

EXPOSURE DRAFT



EXPOSURE DRAFT

Industrial Chemicals (General) Rules 2018

I, Bridget McKenzie, Minister for Rural Health, make the following rules.

Dated 2018

Bridget McKenzie [**DRAFT ONLY—NOT FOR SIGNATURE**]
Minister for Rural Health

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Chapter 1—Preliminary

Part 1—Preliminary

1 Name

This instrument is the *Industrial Chemicals (General) Rules 2018*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	Immediately after the commencement of section 3 of the <i>Industrial Chemicals Act 2017</i> .	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Industrial Chemicals Act 2017*.

4 Simplified outline of this instrument

This instrument prescribes various matters for the purposes of the *Industrial Chemicals Act 2017*.

This Chapter includes preliminary provisions, including definitions for the purposes of the Act and this instrument. It also sets out certain circumstances in which a ban on the use of animal test data for applications under the Act relating to industrial chemicals that are to be introduced for an end use solely in cosmetics will and will not apply.

Chapter 2 deals with the categorisation of industrial chemical introductions. Under the Act, there are 6 different categories of introductions, with provision for the rules to specify the circumstances in which an introduction of an industrial chemical will be an exempted introduction or a reported introduction. Chapter 2 sets out how introductions can be categorised as exempted or reported by dealing with certain circumstances in which introductions will be exempted or

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Chapter 1 Preliminary

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reported, as well as providing a means to determine the level of indicative risk posed by the introduction of an industrial chemical.

Chapter 3 deals with reporting obligations. It sets out the requirements that must be met for pre-introduction reports for reported introductions, as well as for annual declarations that must be made by all persons who introduce industrial chemicals in a registration year (other than excluded introductions).

Chapter 4 sets out the record keeping obligations in relation to all introductions under the Act by reference to the category of introduction, and in some cases the sub-category of introduction.

Chapter 5 deals with the confidentiality and disclosure of information, including the circumstances in which an AACN or generalised end use must be used.

Chapter 6 deals with the movement of industrial chemicals into and out of Australia in accordance with international agreements and arrangements, and the Executive Director's power to approve the import or export of certain industrial chemicals that relate to those agreements and arrangements on application.

5 Definitions

In this instrument:

Act means the *Industrial Chemicals Act 2017*.

Attorney-General's Department means the Department administered by the Minister administering the *Judiciary Act 1903*.

biochemical means an industrial chemical that:

- (a) is directly produced by living, or once-living, cells or cellular components; or
- (b) is a derivative or modification of such an industrial chemical, in which the original industrial chemical remains substantially intact.

biocide means an industrial chemical that is an active constituent in a product that is for an end use to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical means.

biopolymer means a polymer that is a biochemical.

chemical identity holder has the meaning given by the Guidelines.

designated kind of release into the environment has the meaning given by subsection 28(2).

end use in an article with food contact: an industrial chemical has an *end use in an article with food contact* where the industrial chemical becomes part of an article that will come into contact with food, other than:

- (a) where the end use of the industrial chemical is at the non-food contact surface of a glass or metal article; or

- (b) if the food that the article will come into contact with is rainwater—where the contact with the rainwater is transient.

environment categorisation volume for an industrial chemical means the environment categorisation volume for the industrial chemical worked out in accordance with the Guidelines.

Environment Department means the Department administered by the Minister administering the *Environment Protection and Biodiversity Conservation Act 1999*.

environment exposure band for the introduction of an industrial chemical has the meaning given by section 28.

environment hazard characteristic of an industrial chemical means a hazard characteristic, of the industrial chemical, that is mentioned in the table in section 29.

food has the same meaning as in the *Food Standards Australia New Zealand Act 1991*.

fuel has the same meaning as in the *Fuel Quality Standards Act 2000*.

Guidelines means the Industrial Chemicals Categorisation Guidelines issued by the Executive Director, as existing on the commencement day.

hazard characteristic of an industrial chemical means a human health hazard characteristic, or an environment hazard characteristic, of the industrial chemical.

Health Department means the Department administered by the Minister administering the *National Health Act 1953*.

highest indicative risk, in relation to the introduction of an industrial chemical, has the meaning given by step 6 of the method statement in section 19.

highly branched organic chemical means an industrial chemical that is branched at:

- (a) more than one tertiary carbon; or
- (b) more than one quaternary carbon; or
- (c) a combination of tertiary and quaternary carbons.

high molecular weight polymer means a polymer that has a number average molecular weight that is greater than or equal to 1,000 g/mol.

human health exposure band for the introduction of an industrial chemical has the meaning given by section 24.

human health hazard characteristic of an industrial chemical means a hazard characteristic, of the industrial chemical, that is mentioned in the table in section 25.

indicative environment risk, in relation to the introduction of an industrial chemical, has the meaning given by section 30.

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indicative human health risk, in relation to the introduction of an industrial chemical, has the meaning given by section 26.

international assessment body, in relation to the introduction of an industrial chemical that is internationally-assessed for human health or internationally-assessed for the environment, means the body mentioned in the table in subsection 6(3) that assessed or evaluated the industrial chemical.

internationally-assessed for human health: see subsection 6(1).

internationally-assessed for the environment: see subsection 6(2).

IUPAC name, for an industrial chemical, means the International Union of Pure and Applied Chemistry name for the industrial chemical.

known hazard classification, for an industrial chemical, has the meaning given by the Guidelines.

low concern following migration to food has the meaning given by the Guidelines.

monohalogenated organic chemical means a chemical that:

- (a) is carbon based; and
- (b) contains one covalently bonded bromine, chlorine, fluorine or iodine substituent.

monomer means a chemical that is capable of forming covalent bonds with 2 or more like or unlike molecules under the conditions of a polymer-forming reaction used for a process of polymer formation.

monomer unit means the reacted form of a monomer in a polymer.

nanoscale means the particle size range of 1 to 100 nm.

not persistent, in relation to an industrial chemical, has the meaning given by the Guidelines.

particle means a minute piece of matter with defined physical boundaries.

personal vaporiser means a device that produces a vapour or aerosol that is intended to be inhaled into the lungs, including the following devices:

- (a) e-cigarettes;
- (b) e-cigars;
- (c) e-hookah pens;
- (d) e-pens;
- (e) e-pipes;
- (f) vape pens.

polyhalogenated organic chemical means a chemical that:

- (a) is carbon based; and
- (b) contains more than one covalently bonded bromine, chlorine, fluorine or iodine substituent.

polymer means a chemical that consists of molecules that:

- (a) are characterised by the sequence of one or more types of monomer units; and
- (b) are distributed over a range of molecular weights where the difference in molecular weights is primarily attributable to differences in the number of monomer units; and
- (c) are greater than 50% by weight of which have a sequence of at least 3 monomer units covalently bound to at least one other:
 - (i) monomer unit; or
 - (ii) molecule that is linked to one or more sequences of monomer units but cannot, under the conditions of the relevant reaction used for the particular process of polymer formation, become a repeating unit in the polymer structure.

polymer of low concern has the meaning given by Schedule 1.

radioactive chemical means a chemical that:

- (a) is a controlled material (within the meaning of the *Australian Radiation Protection and Nuclear Safety Act 1998*); and
- (b) is a nuclide mentioned in the table in clause 2 of Schedule 2 to the *Australian Radiation Protection and Nuclear Safety Regulations 1999*; and
- (c) has an activity concentration value (within the meaning of the *Australian Radiation Protection and Nuclear Safety Regulations 1999*) greater than the activity concentration value for the nuclide set out in the table in clause 2 of Schedule 2 to those Regulations.

reactant, in relation to a polymer, means a chemical (including a monomer) that is used in the polymer-forming reactions to become chemically a part of the polymer composition.

research and development: an introduction of an industrial chemical is for **research and development** if:

- (a) the introduction is for the purposes of systematic investigation or research, by means of experimentation or analysis; and
- (b) the introduction is not for distribution of the industrial chemical, or a product containing the industrial chemical, to potential customers in order to explore market capability in a competitive situation.

specified class of introduction: see section 7.

supply has the same meaning as in the *Fuel Quality Standards Act 2000*.

tattoo ink means a combination of industrial chemicals that:

- (a) contains one or more colouring agents; and
- (b) is applied to the dermal layer of the skin for the purposes of colouring the skin.

UVCB substance description means a description of a UVCB substance that provides specific identity information about the UVCB substance, including one or more of the following:

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- (a) the manufacturing process for the UVCB substance;
- (b) raw material sources of the UVCB substance;
- (c) carbon number ranges for the UVCB substance;
- (d) physical property ranges for the UVCB substance;
- (e) biological sources of the UVCB substance.

UV filter: an industrial chemical is a **UV filter** if the industrial chemical is intended to protect the skin against ultraviolet radiation in the range of 290 to 400 nm by absorption, reflection or scattering of ultraviolet radiation.

6 Internationally-assessed introductions

- (1) For the purposes of this instrument, an introduction by a person of an industrial chemical is ***internationally-assessed for human health*** if:
 - (a) the industrial chemical has been subject to an assessment or evaluation of a kind mentioned in an item of the table in subsection (3) by the body mentioned in the item; and
 - (b) the assessment or evaluation was conducted in another jurisdiction (the ***overseas jurisdiction***); and
 - (c) the assessment or evaluation in the overseas jurisdiction was in relation to risks to human health; and
 - (d) the assessment or evaluation was:
 - (i) for the same end use for which the industrial chemical is to be introduced in Australia by the person; and
 - (ii) for a volume of the industrial chemical that is the same or higher than the volume of the industrial chemical that is to be introduced in Australia in a registration year by the person; and
 - (iii) for a maximum concentration of the industrial chemical at end use that is the same or higher than the maximum concentration of the industrial chemical at the end use that is to be introduced in Australia by the person; and
 - (e) the risks to human health from the introduction or use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, as determined in accordance with the Guidelines; and
 - (f) introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction.
- (2) For the purposes of this instrument, an introduction by a person of an industrial chemical is ***internationally-assessed for the environment*** if:
 - (a) the industrial chemical has been subject to an assessment or evaluation of a kind mentioned in an item of the table in subsection (3) (other than item 2) by the body mentioned in the item; and
 - (b) the assessment or evaluation was conducted in another jurisdiction (the ***overseas jurisdiction***); and
 - (c) the assessment or evaluation in the overseas jurisdiction was in relation to risks to the environment; and
 - (d) the assessment or evaluation was:

- (i) for the same end use for which the industrial chemical is to be introduced in Australia by the person; and
 - (ii) for a volume of the industrial chemical that is the same or higher than the volume of the industrial chemical that is to be introduced in Australia in a registration year by the person; and
 - (iii) for a maximum concentration of the industrial chemical at end use that is the same or higher than the maximum concentration of the industrial chemical at the end use that is to be introduced in Australia by the person; and
 - (e) the risks to the environment from the introduction or use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, as determined in accordance with the Guidelines; and
 - (f) introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction.
- (3) For the purposes of paragraphs (1)(a) and (2)(a), the following table sets out the kinds of assessments or evaluations, and the bodies that conduct the assessments or evaluations.

Assessments and evaluations conducted by international bodies

Item	Type of assessment or evaluation	International assessment body
1	New substance assessments under the <i>Environmental Protection Act 1999</i> (Canada)	(a) Environment and Climate Change Canada; or (b) Health Canada
2	Opinions from the European Scientific Committee on Consumer Safety that have been taken up in the Annexes of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products	European Scientific Committee on Consumer Safety
3	Risk assessments that: (a) are in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals; and (b) are subsequently reviewed by the European Chemicals Agency Risk Assessment Committee	(a) an authority of a member state of the European Union; or (b) the European Chemicals Agency
4	Risk assessments that: (a) are in accordance with Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012; and (b) are subsequently reviewed by the European Chemicals Agency Biocidal Products Committee	(a) an authority of a member state of the European Union; or (b) the European Chemicals Agency
5	Risk assessments that:	An applicant for authorisation in accordance

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Assessments and evaluations conducted by international bodies		
Item	Type of assessment or evaluation	International assessment body
	(a) are done by applicants for authorisation; and (b) are in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals; and (c) are subsequently reviewed by the European Chemicals Agency Risk Assessment Committee	with Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
6	Assessments: (a) that are new chemical risk assessments under the <i>Environmental Protection Act 1999</i> (Canada); and (b) for which Australia has been involved as a secondary jurisdiction in an international parallel process	(a) Environment and Climate Change Canada; or (b) Health Canada
7	Assessments: (a) that are new chemical risk assessments under the <i>Toxic Substances Control Act 1976</i> (United States of America) as amended by the <i>Frank R. Lautenberg Chemical Safety for the 21st Century Act 2016</i> (United States of America); and (b) for which Australia has been involved as a secondary jurisdiction in an international parallel process	United States Environmental Protection Agency

- (4) To avoid doubt, the introduction of an industrial chemical may be internationally-assessed for human health and internationally-assessed for the environment on the basis of a single assessment or evaluation by an international assessment body mentioned in the table in subsection (3) (other than the body mentioned in item 2 of that table).

7 Specified classes of introductions

- (1) An introduction of an industrial chemical is a *specified class of introduction*, if:
- (a) the introduction is not solely for the industrial chemical to be used in research and development; and
 - (b) subsection (2), (3) or (4) applies to the introduction.
- (2) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions:
- (a) introductions of an industrial chemical that is a gas (other than a gas that is not persistent);
 - (b) introductions of a highly branched organic chemical;

- (c) introductions of an industrial chemical for an end use as a biocide;
 - (d) introductions of an industrial chemical that involve a designated kind of release into the environment.
- (3) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions:
- (a) introductions of a biochemical;
 - (b) introductions of a monohalogenated organic chemical (other than an acyl halide);
 - (c) introductions of an industrial chemical that is a GM product;
 - (d) introductions of an industrial chemical that is a polyhalogenated organic chemical.
- (4) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions:
- (a) introductions of a UV filter;
 - (b) introductions of an industrial chemical for an end use in an article with food contact;
 - (c) introductions of an industrial chemical for an end use in a personal vaporiser;
 - (d) introductions of an industrial chemical for an end use in tattoo ink.

