



Industrial Chemicals (General) Rules 2019

made under the

Industrial Chemicals Act 2019

Compilation No. 5

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About this compilation

This compilation

This is a compilation of the *Industrial Chemicals (General) Rules 2019* that shows the text of the law as amended and in force on 21 July 2023 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Chapter 1—Preliminary

Part 1—Preliminary

1 Name

This instrument is the *Industrial Chemicals (General) Rules 2019*.

3 Authority

This instrument is made under the *Industrial Chemicals Act 2019*.

4 Simplified outline of this instrument

This instrument prescribes various matters for the purposes of the *Industrial Chemicals Act 2019*.

This Chapter contains preliminary provisions, including definitions for the purposes of the Act and this instrument. It also sets out certain circumstances in which the use of animal test data will be restricted for applications relating to industrial chemicals that are to be introduced for an end use in cosmetics.

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. It sets out how introductions can be categorised as exempted or reported by dealing with certain circumstances in which introductions will be exempted or 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 post-introduction declarations for exempted introductions and pre-introduction reports for reported introductions. It also sets out the requirements 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 a 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

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Executive Director's power to approve the import or export of certain industrial chemicals that relate to those agreements and arrangements on application.

Chapter 7 deals with miscellaneous matters, including additional functions for the Executive Director and reviewable decisions.

5 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) AACN;
- (b) end use;
- (c) industrial chemical;
- (d) manufacture;
- (e) use.

In this instrument:

Act means the *Industrial Chemicals Act 2019*.

biochemical means a biological chemical that:

- (a) is directly produced by a microscopic organism; or
- (b) is a protein or a nucleic acid.

biocidal active means an industrial chemical that is intended to act by chemical means on or against a harmful organism by destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, the harmful organism.

biological chemical means an industrial chemical that is derived from, or produced by, a living or once-living organism.

chemical identity holder has the meaning given by the Guidelines.

children's care product means a product that is intended to facilitate:

- (a) children's sleep, relaxation or hygiene; or
- (b) the feeding of children; or
- (c) sucking by children.

consumer end use, for an industrial chemical, means an end use for the industrial chemical that involves making the industrial chemical available to the general public:

- (a) on its own; or
- (b) in combination with one or more other industrial chemicals; or
- (c) as part of an article (other than where the industrial chemical undergoes a chemical change to produce the article).

designated kind of release into the environment has the meaning given by subclause 3(2) of Schedule 1.

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 clause 3 of Schedule 1.

environment hazard band that applies to the environment hazard characteristic of an industrial chemical has the meaning given by clause 4 of Schedule 1.

environment hazard characteristic, of an industrial chemical, means a hazard characteristic, of the industrial chemical, that is mentioned in the table in clause 4 of Schedule 1.

flavour blend means a mixture of industrial chemicals that is formulated to impart a taste.

flavour blend introduction: an introduction of an industrial chemical is a **flavour blend introduction** if:

- (a) the industrial chemical is introduced as part of a flavour blend; and
- (b) the introduction is either of the flavour blend on its own or of the flavour blend in combination with one or more other industrial chemicals.

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

fragrance blend means a mixture of industrial chemicals that is formulated to impart a scent or to cover a malodour.

fragrance blend introduction: an introduction of an industrial chemical is a **fragrance blend introduction** if:

- (a) the industrial chemical is introduced as part of a fragrance blend; and
- (b) the introduction is either of the fragrance blend on its own or of the fragrance blend in combination with one or more other industrial chemicals.

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

GHS has the same meaning as in the *Work Health and Safety Regulations 2011*.

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Note: GHS is short for Globally Harmonised System of Classification and Labelling of Chemicals.

Guidelines means the Industrial Chemicals Categorisation Guidelines issued by the Executive Director, as existing from time to time.

harmful organism means an organism that has an unwanted presence or a detrimental effect on humans, human activities, products used or produced by humans, or the environment.

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

hazard class means the nature of a physical, health or environmental hazard under the GHS.

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 24.

highly branched organic chemical means an industrial chemical that:

- (a) is carbon based; and
- (b) is branched at:
 - (i) more than one tertiary carbon; or
 - (ii) more than one quaternary carbon; or
 - (iii) a combination of tertiary and quaternary carbons; and
- (c) is not a polymer.

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.

Home Affairs Department means the Department administered by the Minister administering the *Australian Border Force Act 2015*.

human health categorisation volume, for an industrial chemical, means the human health categorisation volume for the industrial chemical worked out in accordance with the Guidelines.

human health exposure band, for the introduction of an industrial chemical, has the meaning given by clause 1 of Schedule 1.

human health hazard band, that applies to the human health hazard characteristic of an industrial chemical, has the meaning given by clause 2 of Schedule 1.

human health hazard characteristic, of an industrial chemical, means a hazard characteristic, of the industrial chemical, that is mentioned in the table in clause 2 of Schedule 1.

IFRA Transparency List means the IFRA Transparency List published by the International Fragrance Association, as existing from time to time.

Note: The IFRA Transparency List could in 2019 be viewed on the International Fragrance Association's website (<https://ifrafragrance.org>).

INCI name, for an industrial chemical, means the International Nomenclature of Cosmetic Ingredients name for the industrial chemical.

indicative environment risk, in relation to the introduction of an industrial chemical, has the meaning given by subsection 29(1).

indicative human health risk, in relation to the introduction of an industrial chemical, has the meaning given by subsection 28(1).

international assessment body:

- (a) in relation to an industrial chemical that is internationally-assessed for human health—has the meaning given by paragraph 6(1)(a); and
- (b) in relation to an industrial chemical that is internationally-assessed for the environment—has the meaning given by paragraph 6(2)(a).

international assessment report:

- (a) in relation to an industrial chemical that is internationally-assessed for human health—has the meaning given by paragraph 6(1)(d); and
- (b) in relation to an industrial chemical that is internationally-assessed for the environment—has the meaning given by paragraph 6(2)(d).

