X = Cl, Br, I		Sensitisation		3

Formaldehyde donors	 R = any X = halogen		Sensitisation		3
N mustard	 R = any X = F, Cl, Br, I		Carcinogenicity		4
Halonitrobenzenes	 R = any X = F, Cl, Br OR  X = F, Cl R = F, Cl, NO_2, CN, -C(=O)-R_1, or -C(=O)-OR_1 (where R_1 = alkyl)		Sensitisation	There may be additional R groups which are activating.	1, 3

Dichlorobenzidine based pigments	(any diazo pigment containing dichlorobenzidine coupled with acetoacetanilide)		Carcinogenicity	There are oncogenicity/mutagenicity concerns for dichlorobenzidine-based pigments based on the potential release of 3,3'-dichlorobenzidine and on the presence of residual (unbound) dichlorobenzidine. Concern for the intact pigment is restricted to uses at temperatures exceeding 200^{o}C.	6

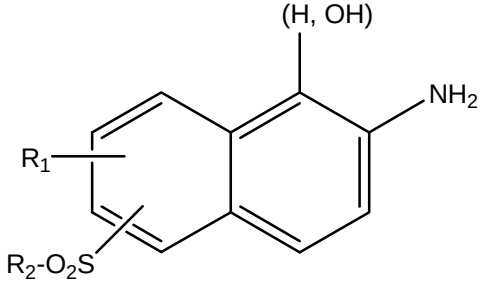
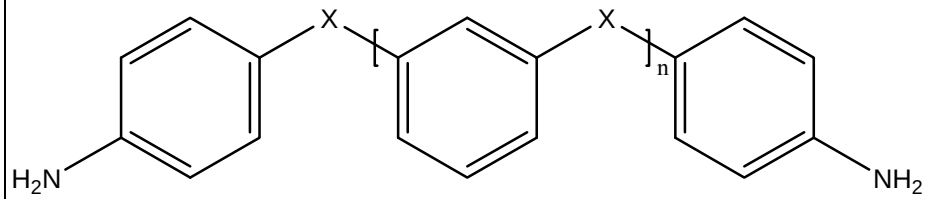
Physicochemical exclusion rules for corrosion and skin/eye irritation for CNHal chemicals[7,8]

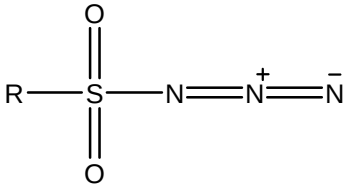
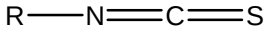
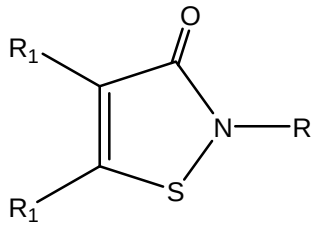
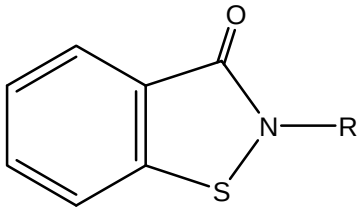
If molecular weight >380, then not classified as R34, R35 or R38