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Part 2 Provisions relating to defined terms in the Act

Section 8

Part 2—Provisions relating to defined terms in the Act

8 Kinds of data or information that relate to tests conducted on animals

For the purposes of the definition of *animal test data* in section 9 of the Act, any data or information that results from tests involving either of the following is prescribed:

- (a) application of an industrial chemical, either on its own, or in combination with one or more other chemicals, to a live vertebrate animal (other than a human);
- (b) experimentation using a live vertebrate animal (other than a human) to test any effects of an industrial chemical, either on its own, or in combination with one or more other chemicals.

9 Kinds of objects that are not articles

For the purposes of the definition of *article* in section 9 of the Act, the following kinds of objects are prescribed:

- (a) objects that are a piece of matter whose purpose is determined to a lesser degree by the object's shape, surface or design, compared to the object's chemical composition;
- (b) objects that are wholly fluid.

10 Prescribed international agreements

For the purposes of paragraph (b) of the definition of *prescribed international agreement* in section 9 of the Act, the following international agreements are prescribed:

- (a) the Rotterdam Convention;
- (b) the Stockholm Convention on Persistent Organic Pollutants done at Stockholm on 22 May 2001, as amended and in force for Australia from time to time.

Note: The Stockholm Convention is in Australian Treaty Series 2004 No. 23 ([2004] ATS 23) and in 2018 could be viewed in the Australian Treaties Library on the AustLII website (<http://www.austlii.edu.au>).

11 Days that are not working days

For the purposes of the definition of *working day* in section 9 of the Act, the following days are prescribed:

- (a) 27 December;
- (b) 28 December;
- (c) 29 December;
- (d) 30 December;
- (e) 31 December.

12 Chemicals or substances that are not industrial chemicals

For the purposes of subsection 10(2) of the Act, radioactive chemicals are prescribed.

13 Introductions that are taken not to be for personal use

For the purposes of subsection 11(6) of the Act, introduction of an industrial chemical for the purpose of carrying on an enterprise (within the meaning of the *A New Tax System (Goods and Services Tax) Act 1999*) is prescribed.

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Part 3—Prescribed bodies

14 Bodies that the Executive Director must seek advice from

For the purposes of subsections 34(1), 46(1), 71(1) and 91(1) of the Act, the following table sets out the bodies from which the Executive Director must seek advice if the Executive Director is considering taking action under the relevant subsection based on a risk mentioned in an item in the table.

Prescribed bodies		
Item	If the Executive Director is considering the action based on ...	Then the prescribed body is ...
1	risks to the environment	the Environment Department
2	risks to human health related to consumer products	the Australian Competition and Consumer Commission
3	risks to human health related to drinking water	the National Health and Medical Research Council
4	risks to human health related to food	Food Standards Australia New Zealand
5	risks to human health related to the health of workers	Safe Work Australia
6	risks to human health related to public health	the Health Department
7	risks to human health or the environment related to transport of an industrial chemical	the National Transport Commission
8	risks to human health or the environment where there may be national security implications	the Attorney-General's Department

15 Bodies that the Executive Director may seek advice from

- (1) For the purposes of subsections 34(2), 46(2), 56(1), 91(2), 107(1) and 111(5) of the Act, the following bodies are prescribed:
- the Attorney-General's Department;
 - the Australian Competition and Consumer Commission;
 - the Environment Department;
 - Food Standards Australia New Zealand;
 - the Health Department;
 - the National Health and Medical Research Council;
 - the National Transport Commission;
 - Safe Work Australia;
 - each body in a State or Territory that has responsibility for matters relating to protection of the environment;

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- (j) each body in a State or Territory that has responsibility for matters relating to public health;
 - (k) each body in a State or Territory that has responsibility for matters relating to work health and safety.
- (2) For the purposes of subsection 71(2) and paragraph 75(a) of the Act, the following bodies are prescribed:
- (a) the Attorney-General's Department;
 - (b) the Australian Competition and Consumer Commission;
 - (c) the Environment Department;
 - (d) Food Standards Australia New Zealand;
 - (e) the Gene Technology Regulator;
 - (f) the Health Department;
 - (g) the National Health and Medical Research Council;
 - (h) the National Transport Commission;
 - (i) Safe Work Australia;
 - (j) each body in a State or Territory that has responsibility for matters relating to protection of the environment;
 - (k) each body in a State or Territory that has responsibility for matters relating to public health;
 - (l) each body in a State or Territory that has responsibility for matters relating to work health and safety.

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Part 4 Commercial evaluation authorisations

Section 16

Part 4—Commercial evaluation authorisations

16 Circumstances in which an application cannot be made

- (1) For the purposes of subparagraph 53(1)(b)(i) of the Act, the following circumstances are prescribed:
 - (a) making the industrial chemical itself available to the general public;
 - (b) making the industrial chemical available to the general public in combination with one or more other chemicals;
 - (c) making the industrial chemical available to the general public as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article.
- (2) For the purposes of subparagraph 53(1)(b)(iv) of the Act, introduction of a volume of an industrial chemical under a commercial evaluation authorisation must not exceed 10 tonnes over the period for which the authorisation is to be in force.

Part 5—Ban on animal test data for applications for cosmetics

17 Ban on animal test data for applications for cosmetics

For the purposes of subsection 168(2) of the Act, all circumstances are prescribed, other than circumstances where:

- (a) animal test data:
 - (i) is available to the applicant; and
 - (ii) is derived from tests conducted on animals involving the industrial chemical to which the application relates; and
 - (iii) is only relevant to identifying a human health hazard characteristic or an environment hazard characteristic of that industrial chemical; and
 - (iv) is not used to establish whether or not that industrial chemical has a human health hazard characteristic, or an environment hazard characteristic, where such information is required to be provided as part of an application made in accordance with section 167 of the Act in relation to the industrial chemical to which the application relates;or
- (b) the environment hazard characteristics of the industrial chemical to which the application relates can only be determined using animal test data; or
- (c) both:
 - (i) the animal test data has been derived from tests conducted on animals involving a chemical other than the industrial chemical to which the application by the person relates; and
 - (ii) the other chemical is not an industrial chemical introduced by the person solely for an end use in cosmetics.

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Chapter 2 Categorisation of industrial chemicals

Part 1 Simplified outline of this Chapter

Section 18

Chapter 2—Categorisation of industrial chemicals

Part 1—Simplified outline of this Chapter

18 Simplified outline of this Chapter

Under the Act, there are 6 categories of introductions of industrial chemicals: listed introductions, exempted introductions, reported introductions, assessed introductions, commercial evaluation introductions and exceptional circumstances introductions.

This Chapter deals with the circumstances in which an introduction is an exempted introduction or a reported introduction.

In order to determine whether an introduction of an industrial chemical is exempted or reported, it is first necessary to determine whether the introduction falls within certain circumstances in which an introduction is exempted or reported, or is not exempted or reported.

If an introduction does not fit within those circumstances, the introduction may still be exempted or reported depending on the level of risk to human health and the environment from the introduction. The level of risk can be determined in accordance with this Chapter and can be used to determine the highest indicative risk from the introduction. If:

- (a) the highest indicative risk is very low, the introduction can be categorised as exempted; and
- (b) the highest indicative risk is low, the introduction can be categorised as reported.

Part 2—Determining if an introduction is exempted or reported

19 Determining if an introduction is exempted or reported

Whether the introduction of an industrial chemical is an exempted introduction or a reported introduction is worked out as follows:

Method statement

Step 1: Work out whether the introduction is covered by section 20.

If the introduction is covered by section 20, the introduction is not an exempted introduction or a reported introduction.

Otherwise, go to step 2.

Step 2: Work out whether the introduction is covered by section 21.

If the introduction is covered by section 21, for the purposes of paragraph 26(2)(a) of the Act, the introduction is an exempted introduction.

Otherwise, go to step 3.

Step 3: Work out whether the introduction is covered by section 22.

If the introduction is covered by section 22, for the purposes of paragraph 27(2)(a) of the Act, the introduction is a reported introduction.

Otherwise, go to step 4.

Step 4: Work out the indicative human health risk for the introduction (see section 23).

Step 5: Work out the indicative environment risk for the introduction (see section 27).

Step 6: Taking the indicative risks from steps 4 and 5, determine which is the highest indicative risk. The result is the **highest indicative risk** for the introduction.

If the highest indicative risk for the introduction is very low risk, for the purposes of paragraph 26(2)(a) of the Act, the introduction is an exempted introduction.

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Part 2 Determining if an introduction is exempted or reported

Section 20

If the highest indicative risk for the introduction is low risk, for the purposes of paragraph 27(2)(a) of the Act, the introduction is a reported introduction.

Otherwise, the highest indicative risk for the introduction is medium to high risk and the introduction is not an exempted introduction or a reported introduction.

Note: If an introduction of an industrial chemical is not categorised as an exempted introduction or a reported introduction and is not listed on the Inventory, it is generally an assessed introduction, see Division 2 of Part 3 of the Act.

20 Circumstances in which introductions are not exempted or reported

- (1) For the purposes of paragraphs 26(2)(b) and 27(2)(b) of the Act, an introduction of an industrial chemical by a person is not an exempted introduction or a reported introduction if subsection (2), (3), (6), (7), (8) or (9) of this section applies to the introduction.

Introduction of industrial chemical that is listed in Rotterdam or Stockholm Convention

- (2) This subsection applies to the introduction if:
- (a) the industrial chemical is:
 - (i) listed in Annex III to the Rotterdam Convention; or
 - (ii) listed in Annex A, B or C to the Stockholm Convention on Persistent Organic Pollutants done at Stockholm, as amended from time to time; and
 - (b) the industrial chemical is not listed in section 64, 65 or 66 of this instrument (which set out rules made for the purposes of subsection 163(1) of the Act).

Introduction of certain industrial chemicals at the nanoscale

- (3) This subsection applies to the introduction if:
- (a) the industrial chemical:
 - (i) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% of which (by number size distribution) have at least one external dimension in the nanoscale; and
 - (ii) is introduced as a solid or in a dispersion; and
 - (b) the introduction is not covered by subsection (4) of this section, or subsection 21(2) or (3).
- (4) For the purposes of paragraph (3)(b), this subsection covers the introduction if any of the following apply:
- (a) the industrial chemical rapidly dissolves in water or has a high dissolution rate;
 - (b) the industrial chemical does not persist at the nanoscale during its intended use;

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Categorisation of industrial chemicals **Chapter 2**
Determining if an introduction is exempted or reported **Part 2**

Section 20

- (c) the introduction of the nanoscale portion of the industrial chemical is incidental to the introduction of the non-nanoscale portion of the industrial chemical.
- (5) For the purposes of paragraph (4)(c), the introduction of the nanoscale portion of the industrial chemical is incidental to the introduction of the non-nanoscale portion if:
- (a) the industrial chemical is manufactured in Australia or overseas; and
 - (b) all of the following apply:
 - (i) the manufacture of the industrial chemical at the nanoscale is not the result of a deliberate manufacturing decision;
 - (ii) the industrial chemical at the nanoscale is not necessary for the manufacture of the non-nanoscale portion of the industrial chemical;
 - (iii) the industrial chemical at the nanoscale does not have specific technical characteristics which are the intended result of changes in the manufacturing process.

Introduction of persistent gas

- (6) This subsection applies to the introduction if:
- (a) the industrial chemical is a gas (other than a gas that is not persistent); and
 - (b) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 100 kg; and
 - (c) the introduction is not covered by subsection 21(2) or (3).

Introduction of certain fluorinated organic chemicals

- (7) This subsection applies to the introduction if:
- (a) the industrial chemical contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms; and
 - (b) the introduction is not covered by subsection 21(2) or (3).

Introduction of persistent polyhalogenated organic chemicals

- (8) This subsection applies to the introduction if:
- (a) the industrial chemical is a polyhalogenated organic chemical; and
 - (b) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 100 kg; and
 - (c) neither of the following apply to the industrial chemical:
 - (i) the industrial chemical is not persistent;
 - (ii) the industrial chemical is a polymer of low concern; and
 - (d) the introduction is not covered by subsection (7) of this section, or subsection 21(2) or (3).

Introduction of industrial chemical that is listed on the Inventory with conditions

- (9) This subsection applies to the introduction if:
- (a) the industrial chemical is listed on the Inventory; and

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Part 2 Determining if an introduction is exempted or reported

Section 21

- (b) the terms of the Inventory listing include a condition relating to the introduction or use of the industrial chemical.

21 Circumstances in which introductions are exempted introductions

- (1) For the purposes of step 2 of the method statement in section 19, the introduction of an industrial chemical by a person is covered by this section if subsection (2), (3), (4), (5), (6) or (7) of this section applies to the introduction.

Introduction of industrial chemical that is imported and subsequently exported

- (2) This subsection applies to the introduction if:
 - (a) the industrial chemical is imported into Australia; and
 - (b) the total volume of the industrial chemical is subsequently exported out of Australia; and
 - (c) at all times whilst the industrial chemical is in Australia, the packaging in which the industrial chemical is immediately contained is not opened; and
 - (d) at all times whilst the industrial chemical is in Australia, the industrial chemical is either:
 - (i) subject to customs control under the *Customs Act 1901*; or
 - (ii) subject to the control of the person who introduces the industrial chemical.