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 environmental degradation products, in relation to an industrial chemical, has the meaning given by the Guidelines.

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

low cationic density: a chemical has a **low cationic density** if:

- (a) it is not cationic or potentially cationic; or
- (b) the chemical contains one or more cationic, or potentially cationic, groups and at least one of the following applies:
 - (i) the total combined functional group equivalent weight of any cationic or potentially cationic groups is at least 5,000 g/mol;
 - (ii) the chemical has a solubility in water of less than 0.1 mg/L and will only be used in its solid phase;
 - (iii) the chemical is not dispersible in water and will only be used in its solid phase.

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Minamata Convention means the Minamata Convention on Mercury done at Minamata on 10 October 2013, as in force for Australia from time to time.

Note: The Convention could in 2021 be viewed in the Australian Treaties Library on the AustLII website (<http://www.austlii.edu.au>).

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.

organism means a biological entity that is:

- (a) viable; or
- (b) capable of reproduction; or
- (c) capable of transferring genetic material.

organotin chemical means a chemical that contains at least one tin atom that is covalently bound to at least one carbon atom.

overseas jurisdiction:

- (a) in relation to an industrial chemical that is internationally-assessed for human health—has the meaning given by paragraph 6(1)(b); and
- (b) in relation to an industrial chemical that is internationally-assessed for the environment—has the meaning given by paragraph 6(2)(b).

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

persistent, in relation to an industrial chemical or its known environmental degradation products, has the meaning given by the Guidelines.

personal vaporiser means a device that is intended to produce a vapour or aerosol that is delivered into a person's body when the person inhales through the device.

Note: Examples of devices that would be personal vaporisers are e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

polyhalogenated organic chemical means a chemical that:

- (a) is carbon based; and
- (b) contains more than one covalently bound 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) 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 molecular weight details, of an industrial chemical that is a polymer, means the following:

- (a) the number average molecular weight of the industrial chemical;
- (b) the weight average molecular weight of the industrial chemical;
- (c) the polydispersity index for the industrial chemical;
- (d) the percentage (by mass) of molecules with a molecular weight that is less than 1,000 g/mol;
- (e) the percentage (by mass) of molecules with a molecular weight that is less than 500 g/mol.

polymer of low concern has the meaning given by Schedule 2.

potentially cationic: a chemical is **potentially cationic** if the chemical is likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9.

pre-introduction report, for an industrial chemical, means a report for the industrial chemical prepared and given to the Executive Director in accordance with section 97 of the Act, including such a report as varied in accordance with section 98 of the Act.

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 Part 1 of Schedule 1 to the *Australian Radiation Protection and Nuclear Safety Regulations 2018*; and
- (c) has an activity concentration value (within the meaning of the *Australian Radiation Protection and Nuclear Safety Regulations 2018*) greater than the activity concentration value for the nuclide set out in the table in Part 1 of Schedule 1 to those Regulations.

REACH Regulation means 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.

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

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 chemical reaction.

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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, including for the analysis of other chemicals; 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.

Stockholm Convention means 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 2019 could be viewed in the Australian Treaties Library on the AustLII website (<http://www.austlii.edu.au>).

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:

- (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 industrial chemicals

- (1) For the purposes of this instrument, 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 column 2 of the item (the **international assessment body**); and
 - (b) the assessment or evaluation was conducted in another jurisdiction (the **overseas jurisdiction**); and
 - (c) the assessment or evaluation was in relation to risks to human health; and
-

- (d) there is a report of the assessment or evaluation (the **international assessment report**).
- (2) For the purposes of this instrument, 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 3, 4, 5 or 10) by the body mentioned in column 2 of the item (the **international assessment body**); and
 - (b) the assessment or evaluation was conducted in another jurisdiction (the **overseas jurisdiction**); and
 - (c) the assessment or evaluation was in relation to risks to the environment; and
 - (d) there is a report of the assessment or evaluation (the **international assessment report**).
- (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 | | |
|--|--|--|
| | Column 1 | Column 2 |
| Item | Type of assessment or evaluation | International assessment body |
| 1 | Risk assessments under the <i>Canadian Environmental Protection Act, 1999</i> (Canada) that are undertaken in accordance with Schedule 5, 6, 9, 10 or 11 of the <i>New Substances Notification Regulations (Chemicals and Polymers)</i> (Canada) on or after 31 October 2005 | (a) Environment and Climate Change Canada; or (b) Health Canada |
| 2 | Risk assessments under the <i>Canadian Environmental Protection Act, 1999</i> (Canada) that are undertaken in accordance with Schedule II, III, VI, VII or VIII of the <i>New Substances Notification Regulations (Chemicals and Polymers)</i> (Canada) before 31 October 2005 | (a) Environment and Climate Change Canada; or (b) Health Canada |
| 3 | Opinions from the European Commission Scientific Committee on Consumer Products that: <ol style="list-style-type: none"> (a) have been finalised and adopted by that Committee; and (b) have terms of reference that include a question about the safety of a chemical in a cosmetic product; and (c) have a conclusion of safety with respect to the question about the safety of the chemical in a cosmetic product | the European Commission Scientific Committee on Consumer Products |