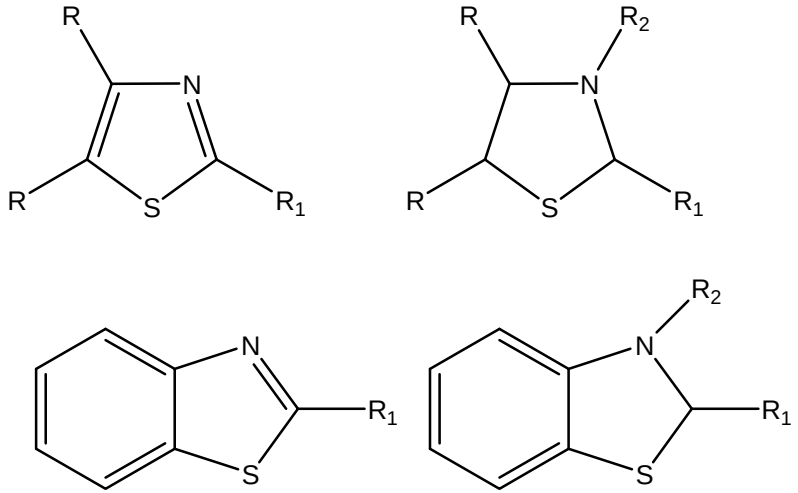
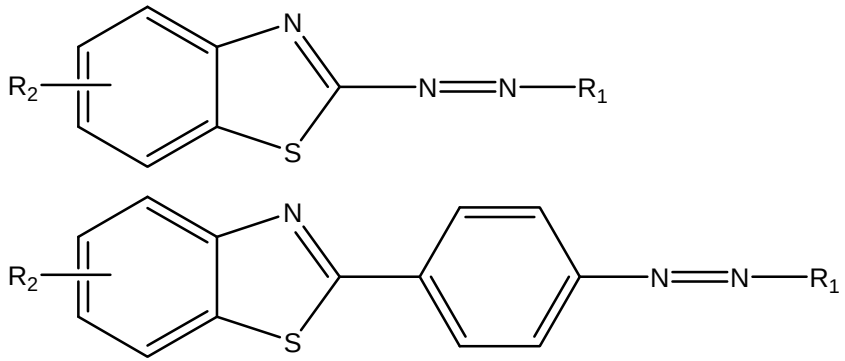
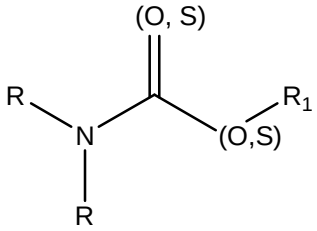
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 3.8, then not classified as R34, R35, R38 or R41
If log Kow > 9, then not classified as R34, R35, R38, R41 or R36

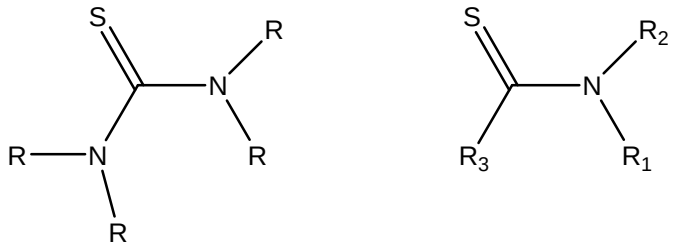
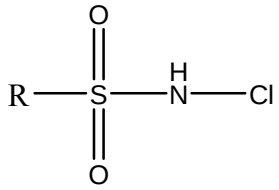
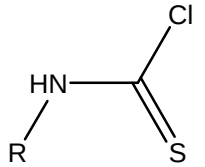
If aqueous solubility < 0.1 g/L, then not classified as R34, R35
If aqueous solubility < 0.004 g/L, then not classified as R34, R35 or R41
If aqueous solubility < 0.001 g/L, then not classified as R34, R35, R41 or R38

Table 5 - CNS/CNSHal - Structure contains only C, H, (O), N and S atoms or Structure contains only C, H, (O), N, S and Hal atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
B-Naphthylamines, sulfonated	 R_1= H, OH, NH_2 R_2= OH, HO_3S-CH_2-CH_2	Included in the category are azo dyes which release a sulfonated ß-naphthylamine upon reduction of azo bonds. Also included in the category are N-acetylated sulfonated ß-naphthylamines. Concern is restricted to sulfonated ß-naphthylamines where not more than two sulfonate or sulfatoethylsulfone group(s) are on the ring distal to the ß-amino group.	Carcinogenicity		6
Dianilines		The chemical must have at least two phenyl rings with a bridging carbon, oxygen, nitrogen, or sulfur Each terminal phenyl ring must have a primary amino group (or a group that can be readily metabolized to a primary amino group) either meta- or para- to the bridging atom Compounds with one or	Carcinogenicity, Systemic toxicity	Systemic toxicity concern regarding retinopathy and reproductive organs. The compounds of greatest concern are those having X = C, N, or O and n = 0 or 1.	6