Introduction of industrial chemical that is solely for use in research and development

- (3) This subsection applies to the introduction if:
 - (a) the introduction of the industrial chemical is solely for the industrial chemical to be used in research and development; and
 - (b) the industrial chemical is not made available to the general public:
 - (i) on its own; or
 - (ii) in combination with one or more other industrial chemicals; or
 - (iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and
 - (c) control measures are used to eliminate or minimise the risks from the introduction or use of the industrial chemical to:
 - (i) persons involved in the research and development for which the industrial chemical is introduced; and
 - (ii) the environment; and
 - (d) the total volume of the industrial chemical introduced in a registration year by the person does not exceed:
 - (i) if the industrial chemical is introduced as a solid or in a dispersion, and, consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale—10 kg; or
 - (ii) otherwise—100 kg.

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Categorisation of industrial chemicals **Chapter 2**
Determining if an introduction is exempted or reported **Part 2**

Section 21

Introduction of polymer that is comparable to a polymer that is listed on the Inventory

- (4) This subsection applies to the introduction if:
- the industrial chemical is a polymer; and
 - the polymer contains all the same reactants as another polymer that is listed on the Inventory (the **listed polymer**); and
 - if the polymer contains reactants that the listed polymer does not—the additional reactants do not constitute more than 2% by weight of the polymer.

Introduction of industrial chemical that is comparable to a listed industrial chemical

- (5) This subsection applies to the introduction if:
- the introduction is of an industrial chemical mentioned in column 1 of an item in the following table; and
 - the industrial chemical is comparable to the industrial chemical, that is listed on the Inventory, mentioned in column 3 of that item; and
 - the introduction complies with the terms of the listing for the industrial chemical mentioned in column 3 of that item.

Industrial chemicals comparable to listed industrial chemicals				
	Column 1	Column 2	Column 3	Column 4
Item	Industrial chemical to be introduced	CAS no. of industrial chemical to be introduced	Listed industrial chemical	CAS no. of listed industrial chemical
1	3,6,9,12,15,18,21,21,27-non aoxanoatriacontan-1-ol	3055-99-0	Poly(oxy-1,2-ethanediyl), α -dodecyl- ω -hydroxy-	9002-92-0
2	Aloe barbadensis extract	94349-62-9	Aloe vera extract	85507-69-3
3	Brassica oleracea botrytis, extract	223749-36-8	Cabbage, extract (Brassica oleracea L., Cruciferae.)	89958-13-4
4	Brassica oleracea, extract	91771-39-0	Cabbage, extract (Brassica oleracea L., Cruciferae.)	89958-13-4
5	Brassica oleracea gemmifera, extract	1174275-27-4	Cabbage, extract (Brassica oleracea L., Cruciferae.)	89958-13-4
6	Chamomilla recutita flower extract	1174275-27-4	Oils, Chamomile, German	8002-66-2
7	Jojoba, extract	90045-98-0	Jojoba oil	61789-91-1
8	Lecithins soya	8030-76-0	Lecithins	8002-43-5
9	Orange, extract	84012-28-2	Orange, sweet, extract	8028-48-6
10	Pelargonium roseum, extract	90082-55-6	Pelargonium graveolens, extract	90082-51-2
11	Sodium palmate	61790-79-2	Fatty acids, C14-18 and C16-18-unsaturated, sodium	67701-11-5

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Part 2 Determining if an introduction is exempted or reported

Section 22

Industrial chemicals comparable to listed industrial chemicals				
	Column 1	Column 2	Column 3	Column 4
Item	Industrial chemical to be introduced	CAS no. of industrial chemical to be introduced	Listed industrial chemical	CAS no. of listed industrial chemical
			salts	
12	Soya phospholipids	308069-41-2	Phospholipids	123465-35-0
13	Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, aluminum salt (3:2)	15876-58-1	Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, aluminum salt (3:1)	27532-17-8
14	Tridymite	15468-32-3	Silica	7631-86-9
15	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (1:1)	74610-55-2	Tylosin, [R-(R*,R*)]-2,3-dihydroxybutanedioate (salt)	1405-54-5
16	Wheat germ oil	313258-61-6	Wheat oil	68917-73-7

Introduction of polymer of low concern

- (6) This subsection applies to the introduction if:
- the industrial chemical is a polymer of low concern; but
 - is not a high molecular weight polymer that has lung overloading potential (within the meaning given by the Guidelines).

Introduction of low concern biopolymer

- (7) This subsection applies to the introduction if:
- the industrial chemical is a biopolymer; and
 - the industrial chemical would be a polymer of low concern if the definition of **polymer of low concern** in Schedule 1 did not include a requirement that the polymer is stable (within the meaning given by the Guidelines).

22 Circumstances in which introductions are reported introductions

- (1) For the purposes of step 3 of the method statement in section 19, the introduction of an industrial chemical is covered by this section if subsection (2) or (3) of this section applies to the introduction.

Introduction of industrial chemical that is internationally-assessed for human health and the environment

- (2) This subsection applies to the introduction of an industrial chemical if the introduction of the industrial chemical is internationally-assessed for human health and internationally-assessed for the environment.

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Categorisation of industrial chemicals **Chapter 2**
Determining if an introduction is exempted or reported **Part 2**

Section 22

Note: For when the introduction of an industrial chemical is internationally-assessed for human health and internationally-assessed for the environment, see section 6.

Introduction of industrial chemical at the nanoscale that is solely for use in research and development

- (3) This subsection applies to the introduction if:
- (a) the introduction of the industrial chemical is solely for the industrial chemical to be used in research and development; and
 - (b) the industrial chemical:
 - (i) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% of which (by number size distribution) have at least one external dimension in the nanoscale; and
 - (ii) is introduced as a solid or in a dispersion; and
 - (c) the industrial chemical is not made available to the general public:
 - (i) on its own; or
 - (ii) in combination with one or more other industrial chemicals; or
 - (iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and
 - (d) control measures are used to eliminate or minimise the risks from the introduction or use of the industrial chemical to:
 - (i) persons involved in the research and development for which the industrial chemical is introduced; and
 - (ii) the environment; and
 - (e) the total volume of the industrial chemical introduced in a registration year by the person is greater than 10 kg and less than or equal to 100 kg.

EXPOSURE DRAFT

Chapter 2 Categorisation of industrial chemicals

Part 3 Determining indicative risk

Division 1 Indicative human health risk

Section 23

Part 3—Determining indicative risk

Division 1—Indicative human health risk

23 How to determine the indicative human health risk for an introduction

For the purposes of step 4 of the method statement in section 19, the indicative human health risk is worked out as follows:

Method statement

Step 1: Work out whether the introduction of the industrial chemical is internationally-assessed for human health (see subsection 6(1)).

If the introduction of the industrial chemical is internationally-assessed for human health, the indicative human health risk for the introduction is low risk.

Otherwise, go to step 2.

Step 2: Work out the human health exposure band for the introduction (see section 24).

Step 3: Work out which human health hazard bands do not apply to the introduction based on the hazard characteristics of the industrial chemical (see section 25).

Step 4: Using the results of steps 2 and 3, work out the indicative human health risk for the introduction (see section 26).

Note: If the introduction of the industrial chemical is internationally-assessed for human health, see also subsection 26(4).

24 Human health exposure band

The following table sets out the *human health exposure bands* for the introduction of an industrial chemical by a person.

Human health exposure band		
Item	If ...	The human health exposure band for the introduction is ...
1	(a) the introduction of the industrial chemical is for an end use other than in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person does not exceed 10 kg	1
2	(a) the introduction of the industrial chemical is for an end use	1

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Categorisation of industrial chemicals **Chapter 2**

Determining indicative risk **Part 3**

Indicative human health risk **Division 1**

Section 24

Human health exposure band		
Item	If ...	The human health exposure band for the introduction is ...
	other than in cosmetics, tattoo ink or personal vaporisers; and (b) the concentration of the industrial chemical at introduction and at the end use is less than 0.1%	
3	(a) the introduction of the industrial chemical is for an end use in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person does not exceed 10 kg; and (c) the concentration of the industrial chemical at the end use is less than 0.1%	1
4	(a) the introduction of the industrial chemical is for an end use other than in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person is greater than 10 kg but no more than 1,000 kg	2
5	(a) the introduction of the industrial chemical is for an end use in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person does not exceed 10 kg; and (c) the concentration of the industrial chemical at the end use is 0.1% or greater	2
6	(a) the introduction of the industrial chemical is solely for the industrial chemical to be used in research and development; and (b) the industrial chemical is not made available to the general public: (i) on its own; or (ii) in combination with one or more other industrial chemicals; or (iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and (c) control measures are used to eliminate or minimise the risks from the introduction or use of the industrial chemical to persons involved in the research and development for which the industrial chemical is introduced; and (d) the total volume of the industrial chemical introduced in a registration year by the person is greater than 100 kg; and (e) the use of the industrial chemical is subject to the control of the person who introduces the industrial chemical	2
7	(a) the concentration of the industrial chemical at introduction and at the end use is 1% or less; and (b) items 1, 2 and 3 do not apply to the introduction	2
8	(a) the introduction of the industrial chemical is for an end use in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a	2

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Chapter 2 Categorisation of industrial chemicals

Part 3 Determining indicative risk

Division 1 Indicative human health risk

Section 25

Human health exposure band		
Item	If ...	The human health exposure band for the introduction is ...
	registration year by the person is greater than 10 kg but no more than 100 kg	
9	(a) the introduction of the industrial chemical is for an end use other than in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person is greater than 1,000 kg; and (c) items 2, 6 and 7 do not apply to the introduction	3
10	(a) the introduction of the industrial chemical is for an end use in cosmetics, tattoo ink or personal vaporisers; and (b) the total volume of the industrial chemical introduced in a registration year by the person is greater than 100 kg; and (c) item 7 does not apply to the introduction	3

25 Human health hazard band

The following table sets out the human health hazard bands that apply to the hazard characteristics of the industrial chemical.

Human health hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The human health hazard band that applies to the hazard characteristic is ...
Hazard band A		
1	acute toxicity (harmful) (within the meaning given by the Guidelines)	A
2	specific target organ toxicity after a single exposure (harmful or transient effects) (within the meaning given by the Guidelines)	A
3	skin irritation (within the meaning given by the Guidelines)	A
4	eye irritation (within the meaning given by the Guidelines)	A
5	aspiration hazard (within the meaning given by the Guidelines)	A
6	high molecular weight polymer that has lung overloading potential (within the meaning given by the Guidelines)	A
7	high molecular weight polymer with other potential hazards (within the meaning given by the Guidelines)	A
Hazard band B		
8	acute toxicity (fatal or toxic) (within the meaning given by the Guidelines)	B
9	specific target organ toxicity after a single exposure (significant toxicity) (within the meaning given by the Guidelines)	B

EXPOSURE DRAFT

Categorisation of industrial chemicals **Chapter 2**

Determining indicative risk **Part 3**

Indicative human health risk **Division 1**

Section 26

Human health hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The human health hazard band that applies to the hazard characteristic is ...
10	specific target organ toxicity after repeated exposure (within the meaning given by the Guidelines)	B
11	skin corrosion (within the meaning given by the Guidelines)	B
12	eye damage (within the meaning given by the Guidelines)	B
13	skin sensitisation (within the meaning given by the Guidelines)	B
14	respiratory sensitisation (within the meaning given by the Guidelines)	B
15	respiratory corrosion (within the meaning given by the Guidelines)	B
16	high molecular weight polymer that is water absorbing (within the meaning given by the Guidelines)	B
17	high molecular weight polymer that is reactive (within the meaning given by the Guidelines)	B
18	high molecular weight polymer that contains certain chemical elements (within the meaning given by the Guidelines)	B
Hazard band C		
19	carcinogenicity (within the meaning given by the Guidelines)	C
20	mutagenicity (within the meaning given by the Guidelines)	C
21	genotoxicity (within the meaning given by the Guidelines)	C
22	reproductive toxicity (within the meaning given by the Guidelines)	C
23	developmental toxicity (within the meaning given by the Guidelines)	C
24	adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines)	C

26 Indicative human health risk

- (1) For the purposes of step 4 of the method statement in section 23, the *indicative human health risk* for the introduction of an industrial chemical is:
- if the introduction is covered by an item in the following table—the indicative human health risk mentioned in the item; or
 - otherwise—medium to high risk.

EXPOSURE DRAFT

Chapter 2 Categorisation of industrial chemicals

Part 3 Determining indicative risk

Division 1 Indicative human health risk

Section 26

Indicative human health risk			
Item	If the human health exposure band for the introduction is ...	And the industrial chemical does not have any of the hazard characteristics in human health hazard band ...	The indicative human health risk for the introduction is ...
1	1	C	very low risk
2	2	C	low risk
3	2	A, B and C	very low risk
4	3	B and C	low risk
5	3	A, B and C	very low risk

Note: If the indicative human health risk for the introduction of an industrial chemical is medium to high risk the introduction may be categorised as an assessed introduction, see Division 2 of Part 3 of the Act.

- (2) Despite subsection (1), the *indicative human health risk* for the introduction of an industrial chemical is taken to be low risk if:
- (a) the industrial chemical is a UV filter; and
 - (b) the indicative human health risk worked out under subsection (1) is very low risk.
- (3) Despite subsection (1), the *indicative human health risk* for the introduction of an industrial chemical is taken to be low risk if:
- (a) the industrial chemical has an end use in an article with food contact, other than where the industrial chemical is of low concern following migration to food; and
 - (b) the indicative human health risk worked out under subsection (1) is very low risk.
- (4) Despite step 1 of the method statement in section 23, the *indicative human health risk* for the introduction of an industrial chemical is taken to be very low risk if:
- (a) the introduction of the industrial chemical is internationally-assessed for human health; and
 - (b) the indicative human health risk worked out under subsection (1) is very low risk.