Section 6

| Assessments and evaluations conducted by international bodies | | |
|--|--|---|
| | Column 1 | Column 2 |
| Item | Type of assessment or evaluation | International assessment body |
| 4 | Opinions from the European Commission Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers that: (a) have been finalised and adopted by that Committee; and (b) have terms of reference that include a question about the safety of a chemical in a cosmetic product; and (c) have a conclusion of safety with respect to the question about the safety of the chemical in a cosmetic product | the European Commission Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers |
| 5 | Opinions from the European Commission Scientific Committee on Consumer Safety that: (a) have been finalised and adopted by that Committee; and (b) have terms of reference that include a question about the safety of a chemical in a cosmetic product; and (c) have a conclusion of safety with respect to the question about the safety of the chemical in a cosmetic product | the European Commission Scientific Committee on Consumer Safety |
| 6 | Opinions from the European Chemicals Agency Committee for Risk Assessment and the Committee for Socio-Economic Analysis that: (a) are in accordance with the REACH Regulation; and (b) have been the basis of a European Commission decision to include or update a restriction in Annex XVII of that Regulation | (a) the European Chemicals Agency Committee for Risk Assessment; and (b) the European Chemicals Agency Committee for Socio-Economic Analysis |
| 7 | 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; and (c) have been the basis of a European Commission decision to approve an active biocidal substance | (a) an authority of a member state of the European Union; or (b) the European Chemicals Agency |
| 8 | Assessments: | (a) Environment and Climate Change Canada; or |

| Assessments and evaluations conducted by international bodies | | |
|--|--|---|
| | Column 1 | Column 2 |
| Item | Type of assessment or evaluation | International assessment body |
| | (a) that are risk assessments, under the <i>Canadian Environmental Protection Act, 1999</i> (Canada), of substances that are not specified on the Domestic Substances List (within the meaning of that Act); and (b) for which Australia has been involved as a secondary jurisdiction in an international parallel process (within the meaning given by the Guidelines) | (b) Health Canada |
| 9 | Assessments: (a) that are new chemical risk assessments under the <i>Toxic Substances Control Act of 1976</i> (United States of America) as amended by the <i>Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016</i> (United States of America); and (b) for which Australia has been involved as a secondary jurisdiction in an international parallel process (within the meaning given by the Guidelines) | the United States Environmental Protection Agency |
| 10 | Opinions from the European Food Safety Authority under Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food | the European Food Safety Authority |

- (4) To avoid doubt, 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 (other than the bodies mentioned in column 2 of items 3, 4, 5 and 10 of the table in subsection (3)).

Note: For the definition of *international assessment body*, see section 5.

7 Specified classes of introductions

- (1) An introduction of an industrial chemical is a *specified class of introduction* if subsection (2), (3) or (4) applies to the introduction.
- (2) For the purposes of subsection (1), this subsection applies to the following classes of introductions:
- (a) introductions of an industrial chemical that:
- (i) is a gas; and
 - (ii) is persistent;

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- (b) introductions of an industrial chemical that is a highly branched organic chemical;
- (c) introductions of an industrial chemical for an end use as a biocidal active;
- (d) introductions of an industrial chemical that involve a designated kind of release into the environment.

Note 1: For the definition of *persistent*, see section 5.

Note 2: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

- (3) For the purposes of subsection (1), this subsection applies to the following classes of introductions:
 - (a) introductions of an industrial chemical that is a biochemical;
 - (b) introductions of an industrial chemical that is a GM product;
 - (c) introductions of an industrial chemical that:
 - (i) is a solid, or is in a dispersion, at the time of introduction; and
 - (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale;
 - (d) introductions of an industrial chemical that is a polyhalogenated organic chemical;
 - (e) introductions of an industrial chemical that contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms.
- (4) For the purposes of subsection (1), this subsection applies to the following classes of introductions:
 - (a) introductions of an industrial chemical that is 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;
 - (e) introductions of an industrial chemical for an end use in an article that is a children's toy or a children's care product.

Note: For the definition of *end use in an article with food contact*, see section 5.

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:
 - (i) a live vertebrate animal (other than a human being); or
 - (ii) an animal of a kind prescribed by section 9 of this instrument;
- (b) experimentation to test any effects of an industrial chemical, either on its own or in combination with one or more other chemicals, using:
 - (i) a live vertebrate animal (other than a human being); or
 - (ii) an animal of a kind prescribed by section 9 of this instrument.

9 Additional kind of animal for the purposes of the definition of *animal test data*

For the purposes of paragraph (b) of the definition of *animal test data* in section 9 of the Act, cephalopods are prescribed.

10 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, than by the object's chemical composition;
- (b) objects that are wholly fluid.

11 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:

- (aa) the Minamata Convention;
- (a) the Rotterdam Convention;
- (b) the Stockholm Convention.

12 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;

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- (c) 29 December;
- (d) 30 December;
- (e) 31 December.

12A Mixtures of mercury

Mixtures of mercury (including alloys of mercury) with a mercury concentration of at least 95% by weight are prescribed:

- (a) for the purposes of paragraph 10(1)(f) of the Act; and
- (b) as a kind of industrial chemical for the purposes of paragraph 11(2)(e) of the Act.

13 Chemicals or substances that are not industrial chemicals

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

14 Circumstances in which introductions are excluded introductions

For the purposes of subsection 11(4) of the Act, an introduction of an industrial chemical is an excluded introduction if:

- (a) the industrial chemical is introduced incidentally to the carriage of passengers, or the importation of other products, on an aircraft or a ship that leaves Australia within 25 working days beginning the day the industrial chemical is introduced; and
- (b) the industrial chemical is used to support the operation of the aircraft or ship; and
- (c) the industrial chemical is not freight.

15 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 purposes of carrying on an enterprise (within the meaning of the *A New Tax System (Goods and Services Tax) Act 1999*) is prescribed.

Part 3—Prescribed bodies

16 Bodies from which the Executive Director must seek advice

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 exposure via the environment | (a) the Environment Department; and (b) the Health Department |
| 5 | risks to human health related to food | Food Standards Australia New Zealand |
| 6 | risks to human health related to the health of workers | Safe Work Australia |
| 7 | risks to human health related to public health | the Health Department |
| 8 | risks to human health or the environment related to transport of an industrial chemical | the National Transport Commission |
| 9 | risks to human health or the environment where there may be national security implications | the Home Affairs Department |

17 Bodies from which the Executive Director may seek advice

For the purposes of subsections 34(2), 46(2), 56(1) and 71(2), paragraph 75(a) and subsections 91(2), 107(1) and 111(5) of the Act, the following bodies are prescribed:

- (a) the Australian Competition and Consumer Commission;
- (b) the Environment Department;
- (c) Food Standards Australia New Zealand;
- (d) the Gene Technology Regulator;
- (e) the Health Department;
- (f) the Home Affairs Department;
- (g) the National Health and Medical Research Council;
- (h) the National Transport Commission;

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- (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.