	X= C,N, O or S n ≥ 0	more additional phenyl ring(s), with or without ring substituents, and one or more bridging atoms are also included in the category.			
Sulphonyl azides			Sensitisation		3
Isothiocyanates		For corrosion: R = aliphatic, else R = any. Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Corrosion, Sensitisation		1,2,3,4
(Benzo)isothiazolinones	  R = H or C- R_1 = H, alkyl or part of an aromatic ring	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes, Sensitisation		1, 3, 5

Thiazoles and thiazolidines	 R_1 = H or C-any R_2 = H or aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5
Aminobenzothiazole azo dyes		The boundaries are not strictly defined. For a typical member of the category, R_1 = N- and/or ring substituted p-aminophenyl groups, and R_2 = halogens or nitro groups.	Systemic toxicity, Carcinogenicity	Concern for thyroid and liver	6
Alkylthiocarbamate	 R = aliphatic carbon or hydrogen R1 = aliphatic carbon		Carcinogenicity		4

Thiocarbonyl	 R_3 = any except OH, SH, O^-, S^-		Carcinogenicity	Nongenotoxic	4
N-Chloro-sulfonamides			Sensitisation		3
Alpha-carbamoyl halogen compounds (a-halo-carbomoyl)	 R = alkyl, aryl	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2
Heterocyclic polycyclic aromatic hydrocarbons	Three or more fused rings, heteroaromatic		Carcinogenicity		4

Physicochemical exclusion rules for corrosion and skin/eye irritation for CNS chemicals[7,8]

If molecular weight > 620, then not classified as R34, R35

If log Kow < -2, then not classified as R34, R35 or R38
If log Kow > 3.6, then not classified as R41*, R36
If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.006 g/L, then not classified as R41* or R36

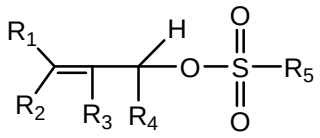
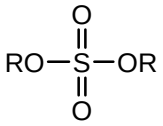
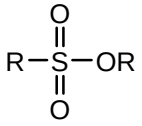
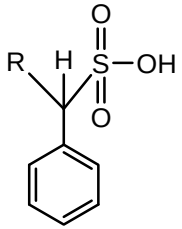
* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

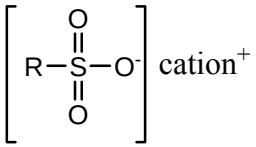
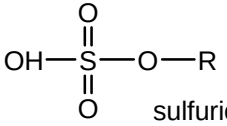
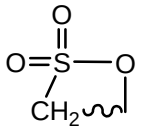
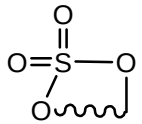
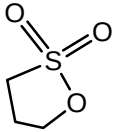
Physicochemical exclusion rules for corrosion and skin/eye irritation for CNSHal chemicals[7,8]
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41 or R36

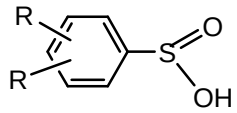
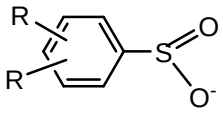
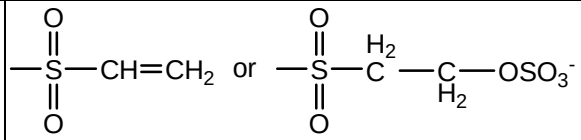
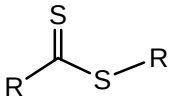
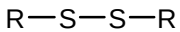
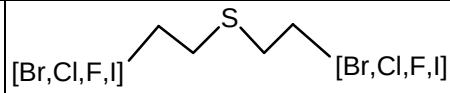
If aqueous solubility < 0.00002 g/L, then not classified as R41*
If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

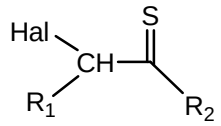
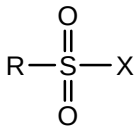
* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

Table 6 - CS/CSHal - Structure contains only C, H, (O) and S atoms or Structure contains only C, H, (O), S and Hal atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
Allyl sulfates	 R_1, R_2, R_3, R_4 = H, alkyl, arylalkyl or aryl group R_5 = alkyl, arylalkyl or aryl group	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2
Dialkylsulfates	 R = alkyl, aryl		Sensitisation		3
Dialkylsulfonates	 R = alkyl, aryl	For Carcinogenicity: R=alkyl with C<5 (also substituted with halogens) or benzyl.	Carcinogenicity, Sensitisation		3,4
Benzyl sulfonate	 R = alkyl, arylalkyl or aryl	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2