EXPOSURE DRAFT

Categorisation of industrial chemicals **Chapter 2**

Determining indicative risk **Part 3**

Indicative environment risk **Division 2**

Section 27

Division 2—Indicative environment risk

27 How to determine the indicative environment risk for an introduction

For the purposes of step 5 of the method statement in section 19, the indicative environment risk is worked out as follows:

Method statement

Step 1: Work out whether the introduction of the industrial chemical is internationally-assessed for the environment (see subsection 6(2)).

If the introduction of the industrial chemical is internationally-assessed for the environment, the indicative environment risk for the introduction is low risk.

Otherwise, go to step 2.

Step 2: Work out the environment exposure band for the introduction (see section 28).

Step 3: Work out which environment hazard bands do not apply to the introduction based on the hazard characteristics of the industrial chemical (see section 29).

Step 4: Using the results of steps 2 and 3, work out the indicative environment risk for the introduction (see section 30).

Note: If the introduction of the industrial chemical is internationally-assessed for the environment, see also subsection 30(3).

28 Environment exposure band

- (1) The following table sets out the *environment exposure bands* for the introduction of an industrial chemical by a person.

Environment exposure band		
Item	If ...	The environment exposure band for the introduction is ...
1	(a) the introduction of the industrial chemical does not involve release into the environment of a kind mentioned in subsection (2); and (b) the environment categorisation volume for the industrial chemical does not exceed 10 kg	1
2	(a) the introduction of the industrial chemical does not involve release into the environment of a kind mentioned in subsection (2); and	2

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Chapter 2 Categorisation of industrial chemicals

Part 3 Determining indicative risk

Division 2 Indicative environment risk

Section 29

Environment exposure band		
Item	If ...	The environment exposure band for the introduction is ...
	(b) the environment categorisation volume for the industrial chemical is greater than 10 kg but no more than 1,000 kg	
3	(a) the introduction of the industrial chemical does not involve release into the environment of a kind mentioned in subsection (2); and (b) the environment categorisation volume for the industrial chemical is greater than 1,000 kg but no more than 10,000 kg	3
4	The introduction of the industrial chemical involves release into the environment of a kind mentioned in subsection (2)	4
5	The environment categorisation volume for the industrial chemical is greater than 10,000 kg	4

(2) For the purposes of the table in subsection (1), each of the following is a kind of release into the environment (a *designated kind of release into the environment*):

- (a) intentional release during use to land, biota, natural waterways or municipal water supplies;
- (b) intentional release to air during use (other than solely domestic or personal use);
- (c) if the industrial chemical is introduced for an end use in fire-fighting—release (intentional or otherwise) into the environment;
- (d) if the industrial chemical is introduced for an end use in offshore drilling—release (intentional or otherwise) into the ocean.

29 Environment hazard band

The following table sets out the environment hazard bands that apply to the hazard characteristics of the industrial chemical.

Environment hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The environment hazard band that applies to the hazard characteristic is ...
Hazard band A		
1	harmful to any aquatic life (within the meaning given by the Guidelines)	A
2	has bioaccumulation potential (within the meaning given by the Guidelines)	A
3	industrial chemicals (other than polymers) that do not meet the	A

EXPOSURE DRAFT

Categorisation of industrial chemicals **Chapter 2**

Determining indicative risk **Part 3**

Indicative environment risk **Division 2**

Section 30

Environment hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The environment hazard band that applies to the hazard characteristic is ...
	criteria for ready biodegradability (within the meaning given by the Guidelines)	
4	contains aluminium, chromium, copper, nickel, selenium, silver or zinc	A
5	polymers that have an overall cationic charge at pH 4 to 9 (determined in accordance with the Guidelines)	A
6	polymers that are not stable (within the meaning given by the Guidelines)	A
Hazard band B		
7	toxic to any aquatic life (within the meaning given by the Guidelines)	B
Hazard band C		
8	very toxic to any aquatic life (within the meaning given by the Guidelines)	C
9	persistent and bioaccumulative (within the meaning given by the Guidelines)	C
Hazard band D		
10	persistent, bioaccumulative and toxic (within the meaning given by the Guidelines)	D
11	ozone depleting chemicals (within the meaning given by the <i>Ozone Protection and Synthetic Greenhouse Gas Management Act 1989</i>)	D
12	synthetic greenhouse gas (within the meaning given by the <i>Ozone Protection and Synthetic Greenhouse Gas Management Act 1989</i>)	D
13	contains arsenic, cadmium, lead or mercury	D
14	adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines)	D

30 Indicative environment risk

- (1) For the purposes of step 4 of the method statement in section 27, the **indicative environment risk** for the introduction of an industrial chemical is:
- if the introduction is covered by an item in the following table—the indicative environment risk mentioned in the item; or
 - otherwise—medium to high risk.

EXPOSURE DRAFT

Chapter 2 Categorisation of industrial chemicals

Part 3 Determining indicative risk

Division 2 Indicative environment risk

Section 30

Indicative environment risk			
Item	If the environment exposure band for the introduction is ...	And the industrial chemical does not have any of the hazard characteristics in environment hazard band ...	The indicative environment risk for the introduction is ...
1	1	D	low risk
2	1	C and D	very low risk
3	2	D	low risk
4	2	B, C and D	very low risk
5	3	C and D	low risk
6	3	A, B, C and D	very low risk
7	4	B, C and D	low risk
8	4	A, B, C and D	very low risk

Note: If the indicative environment risk for the introduction of an industrial chemical is medium to high the introduction may be categorised as an assessed introduction, see Division 2 of Part 3 of the Act.

- (2) Despite subsection (1), the **indicative environment risk** for the introduction of an industrial chemical is taken to be low risk if:
- (a) the industrial chemical:
 - (i) is a highly branched organic chemical; or
 - (ii) is for end use as a biocide; or
 - (iii) is a polyhalogenated organic chemical (other than a polyhalogenated organic chemical covered by subsection 20(8)); and
 - (b) the indicative environment risk worked out under subsection (1) is very low risk.
- (3) Despite step 1 of the method statement in section 27, the **indicative environment risk** for the introduction of an industrial chemical is taken to be very low risk if:
- (a) the introduction of the industrial chemical is internationally-assessed for the environment; and
 - (b) the indicative environment risk worked out under subsection (1) is very low risk.

Part 4—Information required to demonstrate categorisation

31 Information required to demonstrate categorisation

For the purposes of paragraph 102(1)(b) of the Act, a person who introduces an industrial chemical during a registration year must, in determining the category of the introduction:

- (a) have regard to the following information:
 - (i) the end use for the industrial chemical;
 - (ii) the total volume of the industrial chemical that is to be introduced by the person in the registration year;
 - (iii) the concentration of the industrial chemical at introduction and at the end use;
 - (iv) whether the introduction of the industrial chemical involves a designated kind of release into the environment;
 - (v) whether the introduction is covered by subsection 20(2), (3), (6), (7), (8) or (9);
 - (vi) the hazard characteristics of the industrial chemical;
 - (vii) any studies available to the person that are relevant to determining the hazard characteristics of the industrial chemical;
 - (viii) any relevant studies detailed in the Guidelines in relation to the introduction; and
- (b) if the industrial chemical is to be introduced for an end use solely in cosmetics—not use animal test data obtained from tests conducted on or after 1 July 2018 in the circumstances mentioned in section 32.

Note: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

32 Ban on animal test data for determining category for cosmetics

For the purposes of subsection 103(2) of the Act, all circumstances are prescribed, other than circumstances where:

- (a) animal test data:
 - (i) is available to the person who introduces the industrial chemical; and
 - (ii) is derived from tests conducted on animals involving the industrial chemical that the person introduces; and
 - (iii) is only relevant to identifying a human health hazard characteristic or an environment hazard characteristic of that industrial chemical; and
 - (iv) is not used to establish whether or not that industrial chemical has a human health hazard characteristic, or an environment hazard characteristic, for the purposes of this instrument; or
- (b) the environment hazard characteristics of the industrial chemical that is to be introduced can only be determined using animal test data; or
- (c) both:

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Chapter 2 Categorisation of industrial chemicals

Part 4 Information required to demonstrate categorisation

Section 32

- (i) the animal test data has been derived from tests conducted on animals involving a chemical other than the industrial chemical that is to be introduced by the person; and
- (ii) the other chemical is not an industrial chemical introduced by the person solely for an end use in cosmetics.

Chapter 3—Reporting

Part 1—Simplified outline of this Chapter

33 Simplified outline of this Chapter

In order for an introduction to be authorised under section 27 of the Act, the introduction must be in accordance with the terms of the pre-introduction report for the introduction. Part 2 of this Chapter sets out what information must be included in the pre-introduction report. There are general requirements that apply in relation to all reported introductions, as well as specific requirements that only apply in relation to specific classes of reported introductions.

Part 3 of this Chapter sets out what must be included in a declaration under section 99 of the Act. This declaration is about the categories of introduction for the industrial chemicals introduced by a person, and includes a declaration that all introductions made by the person were authorised under the Act.

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Chapter 3 Reporting

Part 2 Pre-introduction reports for reported introductions

Division 1 General requirements

Section 34

Part 2—Pre-introduction reports for reported introductions

Division 1—General requirements

34 Pre-introduction reports for reported introductions

For the purposes of paragraph 97(2)(b) of the Act, the following information is prescribed for a reported introduction of an industrial chemical by a person:

- (a) either:
 - (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); or
 - (ii) the AACN for the industrial chemical;
- (b) any other names by which the industrial chemical is known to the person;
- (c) if the CAS number for the industrial chemical is available—the CAS number for the industrial chemical;
- (d) a declaration that the introduction is not covered by section 20;
- (e) whether the industrial chemical is imported or manufactured in Australia;
- (f) the total volume of the industrial chemical to be introduced by the person in the registration year.

Division 2—Additional requirements for types of introduction

35 Introductions of industrial chemicals that are internationally-assessed for human health and the environment

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 22(2).
- (2) For the purposes of paragraph 97(2)(b) of the Act, the following information is also prescribed:
 - (a) the end use for the industrial chemical;
 - (b) the maximum concentration of the industrial chemical at introduction and at the end use;
 - (c) any known hazard classification for the industrial chemical;
 - (d) the name of the international assessment body that assessed or evaluated the industrial chemical for:
 - (i) human health; and
 - (ii) the environment;
 - (e) any parameters of the assessment or evaluation, including end use, introduction volume and the maximum concentration of the industrial chemical at the end use;
 - (f) the year the assessment or evaluation was completed;
 - (g) the reference number (however described) for the assessment or evaluation, and the name by which the industrial chemical is identified in the assessment or evaluation;
 - (h) a declaration that:
 - (i) the report of the assessment or evaluation in the overseas jurisdiction is available; and
 - (ii) if requested by the Executive Director, can be provided to the Executive Director;
 - (i) if the assessment or evaluation applied any conditions to the introduction or use of the industrial chemical in the overseas jurisdiction:
 - (i) those conditions; and
 - (ii) how those conditions will be met by the person in Australia;
 - (j) a declaration that the risk from the introduction of the industrial chemical into Australia is no higher than the risk identified in the assessment or evaluation;
 - (k) a declaration that no information has become available to the person after the assessment or evaluation about:
 - (i) a hazard to human health or the environment from the introduction or use of the industrial chemical that is not identified in the assessment or evaluation; or
 - (ii) an increase in the severity of a hazard to human health or the environment that is identified in the assessment or evaluation.

Note: These pre-introduction report requirements are in addition to the requirements set out in section 34.

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Chapter 3 Reporting

Part 2 Pre-introduction reports for reported introductions

Division 2 Additional requirements for types of introduction

Section 36

36 Introductions of industrial chemicals that are internationally-assessed for human health

- (1) This section applies if:
 - (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is internationally-assessed for human health but not internationally-assessed for the environment.
- (2) For the purposes of paragraph 97(2)(b) of the Act, the following information is also prescribed:
 - (a) the end use for the industrial chemical;
 - (b) the maximum concentration of the industrial chemical at introduction and at the end use;
 - (c) the environment exposure band for the introduction;
 - (d) whether the introduction of the industrial chemical involves a designated kind of release into the environment;
 - (e) the environment categorisation volume for the industrial chemical (other than if the introduction of the industrial chemical involves a designated kind of release into the environment), and the basis on which the environment categorisation volume is calculated;
 - (f) any environment hazard characteristics of the industrial chemical that are known to the person;
 - (g) any known hazard classification for the industrial chemical;
 - (h) a declaration that the hazard information requirements under subparagraph 31(a)(viii) for the introduction have been met;
 - (i) whether the introduction is a specified class of introduction to which subsection 7(2) or (3) applies;
 - (j) the name of the international assessment body that assessed or evaluated the industrial chemical for human health;
 - (k) any parameters of the assessment or evaluation, including end use, introduction volume and the maximum concentration of the industrial chemical at the end use;
 - (l) the year the assessment or evaluation was completed;
 - (m) the reference number (however described) for the assessment or evaluation, and the name by which the industrial chemical is identified in the assessment or evaluation;
 - (n) a declaration that:
 - (i) the report of the assessment or evaluation in the overseas jurisdiction is available; and
 - (ii) if requested by the Executive Director, can be provided to the Executive Director;
 - (o) if the assessment or evaluation applied any conditions to the introduction or use of the industrial chemical in the overseas jurisdiction:
 - (i) those conditions; and
 - (ii) how those conditions will be met by the person in Australia;

- (p) a declaration that the risk to human health from the introduction of the industrial chemical into Australia is no higher than the risk identified in the assessment or evaluation;
- (q) a declaration that no information has become available to the person after the assessment or evaluation about:
 - (i) a hazard to human health from the introduction or use of the industrial chemical that is not identified in the assessment or evaluation; or
 - (ii) an increase in the severity of a hazard to human health that is identified in the assessment or evaluation.

Note 1: These pre-introduction report requirements are in addition to the requirements set out in section 34.