Part 4—Commercial evaluation authorisations

18 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 available to the general public on its own;
 - (b) making the industrial chemical available to the general public in combination with one or more other industrial chemicals;
 - (c) making the industrial chemical available to the general public as part of an article if:
 - (i) the article was designed to release the industrial chemical; or
 - (ii) the industrial chemical is for an end use in an article with food contact; or
 - (iii) the article is a children's toy or a children's care product.
- (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, over the period for which the authorisation is to be in force, exceed 10 tonnes.

Part 5—Restrictions on animal test data for applications relating to end use in cosmetics

19 Restriction on animal test data for applications for industrial chemicals with multiple end uses including an end use in cosmetics

- (1) This section applies if:
 - (a) an industrial chemical is to be introduced for multiple end uses; and
 - (b) one of those end uses is in cosmetics.
- (2) For the purposes of paragraph 167(1)(da) of the Act, an application by a person under the Act in relation to the introduction of the industrial chemical must not contain any animal test data obtained from tests conducted on or after 1 July 2020 other than:
 - (a) animal test data that:
 - (i) demonstrates that the industrial chemical has a hazard characteristic; and
 - (ii) conflicts with other information contained in the application regarding whether the industrial chemical has that hazard characteristic; or
 - (b) animal test data that is the only information that can demonstrate whether the industrial chemical has a particular environment hazard characteristic; or
 - (c) animal test data that is derived from tests conducted on animals involving a chemical that:
 - (i) is not the industrial chemical to which the application relates; and
 - (ii) is not an industrial chemical introduced by the person for an end use in cosmetics.

Note: This restriction does not apply if the inclusion of the animal test data is approved by the Executive Director: see section 20.

20 Applications for industrial chemicals with multiple end uses including an end use in cosmetics

- (1) For the purposes of subsection 167(1B) of the Act, section 19 of this instrument does not apply in relation to animal test data (other than animal test data of a kind described in paragraphs 19(2)(a), (b) and (c)) if the inclusion of the animal test data is approved by the Executive Director under section 21 of this instrument.
- (2) A person may apply, in writing, to the Executive Director for approval to include the animal test data in an application (the *original application*).

Note: For general requirements relating to applications, see section 167 of the Act.
- (3) A joint application under subsection (2) may be made by 2 or more persons.

Further information

- (4) The Executive Director may, by written notice given to an applicant, request further information to be provided for the purposes of considering the application.
- (5) The requested 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.
- (6) If the requested information is not provided within the period mentioned in subsection (5), the Executive Director may take the application to be withdrawn.

21 Decision on application

- (1) The Executive Director must:
 - (a) consider the application under section 20 in accordance with this section; and
 - (b) make a decision on the application within 10 working days after the day the application is made.
 - (2) In considering the application, the Executive Director must have regard to the following:
 - (a) if the animal test data is for the purpose of identifying a human health hazard characteristic of the industrial chemical—whether the non-cosmetic end use of the industrial chemical to which the original application relates involves, or potentially involves, exposure of humans to the industrial chemical;
 - (b) if the animal test data is for the purpose of identifying an environment hazard characteristic of the industrial chemical—whether the non-cosmetic end use of the industrial chemical to which the original application relates involves, or potentially involves, exposure of the environment to the industrial chemical;
 - (c) any further information provided by the applicant under subsection 20(5);
 - (d) any other information the Executive Director considers relevant.
 - (3) After considering the application, the Executive Director must decide to:
 - (a) approve the inclusion of the animal test data in the original application; or
 - (b) not approve the inclusion of the animal test data in the original application.
 - (4) The Executive Director must give the applicant written notice of:
 - (a) the decision; and
 - (b) if the decision is to refuse the application—the reasons for the decision.
 - (5) If the Executive Director has requested further information under subsection 20(4), the 10 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 is given under subsection 20(4); and
-

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- (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 20(5); or
 - (ii) the last day of the period specified in the notice.

22 Ban on animal test data for applications for industrial chemicals with end use solely in cosmetics

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

- (a) the animal test data:
 - (i) demonstrates that the industrial chemical has a hazard characteristic; and
 - (ii) conflicts with other information contained in the application regarding whether the industrial chemical has that hazard characteristic; or
- (b) the animal test data is the only information that can demonstrate whether the industrial chemical has a particular environment hazard characteristic; 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.

Chapter 2—Categorisation of introductions of industrial chemicals

Part 1—Simplified outline of this Chapter

23 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 for the introduction. If:

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

Part 2—Determining if an introduction is exempted or reported

24 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 25.

If the introduction is covered by section 25:

- (a) for the purposes of paragraph 26(2)(b) of the Act, the introduction is not an exempted introduction; and
- (b) for the purposes of paragraph 27(2)(b) of the Act, the introduction is not a reported introduction.

Otherwise, go to step 2.

Step 2: Work out whether the introduction is covered by section 26.

If the introduction is covered by section 26, 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 27.

If the introduction is covered by section 27, 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 28).

Step 5: Work out the indicative environment risk for the introduction (see section 29).

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.

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.

If the highest indicative risk for the introduction is medium to high risk:

- (a) for the purposes of paragraph 26(2)(b) of the Act, the introduction is not an exempted introduction; and
- (b) for the purposes of paragraph 27(2)(b) of the Act, the introduction is not 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.

25 Circumstances in which introductions are not exempted or reported

- (1) For the purposes of step 1 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.

Introduction of industrial chemical subject to an international agreement or arrangement

- (2) This subsection applies to the introduction of an industrial chemical by a person if the industrial chemical is listed in:
 - (a) Annex III to the Rotterdam Convention; or
 - (b) Part 1 of Annex A, B or C to the Stockholm Convention;unless:
 - (c) the industrial chemical is to be introduced solely for use in research or analysis; and
 - (d) the total volume of the industrial chemical introduced by the person in a registration year does not exceed 100 kg.