Sulfonic salts		Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2, 5
Esters of organic sulfonic or sulfuric esters	 sulfuric esters R can be aromatic ring or aliphatic chain. R = aromatic ring than sulfonic salts Na/SO_3 seem to be non-irritants for 8/10, except when an amine is attached.  cyclic sulfonic esters  cyclic sulfuric esters	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
Propiosultones		Physicochemical exclusion rules apply for corrosion/irritation.	Carcinogenicity, Corrosion		2,4

Aromatic sulphinic acids and salts	 R = any 		Sensitisation		1
Vinyl sulfones			Carcinogenicity		6
Thioesters	 R = any		Sensitisation		3
Disulfides		For sensitisation R = alkyl, aryl For corrosion R = alkyl Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation, Sensitisation		2, 3
S mustard			Carcinogenicity		4

Alpha-halogenated thioaldehydes, thioketones	 R_1, R_2 = H, alkyl, arylalkyl or aryl group	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion/Skin irritation		2
Sulphonyl halides	 R = alkyl, aryl X = Cl, Br		Sensitisation		3

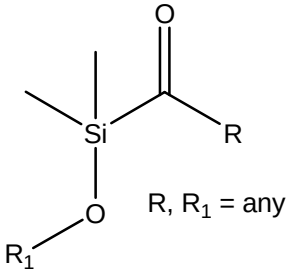
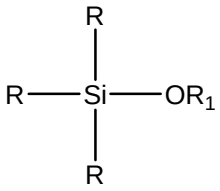
Physicochemical exclusion rules for corrosion and skin/eye irritation for CS and CSHal chemicals[7,8]

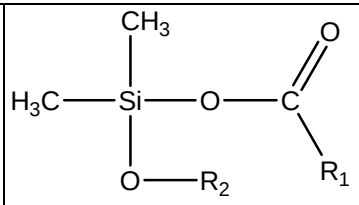
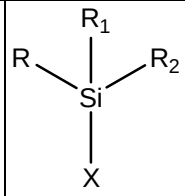
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*
If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

Table 7 CSi and CSiHal - Structure contains only C, H, (O), and Si atoms or Structure contains only C, H, (O), Si and Halogen atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
Silicon ethers with alpha ketone groups	 R, R_1 = any	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
Alkoxy silane	 R = any R1 = alkyl	Methoxy- and ethoxysilanes are presumed not to pose a hazard under any conditions if the equivalent weight is 5,000 and no more than 25% of species have molecular weights less than 1,000 and no more than 10% of species have molecular weights less than 500. For alkoxysilanes with alkyl substituents larger than propyl groups, the equivalent weight cutoff is 1,000. The degree of concern depends on the relative abundance of lower molecular weight species, but there is no molecular weight threshold above which there would be no concern. Physicochemical exclusion rules apply for corrosion/irritation.	Systemic toxicity, skin irritation	Concern for lung toxicity from inhalation of vapors or aerosols	2, 6

Mixed Oxy-Carboxysilanes	 R_1 , R_2 = any	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2
Organic silicon halides	 R, R_1 , R_2 = any X = F, Cl, Br, I	Physicochemical exclusion rules apply for corrosion/irritation.	Corrosion		2

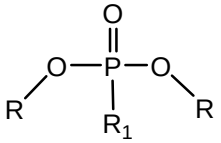
Physicochemical exclusion rules for corrosion and skin/eye irritation for CSi and CSiHal chemicals[7,8]

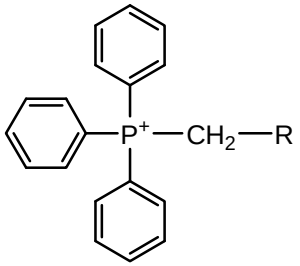
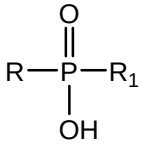
If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*
If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

Table 8 - Other - Structure contains atoms other than C, H, N, O, S, Si and Halogen atoms