Note 2: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

37 Introductions of industrial chemicals that are internationally-assessed for the environment

- (1) This section applies if:
 - (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is internationally-assessed for the environment but not internationally-assessed for human health.
- (2) For the purposes of paragraph 97(2)(b) of the Act, the following information is also prescribed:
 - (a) if the introduction is not solely for the industrial chemical to be used in research and development—the end use for the industrial chemical;
 - (b) the maximum concentration of the industrial chemical at introduction and at the end use;
 - (c) the human health exposure band for the introduction, and the exposure band criteria on which the exposure band is based;
 - (d) if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 3:
 - (i) the number average molecular weight of the industrial chemical; and
 - (ii) the weight average molecular weight of the industrial chemical; and
 - (iii) the polydispersity index for the industrial chemical; and
 - (iv) the percentage by mass of molecules with molecular weight that is less than 1,000 g/mol; and
 - (v) the percentage by mass of molecules with molecular weight that is less than 500 g/mol;
 - (e) any human health hazard characteristics of the industrial chemical that are known to the person;
 - (f) any known hazard classification for the industrial chemical;
 - (g) a declaration that the hazard information requirements under subparagraph 31(a)(viii) for the introduction have been met;

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Chapter 3 Reporting

Part 2 Pre-introduction reports for reported introductions

Division 2 Additional requirements for types of introduction

Section 38

- (h) if the introduction is in accordance with item 6 of the table in section 24—a declaration that the requirements of that item have been met;
- (i) whether the introduction is a specified class of introduction to which subsection 7(3) or (4) applies;
- (j) the name of the international assessment body that assessed or evaluated the industrial chemical for the environment;
- (k) any parameters of the assessment or evaluation, including end use, introduction volume and the maximum concentration of the industrial chemical at the end use;
- (l) the year the assessment or evaluation was completed;
- (m) the reference number (however described) for the assessment or evaluation, and the name by which the industrial chemical is identified in the assessment or evaluation;
- (n) a declaration that:
 - (i) the report of the assessment or evaluation in the overseas jurisdiction is available; and
 - (ii) if requested by the Executive Director, can be provided to the Executive Director;
- (o) if the assessment or evaluation applied any conditions to the introduction or use of the industrial chemical in the overseas jurisdiction:
 - (i) those conditions; and
 - (ii) how those conditions will be met by the person in Australia;
- (p) a declaration that the risk to the environment from the introduction of the industrial chemical into Australia is no higher than the risk identified in the assessment or evaluation;
- (q) a declaration that no information has become available to the person after the assessment or evaluation about:
 - (i) a hazard to the environment from the introduction or use of the industrial chemical that is not identified in the assessment or evaluation; or
 - (ii) an increase in the severity of a hazard to the environment that is identified in the assessment or evaluation.

Note: These pre-introduction report requirements are in addition to the requirements set out in section 34.

38 Introduction of industrial chemical at the nanoscale that is solely for use in research and development

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 22(3).
- (2) For the purposes of paragraph 97(2)(b) of the Act, a declaration that the requirements of subsection 22(3) of this instrument have been met for the introduction is prescribed.

Note: These pre-introduction report requirements are in addition to the requirements set out in section 34.

39 Other introductions where highest indicative risk is low risk

- (1) This section applies if:
 - (a) an introduction is a reported introduction by a person in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is not internationally-assessed for human health or internationally-assessed for the environment.
- (2) For the purposes of paragraph 97(2)(b) of the Act, the following information is also prescribed:
 - (a) if:
 - (i) the industrial chemical is a UVCB substance; and
 - (ii) the introduction is in accordance with item 9 or 10 of the table in section 24, or item 3, 4 or 5 of the table in subsection 28(1);
the UVCB substance description for the industrial chemical;
 - (b) if the introduction is not solely for the industrial chemical to be used in research and development—the end use for the industrial chemical;
 - (c) if the introduction is in accordance with item 2 or 7 of the table in section 24—the maximum concentration of the industrial chemical at introduction;
 - (d) if the introduction is in accordance with item 2, 3, 5 or 7 of the table in section 24—the maximum concentration of the industrial chemical at the end use;
 - (e) the human health exposure band for the introduction, and the exposure band criteria on which the exposure band is based;
 - (f) the environment exposure band for the introduction;
 - (g) whether the introduction of the industrial chemical involves a designated kind of release into the environment;
 - (h) if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 3:
 - (i) the number average molecular weight of the industrial chemical; and
 - (ii) the weight average molecular weight of the industrial chemical; and
 - (iii) the polydispersity index for the industrial chemical; and
 - (iv) the percentage by mass of molecules with molecular weight that is less than 1,000 g/mol; and
 - (v) the percentage by mass of molecules with molecular weight that is less than 500 g/mol;
 - (i) the environment categorisation volume for the industrial chemical (other than if introduction of the industrial chemical involves a designated kind of release into the environment), and the basis on which the environment categorisation volume is calculated;
 - (j) any human health hazard characteristics of the industrial chemical that are known to the person;
 - (k) any environment hazard characteristics of the industrial chemical that are known to the person;
 - (l) a declaration that the hazard information requirements under subparagraph 31(a)(viii) for the introduction have been met;

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Chapter 3 Reporting

Part 2 Pre-introduction reports for reported introductions

Division 2 Additional requirements for types of introduction

Section 39

- (m) if the introduction is in accordance with item 6 of the table in section 24—a declaration that the requirements of that item have been met;
- (n) whether the introduction is a specified class of introduction.

Note 1: These pre-introduction report requirements are in addition to the requirements set out in section 34.

Note 2: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

Part 3—Annual declaration for all introduction categories

40 Annual declaration for all introduction categories

For the purposes of paragraph 99(2)(b) of the Act, the following information for a declaration made by a person for a registration year is prescribed:

- (a) the registration number for the person;
- (b) the categories of introduction for the industrial chemicals introduced by the person;
- (c) a declaration that all introductions made by the person during the registration year were authorised by sections 25 to 30 of the Act.

Note: This declaration is not required for excluded introductions as section 99 of the Act does not apply to excluded introductions: see subsection 11(1) of the Act.

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Chapter 4 Record keeping

Part 1 Simplified outline of this Chapter

Section 41

Chapter 4—Record keeping

Part 1—Simplified outline of this Chapter

41 Simplified outline of this Chapter

Under section 104 of the Act, a person who introduces an industrial chemical (other than an excluded introduction) during a registration year is subject to a requirement that they keep certain information relating to the introduction. This Chapter sets out the kinds of information that must be kept for the 6 categories of introduction under the Act (listed introductions, exempted introductions, reported introductions, assessed introductions, commercial evaluation introductions and exceptional circumstances introductions) as well as for introductions authorised under section 163 of the Act.

Part 2—Record keeping for listed introductions

42 Listed introductions

For the purposes of paragraph 104(2)(b) of the Act, if the terms of the Inventory listing for an industrial chemical include a term mentioned in column 1 of an item in the following table, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the CAS name and number for the industrial chemical are known to the person	the CAS name and number for the industrial chemical
2	the AACN for the industrial chemical is known to the person	the AACN for the industrial chemical
3	neither of the following are known to the person: (a) the CAS name and number for the industrial chemical; (b) the AACN for the industrial chemical	(a) the name by which the industrial chemical is known to the person; and (b) a written undertaking from the chemical identity holder that the CAS name and number for the industrial chemical will be given to the Executive Director if requested
4	there is a defined scope of assessment for the industrial chemical	records to demonstrate that the industrial chemical is being introduced or used in accordance with that defined scope
5	there are any conditions relating to the introduction or use of the industrial chemical	records to demonstrate that the conditions are being complied with
6	there are any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical	records to demonstrate that those requirements are being met

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Chapter 4 Record keeping

Part 3 Record keeping for exempted introductions

Division 1 General requirements

Section 43

Part 3—Record keeping for exempted introductions

Division 1—General requirements

43 Exempted introductions

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an exempted introduction of an industrial chemical, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person	the proper name for the industrial chemical (including the CAS name or the IUPAC name)
2	the CAS number for the industrial chemical is known to the person	the CAS number for the industrial chemical
3	the proper name for the industrial chemical (including the CAS name or the IUPAC name) is not known to the person	(a) the AACN for the industrial chemical; or (b) both: (i) the name by which the industrial chemical is known to the person; and (ii) a written undertaking from the chemical identity holder that the proper name for the industrial chemical (including the CAS name or the IUPAC name), and the CAS number (if assigned) for the industrial chemical, will be given to the Executive Director if requested
4	the introduction is not covered by section 20 (which deals with circumstances in which introductions are not exempted introductions)	records to demonstrate that the introduction is not covered by section 20
5	the introduction is covered by section 21 (which deals with circumstances in which introductions are exempted introductions)	(a) records to demonstrate which subsection of that section applies to the introduction; and

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Records that must be kept		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
		(b) records to demonstrate that the requirements of that subsection are being met
6	the introduction is an exempted introduction in accordance with step 6 of the method statement in section 19	(a) the indicative human health risk for the introduction; and (b) the indicative environment risk for the introduction

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Chapter 4 Record keeping

Part 3 Record keeping for exempted introductions

Division 2 Additional requirements for introductions where highest indicative risk is very low risk

Section 44

Division 2—Additional requirements for introductions where highest indicative risk is very low risk

44 General additional requirements

- (1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with step 6 of the method statement in section 19.
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate the following are also prescribed:
 - (a) the human health exposure band for the introduction, and the exposure band criteria on which the exposure band is based;
 - (b) the environment exposure band for the introduction, and the exposure band criteria on which the exposure band is based;
 - (c) whether the industrial chemical is imported or manufactured in Australia;
 - (d) the total volume of the industrial chemical to be introduced by the person in a registration year;
 - (e) the environment categorisation volume for the industrial chemical (other than if the introduction of the industrial chemical involves a designated kind of release into the environment), and the basis on which the environment categorisation volume is calculated;
 - (f) any human health hazard characteristics of the industrial chemical that are known to the person;
 - (g) any environment hazard characteristics of the industrial chemical that are known to the person;
 - (h) any known hazard classification for the industrial chemical;
 - (i) if the introduction is not solely for the industrial chemical to be used in research and development—the end use for the industrial chemical;
 - (j) if:
 - (i) the industrial chemical is a UVCB substance; and
 - (ii) the introduction is in accordance with one of items 1 to 8 of the table in section 24; and
 - (iii) the introduction is not covered by item 3, 4 or 5 of the table in subsection 28(1); and
 - (iv) the UVCB substance description is known to the person; the UVCB substance description of the industrial chemical;
 - (k) if:
 - (i) the industrial chemical is a UVCB substance; and
 - (ii) the introduction is in accordance with item 9 or 10 of the table in section 24, or item 3, 4 or 5 of the table in subsection 28(1); the UVCB substance description of the industrial chemical;
 - (l) if the introduction is in accordance with item 2 or 7 of the table in section 24—the maximum concentration of the industrial chemical at introduction;

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Record keeping for exempted introductions **Part 3**

Additional requirements for introductions where highest indicative risk is very low risk **Division 2**

Section 45

- (m) if the introduction is in accordance with item 2, 3, 5 or 7 of the table in section 24—the maximum concentration of the industrial chemical at the end use;
- (n) if the introduction is in accordance with item 6 of the table in section 24—records demonstrating that the requirements of that item are being met.

Note: These record keeping requirements are in addition to the requirements set out in sections 43 and 45.

45 Additional requirements for specified classes of introductions

- (1) This section applies if an introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 19.
- (2) For the purposes of paragraph 104(2)(b) of the Act, if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the following table, records of the kind mentioned in column 2 of the item are also prescribed in relation to the introduction of the industrial chemical.

Note: This record keeping requirement is in addition to the requirements set out in sections 43 and 44.

Additional record keeping requirements for specified classes of introductions

Item	Column 1 If ...	Column 2 The records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
3	the introduction is of a kind mentioned in paragraph 7(3)(c) (GM product)	(a) the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity
4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	records to demonstrate that the industrial chemical is of low concern following migration to food

Note: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

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Chapter 4 Record keeping

Part 4 Record keeping for reported introductions

Division 1 General requirements

Section 46

Part 4—Record keeping for reported introductions

Division 1—General requirements

46 Reported introductions

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to a reported introduction of an industrial chemical, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Note: Other record keeping requirements may also apply in relation to the reported introduction: see Division 2 of this Part.

Records that must be kept		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person	the proper name for the industrial chemical (including the CAS name or the IUPAC name)
2	the CAS number for the industrial chemical is known to the person	the CAS number for the industrial chemical
3	the proper name for the industrial chemical (including the CAS name or the IUPAC name) is not known to the person	(a) the AACN for the industrial chemical; or (b) the name by which the industrial chemical is known to the person
4	the introduction is not covered by section 20 (which deals with circumstances in which introductions are not reported introductions)	records to demonstrate that the introduction is not covered by section 20

Division 2—Additional requirements for certain introductions

47 Introductions of industrial chemicals that are internationally-assessed for human health and the environment

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 22(2) (which deals with introductions of industrial chemicals that are internationally-assessed for human health and internationally-assessed for the environment).
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate the following are also prescribed:
 - (a) the end use for the industrial chemical;
 - (b) the total volume of the industrial chemical to be introduced by the person in a registration year;
 - (c) the maximum concentration of the industrial chemical at introduction and at the end use;
 - (d) if the assessment or evaluation in the overseas jurisdiction applied any conditions to the introduction or use of the industrial chemical—that those conditions are being met.