Introduction of industrial chemical listed on Inventory

- (3) This subsection applies to the introduction of an industrial chemical by a person if:
 - (a) the industrial chemical is listed on the Inventory; and
 - (b) the terms of the Inventory listing include one or more conditions relating to the introduction or use of the industrial chemical; and
 - (c) the introduction or use is not in accordance with those conditions.

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Note: An application may be made to vary the terms of the Inventory listing: see section 88 of the Act.

Introduction of industrial chemical where request for information is not complied with

- (4) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the Executive Director has, by written notice under section 102 or 104 of the Act:
 - (i) requested the person to provide information relating to the introduction of the industrial chemical; and
 - (ii) to do so within the period specified in the notice; and
 - (b) the information is not given to the Executive Director within the period specified in the notice.

Note: The information may be given to the Executive Director by the person to whom the Executive Director gave the notice or by another person.

- (5) However, subsection (4) ceases to have effect in relation to the introduction if:
- (a) the information requested is given to the Executive Director; or
 - (b) the Executive Director agrees, in writing, that the information requested is no longer required.

Note: For example, the Executive Director may agree that the information requested is no longer required if the Executive Director is satisfied that the industrial chemical can be introduced under another category of introduction.

26 Circumstances in which introductions are exempted introductions

- (1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.

Introduction of industrial chemicals that are imported and subsequently exported

- (2) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the industrial chemical is introduced at a port or airport in 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; and
 - (e) subsection 11(3) of the Act does not apply to the introduction.

Note: Under subsection 11(3) of Act, if the industrial chemical leaves Australia within 25 working days and is subject to customs control under the *Customs Act 1901* at all times before leaving Australia, the introduction of the industrial chemical is an excluded introduction. Therefore, subparagraph (d)(i) of this subsection may only apply where the industrial chemical is subject to customs control for longer than 25 working days.

Introduction of industrial chemicals that are solely for use in research and development

- (3) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the introduction of the industrial chemical is:
 - (i) solely for the industrial chemical to be used in research and development by the person; or
 - (ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely 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 and 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 subsection (3A) applies to the industrial chemical—10 kg; or
 - (ii) otherwise, and subject to subsection (3B)—250 kg.

- (3A) This section applies to an industrial chemical if:
- (a) the industrial chemical is a solid, or is in a dispersion, at the time of introduction and it consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; or
 - (b) it had not been determined, at the time of introduction, whether the industrial chemical meets the description in paragraph (a).
- (3B) Subparagraph (3)(d)(ii) does not apply to the introduction of an industrial chemical by a person in a registration year if an amount of the industrial chemical to which paragraph (3A)(a) applies has been introduced by the person in the registration year.

Introduction of polymers that are comparable to listed polymers

- (4) This subsection applies to the introduction of an industrial chemical by a person if:
-

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- (a) the industrial chemical is a polymer; and
- (b) the polymer contains each of the reactants that another polymer that is listed on the Inventory (the *listed polymer*) does; and
- (c) the polymer contains one or more other reactants (the *additional reactants*) that the listed polymer does not; and
- (d) each additional reactant does not constitute more than 2% by weight of the polymer; and
- (e) the introduction complies with the following terms of the Inventory listing for the listed polymer:
 - (i) any defined scope of assessment for the industrial chemical;
 - (ii) any conditions relating to the introduction or use of the industrial chemical;
 - (iii) any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical;
 - (iv) any other information relating to the industrial chemical that is prescribed by this instrument for the purposes of paragraph 81(1)(f) of the Act.

Introduction of industrial chemicals that are comparable to listed industrial chemicals

- (5) This subsection applies to the introduction of an industrial chemical by a person if:
 - (a) the introduction is of an industrial chemical mentioned in column 1 of an item in the following table; and
 - (b) the introduction complies with the following terms of the Inventory listing for the industrial chemical mentioned in column 3 of that item:
 - (i) any defined scope of assessment for the industrial chemical;
 - (ii) any conditions relating to the introduction or use of the industrial chemical;
 - (iii) any specific requirements to provide information to the Executive Director in relation to the introduction of the industrial chemical;
 - (iv) any other information relating to the industrial chemical that is prescribed by this instrument for the purposes of paragraph 81(1)(f) of the Act.

| 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 | Aloe barbadensis, extract | 94349-62-9 | Aloe vera, extract | 85507-69-3 |
| 2 | Brassica oleracea botrytis, extract | 223749-36-8 | Cabbage, extract | 89958-13-4 |

| Industrial chemicals comparable to listed industrial chemicals | | | | |
|---|---|---|---|---|
| Item | Column 1 Industrial chemical to be introduced | Column 2 CAS no. of industrial chemical to be introduced | Column 3 Listed industrial chemical | Column 4 CAS no. of listed industrial chemical |
| 3 | Brassica oleracea, extract | 91771-39-0 | Cabbage, extract | 89958-13-4 |
| 4 | Brassica oleracea gemmifera, extract | 1174275-27-4 | Cabbage, extract | 89958-13-4 |
| 5 | Fatty acids, palm-oil, sodium salts | 61790-79-2 | Fatty acids, C14-18 and C16-18-unsaturated, sodium salts | 67701-11-5 |
| 6 | Jojoba, extract | 90045-98-0 | Jojoba oil | 61789-91-1 |
| 7 | 3,6,9,12,15,18,21,21,24,27-No naoxanonatriacontan-1-ol | 3055-99-0 | Poly(oxy-1,2-ethanediyl), α -dodecyl- ω -hydroxy- | 9002-92-0 |
| 8 | Matricaria recutita, extract | 84082-60-0 | Oils, Chamomile, German | 8002-66-2 |
| 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 | Soya lecithins | 8030-76-0 | Lecithins | 8002-43-5 |
| 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 (SiO ₂) | 15468-32-3 | Silica | 7631-86-9 |
| 15 | Wheat germ oil | 313258-61-6 | Oils, wheat | 68917-73-7 |

Introduction of polymers of low concern

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

Introduction of low concern biological polymers

- (7) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the industrial chemical is a biological chemical; and
 - (b) the industrial chemical is a polymer; and

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- (c) the industrial chemical would be a polymer of low concern if the definition of *polymer of low concern* in Schedule 2 did not include a requirement that the polymer is stable (within the meaning given by the Guidelines).