Category	Structure	Boundaries	Endpoints	Comment	Reference
Nickel compounds	Inorganic and organic compounds of nickel in which there is the potential for uptake of either Ni^{2+} or organonickel.		Systemic toxicity, carcinogencity		6
Boron compounds	Includes borates, organoborates, borate esters, boron hydrides, boranes, boroxines.		Systemic toxicity, reproductive toxicity	Concerns for blood and neurotoxicity	6
Organotins	Includes all mono-, di-, tri- and tetra-alkyl or phenyl organotin compounds, including organotin esters/oxides.	Physicochemical exclusion rules apply for corrosion/irritation.	Systemic toxicity, Corrosion/Skin irritation	Concerns for neurotoxicity and immunotoxicity	6
Alkyl or benzyl ester of phosphinic acid	 R = Alkyl with C < 5 (also substituted with halogens), or benzyl R_1 = any atom/group except OH, SH, O^-, S^-	R=alkyl with C<5 (also substituted with halogens) or benzyl.	Carcinogenicity		4

Triphenylphosphonium salts	 R = any	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5
Organic phosphinic acids and their derivatives	 R = aryl or aliphatic chain	Physicochemical exclusion rules apply for corrosion/irritation.	Serious damage to eyes		5

Physicochemical exclusion rules for corrosion and skin/eye irritation for chemicals containing atoms other than C, H, N, O, S, Si and Halogen atoms [7,8]

If log Kow < -3.1, then not classified as R34, R35 or R38
If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*
If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

References:

1) Gerner, I., Barratt, M.D., Zinke, S., Schlegel, K., Schlede, E. (2004) Development and Prevalidation of a List of Structure-Activity Relationship Rules to be Used in Expert Systems for Prediction of the Skin-sensitising Properties of Chemicals. Alternatives to Laboratory Animals . 32: 487-509
2) Hulzebos, E., Walker, J.D., Gerner, I. and Schlegel, K. (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. QSAR Combinatorial Science. 24:332-342
3) Barratt, M.D., Basketter, D.A., Chamberlain, M., Payne, M.P., Admans, G.D., Langowski, J.J. (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839
4) Benigni R, Bossa C, Jeliazkova N, Netzeva T, Worth A (2008) The Benigni / Bossa rulebase for mutagenicity and carcinogenicity - a module of Toxtree. EUR 23241 EN. Luxenbourg, Office for the Official Publications of the European Communities. EUR - Scientific and Technical Report Series. download: http://ecb.jrc.it/documents/QSAR/EUR_23241_EN.pdf
5) Tsakovska, I., Saliner Gallegos, A., Netzeva, T., Pavan, M. and Worth, A.P. (2007) Evaluation of SARs for the prediction of eye irritation/corrosion potential - structural inclusion rules in the BfR decision support system. SAR and QSAR in Environmental Research. 18: 221-235
6) US EPA (2002) TSCA New Chemicals Program (NCP) Chemical Categories. Washington. http://www.epa.gov/opptintr/newchems/pubs/cat02.pdf
7) Rorije E, Hulzebos EM (2005) Evaluation of (Q)SARs for the prediction of Skin Irritation/Corrosion Potential. Physico-chemical exclusion rules. Report submitted by the National Institute of Public Health and Environment (RIVM) to the European Chemicals Bureau (ECB). Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.
8) Tsakovska I, Netzeva T & Worth AP (2005). Evaluation of (Q)SARs for the Prediction of Eye Irritation/Corrosion Potential -Physicochemical Exclusion Rules. EUR 21897 EN. Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.
9) http://www.inchem.org/documents/iarc/vol71/012-catechol.html

16 –POPS CRITERIA AND NATIONAL ENVIRONMENTAL PBT (PERSISTENT, BIOACCUMULATIVE AND TOXIC) CRITERIA

POPs Criteria

The Stockholm Convention on Persistent Organic Pollutants (POPs) entered into force on 17 May 2004. Australia ratified the Convention on 20 May 2004, and obligations of the POPs Convention entered into force for Australia on 18 August 2004.

The Stockholm Convention provides scientifically based criteria for potential POPs (these would also be relevant criteria for very persistent and very bioaccumulative substances). The screening criteria set out in Annex D of the convention are:

For persistence:

- Evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months, or
- Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the Convention.