48 Introductions of industrial chemicals that are internationally-assessed for human health

- (1) This section applies if:
 - (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is internationally-assessed for human health.
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate the following are also prescribed:
 - (a) the end use for the industrial chemical;
 - (b) the total volume of the industrial chemical to be introduced by the person in a registration year;
 - (c) the maximum concentration of the industrial chemical at introduction and at the end use;
 - (d) the environment categorisation volume for the industrial chemical (other than if the introduction of the industrial chemical involves a designated kind of release into the environment);
 - (e) if the assessment or evaluation in the overseas jurisdiction applied any conditions to the introduction or use of the industrial chemical—that those conditions are being met;
 - (f) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (3)—records of the kind mentioned in column 2 of the item.

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Part 4 Record keeping for reported introductions

Division 2 Additional requirements for certain introductions

Section 49

Note: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

(3) For the purpose of paragraph (2)(f), the following table has effect.

Additional record keeping requirements for specified classes of introductions		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment.
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
3	the introduction is of a kind mentioned in paragraph 7(3)(c) (GM product)	(a) the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity

Note: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

49 Introductions of industrial chemicals that are internationally-assessed for the environment

- (1) This section applies if:
- (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is internationally-assessed for the environment.
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate the following are also prescribed:
- (a) the end use for the industrial chemical;
 - (b) the total volume of industrial chemical to be introduced by the person in a registration year;
 - (c) the maximum concentration of the industrial chemical at introduction and at the end use;

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- (d) if the assessment or evaluation in the overseas jurisdiction applied any conditions to the introduction or use of the industrial chemical—that those conditions are being met;
- (e) if the introduction is in accordance with item 6 of the table in section 24—records demonstrating that the requirements of that item are being met;
- (f) if the introduction is in accordance with item 9 or 10 of the table in section 24—any available information regarding the hazard characteristics of the industrial chemical of a kind mentioned in item 3 or 4 of the table in section 25;
- (g) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (3)—records of the kind mentioned in column 2 of the item.

(3) For the purpose of paragraph (2)(g), the following table has effect.

Additional record keeping requirements for specified classes of introductions		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
2	the introduction is of a kind mentioned in paragraph 7(3)(c) (GM product)	(a) the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity
3	(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and (b) the introduction is in accordance with item 9 or 10 of the table in section 24	(a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and (b) photostability information (within the meaning given by the Guidelines) about the industrial chemical; and (c) the potential for interaction (within the meaning given by the Guidelines) of the industrial chemical with other UV filters
4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact—records to demonstrate that the industrial chemical has been so approved; and (b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)

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Chapter 4 Record keeping

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Division 2 Additional requirements for certain introductions

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Additional record keeping requirements for specified classes of introductions		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
5	(a) the introduction is of a kind mentioned in paragraph 7(4)(c) (end use in personal vaporisers); and (b) the introduction is in accordance with item 5, 7 or 8 of the table in section 24	the acute inhalation toxicity potential (within the meaning given by the Guidelines) of the industrial chemical
6	(a) the introduction is of a kind mentioned in paragraph 7(4)(d) (end use in tattoo ink); and (b) the introduction is in accordance with item 5, 7 or 8 of the table in section 24	the skin sensitisation potential (within the meaning given by the Guidelines) of the industrial chemical

50 Introduction of industrial chemicals at the nanoscale that are solely for use in research and development

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 22(3) (which deals with industrial chemicals that are solely for use in research and development).
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate that the requirements of subsection 22(3) of this instrument have been met are also prescribed.

51 Other introductions where highest indicative risk is low risk

- (1) This section applies if:
 - (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 19; and
 - (b) the introduction of the industrial chemical is not internationally-assessed for human health or internationally-assessed for the environment.
- (2) For the purposes of paragraph 104(2)(b) of the Act, records to demonstrate the following are also prescribed:
 - (a) if the introduction is not solely for the industrial chemical to be used in research and development—the end use for the industrial chemical;
 - (b) the total volume of the industrial chemical to be introduced by the person in a registration year;
 - (c) if the introduction is in accordance with item 2 or 7 of the table in section 24—the maximum concentration of the industrial chemical at introduction;
 - (d) if the introduction is in accordance with item 2, 3, 5 or 7 of the table in section 24—the maximum concentration of the industrial chemical at the end use;
 - (e) if the introduction is in accordance with item 6 of the table in section 24—records demonstrating that the requirements of that item are being met;

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Record keeping **Chapter 4**

Record keeping for reported introductions **Part 4**

Additional requirements for certain introductions **Division 2**

Section 51

- (f) the environment categorisation volume for the industrial chemical (other than if the introduction of the industrial chemical involves a designated kind of release into the environment);
- (g) if:
- (i) the industrial chemical is a UVCB substance; and
 - (ii) the introduction is in accordance with one of items 1 to 8 of the table in section 24; and
 - (iii) the introduction is not covered by item 3, 4 or 5 of the table in subsection 28(1); and
 - (iv) the UVCB substance description is known to the person; the UVCB substance description of the industrial chemical;
- (h) if the introduction is in accordance with item 9 or 10 of the table in section 24—any available information regarding the hazard characteristics of the industrial chemical of a kind mentioned in item 3 or 4 of the table in section 25;
- (i) if the introduction is of a kind mentioned in column 1 of an item in the table in subsection (3)—records of the kind mentioned in column 2 of the item.

(3) For the purpose of paragraph (2)(i), the following table has effect.

Additional record keeping obligations for certain kinds of introductions		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: <ul style="list-style-type: none">(a) the location of the release into the environment (including all receiving water bodies); and(b) the frequency of the release into the environment.
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	<ul style="list-style-type: none">(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and(b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
3	the introduction is of a kind mentioned in paragraph 7(3)(c) (GM product)	<ul style="list-style-type: none">(a) the genetically modified organism from which the GM product was derived or produced; and(b) information on any genetically modified organism that remains in the GM product as an impurity
4	<ul style="list-style-type: none">(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and(b) the introduction is in accordance with	<ul style="list-style-type: none">(a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and

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Part 4 Record keeping for reported introductions

Division 2 Additional requirements for certain introductions

Section 51

Additional record keeping obligations for certain kinds of introductions		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
	item 9 or 10 of the table in section 24	(b) photostability information (within the meaning given by the Guidelines) about the industrial chemical; and (c) the potential for interaction (within the meaning given by the Guidelines) of the industrial chemical with other UV filters
5	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for use in an article with food contact in another country—records to demonstrate that the industrial chemical has been so approved; and (b) the potential for the industrial chemical to migrate to the food (within the meaning given by the Guidelines)
6	(a) the introduction is of a kind mentioned in paragraph 7(4)(c) (end use in personal vaporisers); and (b) the introduction is in accordance with item 5, 7 or 8 of the table in section 24	the acute inhalation toxicity potential (within the meaning given by the Guidelines) of the industrial chemical
7	(a) the introduction is of a kind mentioned in paragraph 7(4)(d) (end use in tattoo ink); and (b) the introduction is in accordance with item 5, 7 or 8 of the table in section 24	the skin sensitisation potential (within the meaning given by the Guidelines) of the industrial chemical
	Note:	For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subsection 28(2).

Part 5—Record keeping for assessed introductions

52 Assessed introductions

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an assessed introduction of an industrial chemical, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If the terms of the assessment certificate include ...	The records that must be kept are ...
1	the proper name for the industrial chemical	the proper name for the industrial chemical
2	the AACN for the industrial chemical	the AACN for the industrial chemical
3	a defined scope of assessment for the industrial chemical	records to demonstrate that the industrial chemical is being introduced or used in accordance with that defined scope
4	any conditions relating to the introduction or use of the industrial chemical	records to demonstrate that the conditions are being complied with
5	any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical	records to demonstrate that those requirements are being met

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Chapter 4 Record keeping

Part 6 Record keeping for commercial evaluation introductions

Section 53

Part 6—Record keeping for commercial evaluation introductions

53 Commercial evaluation introductions

For the purposes of paragraph 104(2)(b) of the Act, if the terms of a commercial evaluation authorisation for the introduction of an industrial chemical include a term mentioned in column 1 of an item in the following table, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If the terms of the commercial evaluation authorisation include ...	The records that must be kept are ...
1	the proper name for the industrial chemical	the proper name for the industrial chemical
2	the AACN for the industrial chemical	the AACN for the industrial chemical
3	any conditions relating to the introduction or use of the industrial chemical	records to demonstrate that the conditions are being complied with
4	any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical	records to demonstrate that those requirements are being met

Part 7—Record keeping for exceptional circumstances introductions

54 Exceptional circumstances introductions

For the purposes of paragraph 104(2)(b) of the Act, if the terms of an exceptional circumstances authorisation for the introduction of an industrial chemical include a term mentioned in column 1 of an item in the following table, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If the terms of the exceptional circumstances authorisation include ...	The records that must be kept are ...
1	the proper name for the industrial chemical	the proper name for the industrial chemical
2	any conditions relating to the introduction or use of the industrial chemical	records to demonstrate that the conditions are being complied with
3	any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical	records to demonstrate that those requirements are being met

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Chapter 4 Record keeping

Part 8 Record keeping for introductions under section 163 of the Act

Section 55

Part 8—Record keeping for introductions under section 163 of the Act

55 Introductions under section 163 of the Act

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an introduction or export of an industrial chemical that is authorised under section 163 of the Act, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
Item	Column 1	Column 2
	If ...	The records that must be kept are ...
1	the proper name for the industrial chemical is known to the person	the proper name for the industrial chemical
2	the AACN for the industrial chemical is known to the person	the AACN for the industrial chemical
3	any conditions relating to the introduction or use of the industrial chemical	records to demonstrate that the conditions are being complied with

Chapter 5—Confidentiality and disclosure

Part 1—Simplified outline of this Chapter

56 Simplified outline of this Chapter

Under section 97 of the Act, the Executive Director may publish prescribed kinds of information relating to reported introductions. Part 2 of this Chapter prescribes those kinds of information relating to reported introductions of industrial chemicals that are internationally-assessed for human health or the environment for the purposes of that section.

The Act also provides for the protection of the proper name and end use for an industrial chemical in certain circumstances. Protection may also be available under the Act for other kinds of information. Part 3 of this Chapter deals with rules regarding the publication and disclosure of such information, including by prescribing the circumstances in which an AACN or generalised end use must be published in lieu of the proper name or end use.

This Chapter also prescribes the State, Territory and international entities to whom the Executive Director may disclose protected information.

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Chapter 5 Confidentiality and disclosure

Part 2 Publication of certain information

Section 57

Part 2—Publication of certain information

57 Publication of information relating to reported introductions

For the purposes of subsection 97(5) of the Act, information is prescribed if:

- (a) the information relates to a reported introduction that is:
 - (i) an introduction of an industrial chemical that is internationally-assessed for human health; or
 - (ii) an introduction of an industrial chemical that is internationally-assessed for the environment; and
- (b) the introduction is in accordance with:
 - (i) if subparagraph (a)(i) applies—step 1 of the method statement in section 23; or
 - (ii) if subparagraph (a)(ii) applies—step 1 of the method statement in section 27; and
- (c) the information is of the following kind:
 - (i) the proper name for the industrial chemical;
 - (ii) the end use for the industrial chemical;
 - (iii) the name of the international assessment body that assessed or evaluated the industrial chemical.

Note: If an application to treat the proper name or end use for the industrial chemical as confidential business information has been approved, an AACN or generalised end use must be included in the information published instead of the proper name or end use if prescribed circumstances apply: see section 109 of the Act.

Part 3—Confidentiality and disclosure

58 Notice of proposed variations to Inventory listings

For the purposes of paragraph 87(3)(b) of the Act, a person is prescribed if:

- (a) the person is a confidence holder for an approval to treat an end use for the industrial chemical as confidential business information; and
- (b) the proposed variation to the Inventory listing for the industrial chemical would, if published, disclose that end use.

59 Protection of proper name or end use

Applying for protection for the proper name

- (1) For the purposes of paragraph 105(1)(d) of the Act, the circumstances mentioned in subsection (2) of this section are prescribed.
- (2) For the purposes of subsection (1), the circumstances are:
 - (a) the person gives notice under subsection 112(1) of the Act for information relating to the industrial chemical to be subject to Subdivision B of Division 4 of Part 6 of the Act; and
 - (b) the Executive Director gives the person notice under subsection 113(1) of the Act of a proposal to publish the information.

Applying for protection for an end use

- (3) For the purposes of paragraph 105(2)(f) of the Act, the circumstances mentioned in subsection (4) are prescribed.
- (4) For the purposes of subsection (3), the circumstances are:
 - (a) the person gives notice under subsection 112(1) of the Act for information relating to the industrial chemical to be subject to Subdivision B of Division 4 of Part 6 of the Act; and
 - (b) the Executive Director gives the person notice under subsection 113(1) of the Act of a proposal to publish the information.

Time for making applications

- (5) For the purposes of paragraph 105(4)(b) of the Act, the time for giving an application in circumstances mentioned in subsection (2) or (4) of this section is within 20 working days after the day notice is given as mentioned in paragraph (2)(b) or (4)(b) of this section (as the case requires).

60 When an AACN or generalised end use must be used

- (1) For the purposes of paragraphs 109(1)(b) and (2)(b) of the Act, the circumstances mentioned in subsection (2) of this section are prescribed in relation to an application made under subsection 105(1) or (2) of the Act for the proper name

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Chapter 5 Confidentiality and disclosure

Part 3 Confidentiality and disclosure

Section 61

or end use for an industrial chemical to be treated as confidential business information.

- (2) For the purposes of subsection (1), the circumstances are that the Executive Director is publishing information (including by giving it to a person) under any of the following provisions of the Act in relation to the industrial chemical:
 - (a) section 37 (which deals with the issue of assessment statements and certificates);
 - (b) section 58 (which deals with the issue of commercial evaluation authorisations);
 - (c) subsection 73(3) (which deals with publishing evaluation statements of introductions authorised by assessment certificates);
 - (d) subsection 74(3) (which deals with publishing information about evaluations of other introductions or matters);
 - (e) subsection 78(3) (which deals with publishing evaluation statements of other introductions or matters);
 - (f) section 83 (which deals with listing on the Inventory before 5 years);
 - (g) section 87 (which deals with variations to the Inventory relating to subsequent assessment certificates);
 - (h) subsection 97(5) (which deals with publishing certain information relating to reported introductions).