Introduction of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals

- (8) This subsection applies to the introduction of an industrial chemical by a person if:
 - (a) the industrial chemical is the result of a reaction between 2 or more chemicals where the reaction occurs at the surface of one of the chemicals (the *substrate chemical*); and
 - (b) the substrate chemical and each of the other chemicals that reacts with the substrate chemical is listed on the Inventory; and
 - (c) the industrial chemical is not an industrial chemical that:
 - (i) is a solid, or is in a dispersion, at the time of introduction; and
 - (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and
 - (d) the industrial chemical does not have any reactive functional groups that were not present on the substrate chemical.

27 Circumstances in which introductions are reported introductions

- (1) For the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3), (4) or (6) of this section applies to the introduction.

Low volume introductions of industrial chemicals that are solely for use in research and development

- (2) This subsection applies to the introduction of an industrial chemical by a person if:
 - (a) the introduction of the industrial chemical is:
 - (i) solely for the industrial chemical to be used in research and development by the person; or
 - (ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely in research and development; and
 - (b) either:
 - (i) the industrial chemical is a solid, or is in a dispersion, at the time of introduction and it consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; or
 - (ii) it had not been determined, at the time of introduction, whether the industrial chemical meets the description in subparagraph (i); 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 and 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.

Other introductions of industrial chemicals that are solely for use in research and development

- (3) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the introduction of the industrial chemical is solely for the industrial chemical to be used in research and development by the person (the **introducer**); and
 - (b) the industrial chemical is not an industrial chemical that:
 - (i) is a solid, or is in a dispersion, at the time of introduction; and
 - (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; 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 and 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 introducer is greater than 250 kg, and no amount of the industrial chemical that meets the description in subparagraph (2)(b)(i) has been introduced by the person in the registration year; and
 - (f) the use of the industrial chemical is subject to the control of the introducer.

Low-risk flavour or fragrance blend introductions

- (4) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the introduction of the industrial chemical is either:

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- (i) a flavour blend introduction; or
 - (ii) a fragrance blend introduction; and
 - (b) the concentration of the industrial chemical at introduction and at end use is 1% or less; and
 - (c) the introduction is not for an end use in a personal vaporiser; and
 - (d) the industrial chemical does not have:
 - (i) any of the human health hazard characteristics in human health hazard band C; or
 - (ii) any of the environment hazard characteristics in environment hazard band D; and
 - (e) either:
 - (i) when the pre-introduction report for the industrial chemical is given to the Executive Director by the person, the industrial chemical is included on the IFRA Transparency List; or
 - (ii) before the industrial chemical is first introduced by the person, the Executive Director is given written notice of the information specified in subsection (5).
- (5) For the purposes of subparagraph (4)(e)(ii), the information is the following:
- (a) 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;
 - (b) any hazard characteristics of the industrial chemical that are known to the person giving the notice;
 - (c) the maximum concentration of the industrial chemical in the flavour blend or fragrance blend (as the case requires) at introduction and at end use;
 - (d) the name by which the flavour blend or fragrance blend (as the case requires) is known to the person introducing the industrial chemical.

Introductions of 10 kg or less of an industrial chemical

- (6) This subsection applies to the introduction of an industrial chemical by a person if:
- (a) the total volume of the industrial chemical introduced by the person in a registration year does not exceed 10 kg; and
 - (b) the industrial chemical is not known by the person to satisfy the criteria for any of the following hazard classes in the GHS:
 - (i) germ cell mutagenicity;
 - (ii) carcinogenicity;
 - (iii) reproductive toxicity; and
 - (c) if the industrial chemical is introduced for an end use in cosmetics—the industrial chemical is not prohibited or restricted for use as a cosmetic, or for use in cosmetics:
 - (i) in the European Union under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as in force from time to time; or

- (ii) in the United States of America under the Federal Food, Drug, and Cosmetic Act, as in force from time to time; and
 - (d) the industrial chemical:
 - (i) is not, to the person's knowledge, to be introduced as a solid or in a dispersion; or
 - (ii) is not known by the person to consist of particles, in an unbound state or as an aggregate or agglomerate, any of which have at least one external dimension in the nanoscale; and
 - (e) the industrial chemical:
 - (i) is not known by the person to contain fluorine; or
 - (ii) is known by the person to be an inorganic salt; and
 - (f) the industrial chemical is not known by the person to be persistent, bioaccumulative and toxic (within the meaning given by the Guidelines); and
 - (g) neither of the following subparagraphs apply:
 - (i) the Executive Director has cancelled an assessment certificate for the industrial chemical under section 52 of the Act;
 - (ii) the Executive Director has removed an Inventory listing for the industrial chemical under section 95 of the Act in circumstances to which subparagraph 95(1)(c)(i) of the Act applied.
- (7) To avoid doubt, for the purposes of subparagraph (6)(g)(i), it does not matter:
- (a) who was the holder of the assessment certificate; or
 - (b) who was covered by the certificate.