For bioaccumulation:

- Evidence that the bioconcentration factor (BCF) or bioaccumulation factor (BAF)in aquatic species for the chemical is greater than 5000 or, in the absence of such data, that the log Kow is greater than 5; or
- Evidence that a chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity; or
- Monitoring data in biota indicating that the bioaccumulation potential of the chemical is sufficient to justify its consideration within the scope of the Convention.

Potential for Long Range Transport:

- Measured levels of the chemical in locations distant from the sources of its release that are of potential concern;
- Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or
- Environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days;

Adverse Effects:

- Evidence of adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this Convention, or
- Toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

PBT Criteria for Australia

The Stockholm Convention criteria are in the context of POPs, therefore, can be defined as being for *very* persistent and *very* bioaccumulative substances. A chemical deemed persistent or bioaccumulative may not carry values as high as those prescribed in the POPs criteria and warranting collective international action.

National Environmental PBT criteria are set out below. More information regarding these criteria can be found in the Environmental Risk Assessment Guidance Manual for Industrial Chemicals located on the website of the National Environment Protect Council (http://www.ephc.gov.au/sites/default/files/CMgt_NChEM__ERAGM_for_Industrial_Chemicals_200902.pdf).

For persistence:

- Evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months, or that its half-life in air is >2 days.

For bioaccumulation:

A BCF of >2000, or in its absence, a logKow $\geq$ 4.2

For toxicity (environmental):

- For toxicity to the aquatic environment the levels classified as Category Chronic 1 under long term aquatic hazard of the proposed GHS classifications (see table below);
- If inadequate chronic toxicity data are available (and providing the substance is not readily biodegradable and/or the experimentally determined BCF is $\geq$500), the levels classified as Category Chronic 1 based on acute toxicity of the proposed GHS classifications (see table below); and
- Toxicity to other (terrestrial) organisms or evidence such as endocrine disruption effects should be considered on a case by case basis, the former should be compared with the ecotoxicity categories DEWHA has developed for agvet chemicals (see table below).

Table summarising National Environmental Criteria for PBT Chemicals

<table>
<tr><td colspan="3">Persistence</td></tr>
<tr><td colspan="3">For PBT purposes a chemical is considered persistent in a particular media if its half life in the media exceeds the following:</td></tr>
<tr><td rowspan="6"></td><td>Media</td><td>Half-Life</td></tr>
<tr><td>Water</td><td>2 months</td></tr>
<tr><td>Soil</td><td>6 months</td></tr>
<tr><td>Sediment</td><td>6 months</td></tr>
<tr><td>Air</td><td>2 days</td></tr>
<tr><td colspan="3">Bioaccumulation</td></tr>
<tr><td colspan="3">For PBT purposes a chemical is considered to be Bioaccumulative if it has a BCF/BAF of >2000, or in the absence of any BCF/BAF measurement, a logKow $\geq$ 4.2.</td></tr>
</table>

Toxicity		
For PBT purposes, in respect of aquatic toxicity, a chemical may be considered toxic under the following circumstances (corresponding to criteria for GHS chronic category 1):		
Non-rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic NOEC or EC_x (for fish)	≤ 0.1 mg/L and/or
	Chronic NOEC or EC_x (for crustacea)	≤ 0.1 mg/L and/or
	Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 0.1 mg/L
Rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic NOEC or EC_x (for fish)	≤ 0.01 mg/L and/or
	Chronic NOEC or EC_x (for crustacea)	≤ 0.01 mg/L and/or
	Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 0.01 mg/L
Substances for which adequate chronic toxicity data are not available (providing criteria for P and B are met)	96 h LC_{50} (for fish)	≤ 1 mg/L and/or
	48 h EC_{50} (for crustacea)	≤ 1 mg/L and/or
	72 or 96 h ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/L
	and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K_{ow} ≥ 4).	
Toxicity to other (terrestrial) organisms	Should be considered on a case by case basis, compared with the "highly toxic classifications" DEWHA has developed for Agvet chemicals.	
Long term toxicity or evidence such as endocrine disruption effects	Should be considered on a case by case basis.	