61 Review of protection of proper name or end use

- (1) For the purposes of paragraph 110(1)(c) of the Act, the circumstances mentioned in subsection (2) of this section are prescribed.
- (2) For the purposes of subsection (1), the circumstances are that the Executive Director has concluded as part of an evaluation under Part 4 of the Act in relation to the introduction of an industrial chemical that a review of the approval to treat the proper name or end use for the industrial chemical as confidential business information is in the public interest.
- (3) For the purposes of paragraph 110(2)(b) of the Act, if circumstances mentioned in subsection (4) of this section apply in relation to an industrial chemical, the following persons are prescribed for those circumstances:
 - (a) a person to whom an entrusted person has disclosed protected information relating to the industrial chemical under subsection 120(1) of the Act;
 - (b) any person specified in a notice under subsection (5) of this section by the holder of the approval;
 - (c) for an approval to treat the proper name of the industrial chemical as confidential business information:
 - (i) each holder of any other approval to treat the proper name of the industrial chemical as confidential business information; and
 - (ii) a person to whom an assessment certificate, assessment statement, commercial evaluation authorisation or evaluation statement was given with an AACN in lieu of the proper name for the industrial chemical;

- (d) for an approval to treat an end use of an industrial chemical as confidential business information:
 - (i) each holder of any other approval to treat the end use of the industrial chemical as confidential business information; and
 - (ii) a person to whom an assessment certificate, assessment statement, commercial evaluation authorisation or evaluation statement was given with a generalised end use in lieu of the end use for the industrial chemical.
- (4) The circumstances are circumstances mentioned in any of the following provisions:
 - (a) subsection (2) of this section;
 - (b) section 58 of this instrument;
 - (c) section 83 of the Act;
 - (d) paragraph 110(1)(a) or (b) of the Act.
- (5) The holder of an approval may give written notice to the Executive Director to notify a person for the purposes of paragraph (3)(b).

62 Disclosure to certain entities

- (1) For the purposes of paragraph 117(2)(b) of the Act, the following entities are prescribed:
 - (a) each body in a State or Territory that has responsibility for matters relating to protection of the environment;
 - (b) each body in a State or Territory that has responsibility for matters relating to public health;
 - (c) each body in a State or Territory that has responsibility for matters relating to work health and safety.
- (2) For the purposes of paragraph 117(2)(c) of the Act, the following entities are prescribed:
 - (a) each Canadian government authority with responsibility for matters relating to the environment in relation to industrial chemicals;
 - (b) each Canadian government authority with responsibility for matters relating to health in relation to industrial chemicals;
 - (c) the European Chemicals Agency;
 - (d) each New Zealand government authority with responsibility for matters relating to the environment in relation to industrial chemicals;
 - (e) each New Zealand government authority with responsibility for matters relating to health in relation to industrial chemicals;
 - (f) each United States of America government authority with responsibility for matters relating to the environment in relation to industrial chemicals;
 - (g) each United States of America government authority with responsibility for matters relating to health in relation to industrial chemicals.

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Chapter 6 International agreements and arrangements

Part 1 Simplified outline of this Chapter

Section 63

Chapter 6—International agreements and arrangements

Part 1—Simplified outline of this Chapter

63 Simplified outline of this Chapter

The Act empowers the rules to prohibit the introduction or export of industrial chemicals that are the subject of a prescribed international agreement or a prescribed international arrangement, or to impose conditions to which the introduction or export is subject. This Chapter sets out the industrial chemicals that can be introduced or exported, and the conditions to which those introductions or exports are subject. This Chapter also prescribes the industrial chemicals the introduction of which is prohibited.

Part 2—Movement of industrial chemicals into or out of Australia

64 Introduction of certain industrial chemicals subject to conditions

- (1) This section applies in relation to the following industrial chemicals, which are the subject of the Rotterdam Convention:
- (a) commercial octabromodiphenyl ether including:
 - (i) hexabromodiphenyl ether; and
 - (ii) heptabromodiphenyl ether;
 - (b) commercial pentabromodiphenyl ether including:
 - (i) tetrabromodiphenyl ether; and
 - (ii) pentabromodiphenyl ether;
 - (c) perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls including the following:
 - (i) potassium perfluorooctane sulfonate;
 - (ii) lithium perfluorooctane sulfonate;
 - (iii) ammonium perfluorooctane sulfonate;
 - (iv) diethanolammonium perfluorooctane sulfonate;
 - (v) tetraethylammonium perfluorooctane sulfonate;
 - (vi) didecyldimethylammonium perfluorooctane sulfonate;
 - (vii) N-ethylperfluorooctane sulfonamide;
 - (viii) N-methylperfluorooctane sulfonamide;
 - (ix) N-ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide;
 - (x) N-(2-hydroxyethyl)-N-methylperfluorooctane sulfonamide;
 - (xi) perfluorooctane sulfonyl fluoride;
 - (d) each of the following kinds of polybrominated biphenyls:
 - (i) hexabromobiphenyl;
 - (ii) octabromobiphenyl;
 - (iii) decabromobiphenyl;
 - (e) short chain chlorinated paraffins;
 - (f) tetramethyl lead;
 - (g) tributyl tin compounds.
- (2) For the purposes of paragraph 163(1)(b) of the Act, introduction of the industrial chemical is subject to the following conditions:
- (a) that the introduction must have been approved by the Executive Director, in writing, before the industrial chemical is introduced;
 - (b) that the person must keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4.

Note: Applications for approval must be made to the Executive Director in writing, see section 67.

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Chapter 6 International agreements and arrangements

Part 2 Movement of industrial chemicals into or out of Australia

Section 65

65 Introduction of tetraethyl lead subject to conditions

- (1) For the purposes of paragraph 163(1)(b) of the Act, introduction of tetraethyl lead is subject to the following conditions:
 - (a) that the introduction must comply with one or more of the following:
 - (i) the introduction has been approved by the Executive Director, in writing, before the tetraethyl lead is introduced;
 - (ii) the tetraethyl lead must only be introduced in aviation gasoline, or for use in the production of aviation gasoline;
 - (iii) the tetraethyl lead must only be introduced in the circumstances set out in subsection (2);
 - (b) that the person must keep the records relating to the introduction of the tetraethyl lead that are required by Part 8 of Chapter 4.

Note: Applications for approval must be made to the Executive Director in writing, see section 67.

- (2) For the purposes of subparagraph (1)(a)(iii), tetraethyl lead may be introduced:
 - (a) in leaded fuel; and
 - (b) by a person who has been granted an approval under subsection 13(1) of the *Fuel Quality Standards Act 2000* in relation to the fuel; and
 - (c) the approval is in force on the day the tetraethyl lead is introduced; and
 - (d) the introduction is for the purposes of a supply specified in the approval.

66 Export of certain industrial chemicals subject to conditions

- (1) This section applies in relation to the following industrial chemicals, which are the subject of the Rotterdam Convention:
 - (a) commercial octabromodiphenyl ether including:
 - (i) hexabromodiphenyl ether; and
 - (ii) heptabromodiphenyl ether;
 - (b) commercial pentabromodiphenyl ether including:
 - (i) tetrabromodiphenyl ether; and
 - (ii) pentabromodiphenyl ether;
 - (c) perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls including the following:
 - (i) potassium perfluorooctane sulfonate;
 - (ii) lithium perfluorooctane sulfonate;
 - (iii) ammonium perfluorooctane sulfonate;
 - (iv) diethanolammonium perfluorooctane sulfonate;
 - (v) tetraethylammonium perfluorooctane sulfonate;
 - (vi) didecyldimethylammonium perfluorooctane sulfonate;
 - (vii) N-ethylperfluorooctane sulfonamide;
 - (viii) N-methylperfluorooctane sulfonamide;
 - (ix) N-ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide;
 - (x) N-(2-hydroxyethyl)-N-methylperfluorooctane sulfonamide;
 - (xi) perfluorooctane sulfonyl fluoride;

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- (d) polybrominated biphenyls, including the following:
 - (i) hexabromobiphenyl;
 - (ii) octabromobiphenyl;
 - (iii) decabromobiphenyl;
 - (e) polychlorinated biphenyls;
 - (f) polychlorinated terphenyls;
 - (g) short chain chlorinated paraffins;
 - (h) tetraethyl lead;
 - (i) tetramethyl lead;
 - (j) tributyl tin compounds;
 - (k) tris (2,3-dibromopropyl) phosphate.
- (2) For the purposes of paragraph 163(1)(b) of the Act, export of the industrial chemical is subject to the following conditions:
- (a) that the export must have been approved by the Executive Director, in writing, before the industrial chemical is exported;
 - (b) that the person must keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4.

Note: Applications for approval must be made to the Executive Director in writing, see section 67.

67 Applying for approval to introduce or export restricted industrial chemicals

- (1) A person may apply, in writing, to the Executive Director for approval to introduce an industrial chemical mentioned in section 64 or 65, or to export an industrial chemical mentioned in section 66.

Note 1: For general requirements relating to applications: see section 167 of the Act.

Note 2: The application fee is prescribed by the *Industrial Chemicals (Fees and Charges) Rules 2018*: see section 5 of that instrument.

- (2) A joint application under subsection (1) may be made by 2 or more persons.

Further information

- (3) The Executive Director may, by written notice given to an applicant, request further information to be provided for the purposes of considering the application.
- (4) The information must be provided within the period specified in the notice, which must not be less than 10 working days after the day the notice is given.
- (5) If the requested information is not provided within the period mentioned in subsection (4), the Executive Director may take the application to be withdrawn.

68 Decision on application

- (1) The Executive Director must:
- (a) consider the application in accordance with this section; and

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Chapter 6 International agreements and arrangements

Part 2 Movement of industrial chemicals into or out of Australia

Section 68

- (b) make a decision on the application within 20 working days after the day the application is made.
- (2) In considering the application, the Executive Director must have regard to:
- (a) any further information provided by the applicant under subsection 67(4); and
 - (b) if the applicant has held a previous approval to introduce or export the industrial chemical—the applicant’s compliance with the terms of the previous approval; and
 - (c) any other information the Executive Director considers relevant.
- (3) After considering the application, the Executive Director must decide to:
- (a) approve the introduction or export; or
 - (b) not approve the introduction or export.
- (4) The Executive Director must give the applicant written notice of:
- (a) the decision; and
 - (b) if the decision is to not approve the application—the reasons for the decision.
- (5) If the Executive Director has requested further information under subsection 67(3), the 20 working day period mentioned in paragraph (1)(b) of this section excludes the number of days falling within the period:
- (a) beginning on the day on which the notice was given under subsection 67(3); and
 - (b) ending on the earlier of:
 - (i) the day a complete response to the notice is provided to the Executive Director in accordance with subsection 67(4); or
 - (ii) the last day of the period specified in the notice.

Schedule 1—Polymers of low concern

Note: See the definition of *polymer of low concern* in section 5.

Part 1—Polymers of low concern

1 Polymers of low concern

For the purposes of this instrument, a polymer is a *polymer of low concern* if:

- (a) one of the following applies:
 - (i) the polymer has a number average molecular weight that is greater than or equal to 1,000 g/mol, but less than 10,000 g/mol and has such other characteristics relating to weight as are set out in clause 2;
 - (ii) the polymer has a number average molecular weight that is greater than or equal to 10,000 g/mol and has such other characteristics relating to weight as are set out in clause 3;
 - (iii) the polymer is made from a prescribed reactant and has molecules that contain 2 or more carboxylic acid ester linkages, one or more of which links internal monomer units together; and
- (b) the polymer has a low charge density; and
- (c) the polymer does not have any known hazard classification; and
- (d) the polymer is stable (within the meaning given by the Guidelines); and
- (e) the polymer contains, as an integral part of its composition, at least 2 of the chemical elements set out in clause 6; and
- (f) the polymer does not contain, as an integral part of its composition (other than as an impurity), an element other than a chemical element set out in clause 7; and
- (g) the polymer does not contain, as an integral part of its composition (other than as an impurity), 0.2% or more (by weight) of any combination of the chemical elements set out in paragraph 7(s); and
- (h) the polymer does not contain any difluoromethylene or trifluoromethyl groups; and
- (i) if the polymer is capable of absorbing its own weight in water—the number average molecular weight for the polymer is less than 10,000 g/mol.

Note 1: For the meaning of prescribed reactant, see clause 4.

Note 2: For when a polymer has a low charge density, see clause 5.

2 Number average molecular weight greater than or equal to 1,000 g/mol and less than 10,000 g/mol

- (1) For the purposes of subparagraph 1(a)(i), the characteristics are covered by subclauses (2), (3) and (4) of this clause.

General

- (2) The polymer must:

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Clause 2

- (a) have less than 10% by mass of molecules with molecular weight that is less than 500 g/mol; and
- (b) have less than 25% by mass of molecules with molecular weight that is less than 1,000 g/mol.

Polymers that include moderate concern reactive functional groups and do not include high concern reactive functional groups

- (3) If the polymer:
 - (a) includes moderate concern reactive functional groups; and
 - (b) does not include high concern reactive functional groups;the polymer must have a combined functional group equivalent weight of 1,000 g/mol or more (taking into account all moderate concern reactive functional groups included in the polymer).

Polymers that include high concern reactive functional groups

- (4) If the polymer includes high concern reactive functional groups, the polymer must have a combined functional group equivalent weight of 5,000 g/mol or more (taking into account any moderate concern reactive functional groups, and all high concern reactive functional groups, included in the polymer).