Part 3—Determining indicative risk

28 Indicative human health risk for introduction of an industrial chemical

- (1) For the purposes of step 4 of the method statement in section 24, the following table sets out the *indicative human health risk* for the introduction of an industrial chemical.

| Indicative human health risk for an introduction | | |
|---|---|---|
| Item | If ... | the indicative human health risk for the introduction is ... |
| Medium to high risk | | |
| 1 | the industrial chemical contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms | medium to high risk |
| 2 | (a) the industrial chemical is a polyhalogenated organic chemical (other than an organic chemical that is covered by item 1); and (b) the industrial chemical, or one or more of its known environmental degradation products, is persistent; and (c) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 100 kg | medium to high risk |
| 3 | (a) the industrial chemical is an industrial chemical that: (i) is a solid, or is in a dispersion, at the time of introduction; and (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical | medium to high risk |
| 4 | (a) the human health exposure band for the introduction is 2 or 3; and (b) the industrial chemical has one or more of the human health hazard characteristics in human health hazard band C | medium to high risk |
| 5 | (a) the human health exposure band for the introduction is 4; and (b) the industrial chemical has one or more of the human health hazard characteristics in human health hazard band B or C | medium to high risk |
| Low risk | | |
| 6 | (a) the industrial chemical is internationally-assessed for human health; and (b) the international assessment or evaluation was: (i) for the same end use for which the industrial chemical is | low risk |

Indicative human health risk for an introduction

| Item | If ... | the indicative human health risk for the introduction is ... |
|-------------|---|---|
| | to be introduced in Australia by the person; and (ii) 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 for which the industrial chemical is to be introduced in Australia by the person; and (c) the risks to human health from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, as determined in accordance with the Guidelines; and (d) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (e) either of the following applies: (i) if the international assessment or evaluation is of a kind mentioned in item 6 of the table in subsection 6(3)—the restrictions (if any) set out in Annex XVII of the REACH Regulation relating to the industrial chemical are able to be complied with in Australia; (ii) otherwise—the conditions (if any) that the international assessment body determines must be complied with in order to manage any risks to human health from the industrial chemical are able to be complied with in Australia; and (f) no further information becomes available to the person after the international assessment or evaluation is completed about: (i) a hazard to human health from the industrial chemical that is not identified in the international assessment or evaluation; or (ii) a hazard to human health from the industrial chemical that is identified in the international assessment or evaluation and indicates an increase in the severity of the hazard; and (g) none of table items 1 to 3 or 12 to 14 apply to the introduction; and (h) introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction | |
| 7 | (a) the industrial chemical is an industrial chemical that: (i) is a solid, or is in a dispersion, at the time of introduction; and (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given | low risk |

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| Indicative human health risk for an introduction | | |
|---|---|---|
| Item | If ... | the indicative human health risk for the introduction is ... |
| | by the Guidelines); and (c) none of table items 1 to 5 apply to the introduction | |
| 8 | (a) the industrial chemical is a UV filter; and (b) none of table items 1 to 5 apply to the introduction | low risk |
| 9 | (a) the human health exposure band for the introduction is 1; and (b) the industrial chemical has one or more of the human health hazard characteristics in human health hazard band C; and (c) none of table items 1 to 3 apply to the introduction | low risk |
| 10 | (a) the human health exposure band for the introduction is 3; and (b) the industrial chemical does not have any of the human health hazard characteristics in human health hazard band C; and (c) none of table items 1 to 3 or 14 apply to the introduction | low risk |
| 11 | (a) the human health exposure band for the introduction is 4; and (b) the industrial chemical does not have any of the human health hazard characteristics in human health hazard band B or C; and (c) none of table items 1 to 3 or 14 apply to the introduction | low risk |
| Very low risk | | |
| 12 | (a) the human health exposure band for the introduction is 1; and (b) the industrial chemical does not have any of the human health hazard characteristics in human health hazard band C; and (c) none of table items 1 to 3, 7 or 8 apply to the introduction | very low risk |
| 13 | (a) the human health exposure band for the introduction is 2; and (b) the industrial chemical does not have any of the human health hazard characteristics in human health hazard band C; and (c) none of table items 1 to 3, 7 or 8 apply to the introduction | very low risk |
| 14 | (a) the human health exposure band for the introduction is 3 or 4; and (b) the industrial chemical does not have any of the human health hazard characteristics in human health hazard band A, B or C; and (c) none of table items 1 to 3, 7 or 8 apply to the introduction | very low risk |

Note 1: For the definitions of *international assessment body*, *overseas jurisdiction* and *persistent*, see section 5.

Note 2: To work out the human health exposure band for an introduction, or the human health hazard characteristics of an industrial chemical, see Part 1 of Schedule 1.

- (2) For the purposes of table item 3, the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical if:

- (a) the manufacture (whether in Australia or otherwise) of the industrial chemical at the nanoscale is the result of a deliberate manufacturing decision; or
- (b) the manufacture (whether in Australia or otherwise) of the industrial chemical at the nanoscale is necessary for the manufacture (whether in Australia or otherwise) of the non-nanoscale portion of the industrial chemical; or
- (c) the industrial chemical at the nanoscale has specific technical characteristics that are the intended result of changes in the manufacturing process.

29 Indicative environment risk for introduction of an industrial chemical

- (1) For the purposes of step 5 of the method statement in section 24, the following table sets out the *indicative environment risk* for the introduction of an industrial chemical.

| Indicative environment risk for an introduction | | |
|--|---|--|
| Item | If ... | the indicative environment risk for the introduction is ... |
| Medium to high risk | | |
| 1 | the industrial chemical contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms | medium to high risk |
| 2 | (a) the industrial chemical is a polyhalogenated organic chemical (other than an organic chemical that is covered by item 1); and (b) the industrial chemical, or one or more of its known environmental degradation products, is persistent; and (c) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 100 kg | medium to high risk |
| 3 | (a) the industrial chemical is an industrial chemical that: (i) is a solid, or is in a dispersion, at the time of introduction; and (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical | medium to high risk |
| 4 | (a) the industrial chemical is a gas; and (b) the industrial chemical is persistent; and (c) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 100 kg | medium to high risk |
| 5 | (a) the industrial chemical is an organotin chemical; and | medium to high risk |