Reactive functional groups

- (5) For the purposes of subclauses (3) and (4), each of the following reactive functional groups is a low concern reactive functional group:
 - (a) aliphatic hydroxyls;
 - (b) blocked isocyanates (including ketoxime-blocked isocyanates);
 - (c) butenedioic acid groups;
 - (d) carboxylic acids;
 - (e) conjugated olefinic groups contained in naturally occurring fats, oils and carboxylic acids;
 - (f) halogens (other than reactive halogen-containing groups such as benzylic or allylic halides);
 - (g) imidazolidinone groups;
 - (h) imides;
 - (i) organic phosphate esters;
 - (j) thiols;
 - (k) unconjugated nitriles;
 - (l) unconjugated olefinic groups that are not specifically activated by being part of a larger functional group or by other activating influences.
- (6) For the purposes of subclauses (3) and (4), each of the following reactive functional groups is a moderate concern reactive functional group:
 - (a) acid anhydrides;
 - (b) acid halides;
 - (c) aldehydes;
 - (d) aldimines;

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Clause 3

- (e) alkoxy silanes (with alkoxy greater than C₂-alkoxy silane);
 - (f) allyl ethers;
 - (g) conjugated olefinic groups not contained in naturally occurring fats, oils and carboxylic acids;
 - (h) cyanates;
 - (i) epoxides;
 - (j) hemiacetals;
 - (k) ketimines;
 - (l) methylol-amides;
 - (m) methylol-amines;
 - (n) methylol-ureas;
 - (o) unsubstituted positions ortho or para to phenolic hydroxyl.
- (7) For the purposes of subclauses (3) and (4), each of the following reactive functional groups is a high concern reactive functional group:
- (a) alkoxy silanes (with alkoxy of C₁- or C₂- alkoxy silane);
 - (b) alpha lactones;
 - (c) amines;
 - (d) aziridines;
 - (e) azo groups;
 - (f) beta lactones;
 - (g) carbodi-imides;
 - (h) disulfides;
 - (i) halosilanes;
 - (j) hydrazines;
 - (k) hydrosilanes;
 - (l) isocyanates;
 - (m) isothiocyanates;
 - (n) partially-hydrolysed acrylamides;
 - (o) pendant acrylates;
 - (p) pendant methacrylates;
 - (q) trithiocarbonates;
 - (r) vinyl sulfones;
 - (s) any other reactive functional group that is not a low concern reactive functional group or a moderate concern reactive functional group.
- (8) In this clause, **reactive functional group** means an atom, or an associated group of atoms, in an industrial chemical that is intended, or may reasonably be expected, to undergo further chemical reaction.

3 Number average molecular weight that is greater than or equal to 10,000 g/mol

For the purposes of subparagraph 1(a)(ii), the characteristics are that the polymer must:

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Clause 4

- (a) have less than 2% by mass of molecules with molecular weight that is less than 500 g/mol; and
- (b) have less than 5% by mass of molecules with molecular weight that is less than 1,000 g/mol.

4 Prescribed reactants

For the purposes of subparagraph 1(a)(iii), the following are prescribed reactants:

- (a) a dibasic or tribasic acid mentioned in the table in clause 8;
- (b) a modifier mentioned in the table in clause 9;
- (c) a monobasic acid or natural oil mentioned in clause 10;
- (d) a polyol mentioned in clause 11;
- (e) a derivative substance mentioned in clause 12.

5 Low charge density

For the purposes of paragraph 1(b), a polymer has a low charge density if:

- (a) it is both:
 - (i) not cationic; and
 - (ii) not likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9; or
- (b) it is a solid that is:
 - (i) not soluble or dispersible in water; and
 - (ii) to be used only in its solid phase; or
- (c) if the polymer includes one or more cationic groups—the total combined functional group equivalent weight of any cationic group is at least 5,000 g/mol.

6 Chemical elements the polymer must contain as integral part of composition

For the purposes of paragraph 1(e), the chemical elements are the following:

- (a) carbon;
- (b) hydrogen;
- (c) nitrogen;
- (d) oxygen;
- (e) silicon;
- (f) sulfur.

7 Chemical elements the polymer may contain as integral part of composition

For the purposes of paragraph 1(f), the chemical elements are the following:

- (a) aluminium as the monatomic counterion Al^{3+} ;
- (b) bromine as the monatomic counterion Br^- ;
- (c) bromine covalently bound to carbon;
- (d) calcium as the monatomic counterion Ca^{2+} ;
- (e) carbon;
- (f) chlorine as the monatomic counterion Cl^- ;

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Clause 7

- (g) chlorine covalently bound to carbon;
- (h) fluorine covalently bound to carbon;
- (i) hydrogen;
- (j) iodine as the monatomic counterion I⁻;
- (k) iodine covalently bound to carbon;
- (l) magnesium as the monatomic counterion Mg²⁺;
- (m) nitrogen;
- (n) oxygen;
- (o) potassium as the monatomic counterion K⁺;
- (p) silicon;
- (q) sodium as the monatomic counterion Na⁺;
- (r) sulfur;
- (s) less than 0.2% (by weight) of any combination of the following chemical elements:
 - (i) boron;
 - (ii) copper;
 - (iii) iron;
 - (iv) lithium;
 - (v) manganese;
 - (vi) nickel;
 - (vii) phosphorus;
 - (viii) tin;
 - (ix) titanium;
 - (x) zinc;
 - (xi) zirconium.

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Part 2 Prescribed reactants

Clause 8

Part 2—Prescribed reactants

8 Dibasic and tribasic acids

For the purposes of paragraph 4(a), a dibasic or tribasic acid mentioned in an item in the following table is a prescribed reactant.

Dibasic and tribasic acids		
Item	Substance	CAS no.
1	1,2-Benzenedicarboxylic acid	88-99-3
2	1,3-Benzenedicarboxylic acid	121-91-5
3	1,3-Benzenedicarboxylic acid, dimethyl ester	1459-93-4
4	1,4-Benzenedicarboxylic acid	100-21-0
5	1,4-Benzenedicarboxylic acid, diethyl ester	636-09-9
6	1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6
7	1,2,4-Benzenetricarboxylic acid	528-44-9
8	Butanedioic acid	110-15-6
9	Butanedioic acid, diethyl ester	123-25-1
10	Butanedioic acid, dimethyl ester	106-65-0
11	2-Butenedioic acid (E)-	110-17-8
12	1,4-Cyclohexanedicarboxylic acid	1076-97-7
13	Decanedioic acid	111-20-6
14	Decanedioic acid, diethyl ester	110-40-7
15	Decanedioic acid, dimethyl ester	106-79-6
16	Dodecanedioic acid	693-23-2
17	Fatty acids, C18-unsaturated, dimers	61788-89-4
18	2,5-Furandione, dihydro-	108-30-5
19	Heptanedioic acid	111-16-0
20	Heptanedioic acid, dimethyl ester	1732-08-7
21	Hexanedioic acid	124-04-9
22	Hexanedioic acid, diethyl ester	141-28-6
23	Hexanedioic acid, dimethyl ester	627-93-0
24	5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-	552-30-7
25	1,3-Isobenzofurandione	85-44-9
26	Nonanedioic acid	123-99-9
27	Nonanedioic acid, diethyl ester	624-17-9
28	Nonanedioic acid, dimethyl ester	1732-10-1
29	Octanedioic acid	505-48-6
30	Octanedioic acid, dimethyl ester	1732-09-8
31	Pentanedioic acid	110-94-1
32	Pentanedioic acid, diethyl ester	818-38-2

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Clause 9

Dibasic and tribasic acids

Item	Substance	CAS no.
33	Pentanedioic acid, dimethyl ester	1119-40-0
34	Undecanedioic acid	1852-04-6
35	Unsaturated fatty acids, C ₁₈ , dimers, hydrogenated	68783-41-5

9 Modifiers

For the purposes of paragraph 4(b), a modifier mentioned in an item in the following table is a prescribed reactant.

Modifiers

Item	Substance	CAS no.
1	Acetic acid, 2,2'-oxybis-	110-99-6
2	1-Butanol (other than 1-butanol that is used to manufacture a polyester with maleic or fumaric acid)	71-36-3
3	Cyclohexanol	108-93-0
4	Cyclohexanol, 4,4'-(1-methylethylidene)bis-	80-04-6
5	Ethanol	64-17-5
6	Ethanol, 2-(2-butoxyethoxy)-	112-34-5
7	1-Hexanol	111-27-3
8	Methanol	67-56-1
9	Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane	72318-84-4
10	1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-	13393-93-6
11	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane]	25036-25-3
12	1-Propanol, 2-methyl-	78-83-1
13	Siloxanes and silicones, dimethyl, diphenyl, polymers with phenyl silsesquioxanes, methoxy-terminated	68440-65-3
14	Siloxanes and silicones, dimethyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy-terminated	68957-04-0
15	Siloxanes and silicones, methyl phenyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated	68957-06-2
16	Silsesquioxanes, phenyl propyl	68037-90-1

10 Monobasic acids and natural oils

For the purposes of paragraph 4(c), a monobasic acid or a natural oil mentioned in an item in the following table is a prescribed reactant.

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Clause 10

Monobasic acids and natural oils		
Item	Substance	CAS no. (if any)
1	Benzoic acid	65-85-0
2	Canola oil	120962-03-0
3	Castor oil	8001-79-4
4	Castor oil, dehydrated	64147-40-6
5	Castor oil, dehydrated, polymerised	68038-02-8
6	Coconut oil	8001-31-8
7	Coconut oil, hydrogenated	84836-98-6
8	Corn oil	8001-30-7
9	Corn-oil fatty acids	68308-50-9
10	Cottonseed oil	8001-29-4
11	Dodecanoic acid	143-07-7
12	Fats and glyceridic oils, anchovy	128952-11-4
13	Fats and glyceridic oils, babassu	91078-92-1
14	Fats and glyceridic oils, herring	68153-06-0
15	Fats and glyceridic oils, menhaden	8002-50-4
16	Fats and glyceridic oils, sardine	93334-41-9
17	Fats and glyceridic oils, oiticica	8016-35-1
18	Fatty acids, C ₈₋₁₀	68937-75-7
19	Fatty acids, C ₁₄₋₁₈ and C ₁₆₋₁₈ -unsaturated	67701-06-8
20	Fatty acids, C ₁₆₋₁₈ and C ₁₈ -unsaturated	67701-08-0
21	Fatty acids, castor-oil	61789-44-4
22	Fatty acids, coco	61788-47-4
23	Fatty acids, dehydrated castor-oil	61789-45-5
24	Fatty acids, linseed oil	68424-45-3
25	Fatty acids, olive-oil	92044-96-7
26	Fatty acids, safflower oil	93165-34-5
27	Fatty acids, soya	68308-53-2
28	Fatty acids, sunflower oil	84625-38-7
29	Fatty acids, sunflower-oil, conjugated	68953-27-5
30	Fatty acids, tall-oil	61790-12-3
31	Fatty acids, tall-oil, conjugated	
32	Fatty acids, vegetable oil	61788-66-7
33	Fish oil	8016-13-5
34	Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsaturated	67701-30-8
35	Heptanoic acid	111-14-8
36	Hexadecanoic acid	57-10-3
37	9-Hexadecenoic acid, (9Z)-	373-49-9
38	Hexanoic acid	142-62-1
39	Hexanoic acid, 3,3,5-trimethyl-	23373-12-8

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Clause 11

Monobasic acids and natural oils		
Item	Substance	CAS no. (if any)
40	Hexanoic acid, 3,5,5-trimethyl-	3302-10-1
41	Linseed oil	8001-26-1
42	Linseed oil, oxidised	68649-95-6
43	Linseed oil, polymerised	67746-08-1
44	Nonanoic acid	112-05-0
45	Octadecanoic acid	57-11-4
46	9-Octadecenoic acid (9Z)-	112-80-1
47	9,12-Octadecadienoic acid (9Z,12Z)-	60-33-3
48	Oils, cannabis	
49	Oils, palm kernel	8023-79-8
50	Oils, perilla	68132-21-8
51	Oils, walnut	8024-09-7
52	Olive oil	8001-25-0
53	Safflower oil	8001-23-8
54	Soybean oil	8001-22-7
55	Sunflower oil	8001-21-6
56	Tung oil	8001-20-5

11 Polyols

For the purposes of paragraph 4(d), a polyol mentioned in an item in the following table is a prescribed reactant.

Polyols		
Item	Substance	CAS no.
1	1,3-Butanediol	107-88-0
2	1,4-Butanediol	110-63-4
3	1,4-Cyclohexanedimethanol	105-08-8
4	1,2-Ethandiol	107-21-1
5	Ethanol, 2,2'-oxybis-	111-46-6
6	1,6-Hexanediol	629-11-8
7	1,3-Pentanediol, 2,2,4-trimethyl-	144-19-4
8	1,2-Propanediol	57-55-6
9	1,3-Propanediol	504-63-2
10	1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115-77-5
11	1,3-Propanediol, 2,2-dimethyl-	126-30-7
12	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77-99-6
13	1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-	77-85-0
14	1,3-Propanediol, 2-methyl-	2163-42-0

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Clause 12

Polyols		
Item	Substance	CAS no.
15	1,2,3-Propanetriol	56-81-5
16	1,2,3-Propanetriol, homopolymer	25618-55-7
17	2-Propen-1-ol, polymer with ethenylbenzene	25119-62-4

12 Derivatives

For the purposes of paragraph 4(e), a derivative mentioned in an item in the following table is a prescribed reactant.

Derivatives	
Item	Substances
1	A diethyl or triethyl ester of a substance listed in clause 8
2	A dimethyl or trimethyl ester of a substance listed in clause 8
3	A methyl ester of a substance listed in clause 8 or 10
4	An anhydride of a substance listed in clause 8 or 10
5	An ethyl ester of a substance listed in clause 8 or 10