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| Indicative environment risk for an introduction | | |
|--|---|--|
| Item | If ... | the indicative environment risk for the introduction is ... |
| | (b) the total volume of the industrial chemical to be introduced by the person in a registration year is greater than 10 kg | |
| 6 | (a) the environment exposure band for the introduction is 1 or 2; and (b) the industrial chemical has one or more of the environment hazard characteristics in environment hazard band D | medium to high risk |
| 7 | (a) the environment exposure band for the introduction is 3; and (b) the industrial chemical has one or more of the environment hazard characteristics in environment hazard band C or D | medium to high risk |
| 8 | (a) the environment exposure band for the introduction is 4; and (b) the industrial chemical has one or more of the environment hazard characteristics in environment hazard band B, C or D | medium to high risk |
| Low risk | | |
| 9 | (a) the industrial chemical is internationally-assessed for the environment; and (b) the international 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 (c) the risks to the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, as determined in accordance with the Guidelines; and (d) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (e) either of the following applies: (i) if the international assessment or evaluation is of a kind mentioned in item 6 of the table in subsection 6(3)—the restrictions (if any) set out in Annex XVII of the REACH Regulation relating to the industrial chemical are able to be complied with in Australia; (ii) otherwise—the conditions (if any) that the international assessment body determines must be complied with in order to manage any risks to the environment from the industrial chemical are able to be complied with in Australia; and (f) no further information becomes available to the person after the international assessment or evaluation is completed about: (i) a hazard to the environment from the industrial chemical that is not identified in the international assessment or | low risk |

| Indicative environment risk for an introduction | | |
|--|---|--|
| Item | If ... | the indicative environment risk for the introduction is ... |
| | evaluation; or (ii) a hazard to the environment from the industrial chemical that is identified in the international assessment or evaluation and indicates an increase in the severity of the hazard; and (g) none of table items 1 to 5 or 15 to 17 apply to the introduction; and (h) introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction | |
| 10 | (a) the industrial chemical is an industrial chemical that: (i) is a solid, or is in a dispersion, at the time of introduction; and (ii) consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) none of table items 1 to 8 apply to the introduction | low risk |
| 11 | (a) one of the following applies: (i) the industrial chemical is an organotin chemical; (ii) the industrial chemical is a polyhalogenated organic chemical; (iii) the introduction of the industrial chemical is for an end use as a biocidal active; and (b) none of table items 1 to 8 apply to the introduction | low risk |
| 12 | (a) the environment exposure band for the introduction is 1 or 2; and (b) the industrial chemical does not have any of the environment hazard characteristics in environment hazard band D; and (c) none of table items 1 to 5, 15 or 16 apply to the introduction | low risk |
| 13 | (a) the environment exposure band for the introduction is 3; and (b) the industrial chemical does not have any of the environment hazard characteristics in environment hazard band C or D; and (c) none of table items 1 to 5 or 17 apply to the introduction | low risk |
| 14 | (a) the environment exposure band for the introduction is 4; and (b) the industrial chemical does not have any of the environment hazard characteristics in environment hazard band B, C or D; and (c) none of table items 1 to 5 or 17 apply to the introduction | low risk |
| Very low risk | | |
| 15 | (a) the environment exposure band for the introduction is 1; and (b) the industrial chemical does not have any of the environment | very low risk |

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Indicative environment risk for an introduction

| Item | If ... | the indicative environment risk for the introduction is ... |
|-------------|---|--|
| | hazard characteristics in environment hazard band C or D; and (c) none of table items 1 to 5, 10 or 11 apply to the introduction | |
| 16 | (a) the environment exposure band for the introduction is 2; and (b) the industrial chemical does not have any of the environment hazard characteristics in environment hazard band B, C or D; and (c) none of table items 1 to 5, 10 or 11 apply to the introduction | very low risk |
| 17 | (a) the environment exposure band for the introduction is 3 or 4; and (b) the industrial chemical does not have any of the environment hazard characteristics in environment hazard band A, B, C or D; and (c) none of table items 1 to 5, 10 or 11 apply to the introduction | very low risk |

Note 1: For the definitions of *international assessment body*, *known environmental degradation products*, *overseas jurisdiction* and *persistent*, see section 5.

Note 2: To work out the environment exposure band for an introduction, or the environment hazard characteristics of an industrial chemical, see Part 2 of Schedule 1.

- (2) For the purposes of table item 3, the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical if:
- (a) the manufacture of the industrial chemical (in Australia or overseas) at the nanoscale is the result of a deliberate manufacturing decision; or
 - (b) the industrial chemical at the nanoscale is necessary for the manufacture of the non-nanoscale portion of the industrial chemical; or
 - (c) the industrial chemical at the nanoscale has specific technical characteristics that are the intended result of changes in the manufacturing process.

Part 4—Information required to demonstrate categorisation

30 Information required to demonstrate categorisation

- (1) This section applies in relation to the introduction of an industrial chemical by a person during a registration year if:
 - (a) the introduction is not authorised by section 25, 28, 29 or 30 of the Act;
and
 - (b) the introduction is not covered by section 25 of this instrument.
- (2) For the purposes of paragraph 102(1)(b) of the Act, the person must, in determining the category of the introduction, have regard to the following:
 - (a) such introduction and use information as is necessary to determine whether the introduction is to be covered by section 26 or 27 of this instrument;
 - (b) if the introduction is to be covered by subsection 27(4) of this instrument—the information detailed in the Guidelines to demonstrate the absence of the hazard characteristics;
 - (c) if the introduction is not to be covered by section 26 or 27 of this instrument:
 - (i) such introduction and use information as is necessary to determine the highest indicative risk for the introduction; and
 - (ii) such information as is necessary to determine whether the introduction is covered by any of items 1 to 3 of the table in subsection 28(1), or any of items 1 to 5 of the table in subsection 29(1), of this instrument; and
 - (iii) such information as is known to the person that demonstrates that the industrial chemical has hazard characteristics that are relevant for determining the highest indicative risk for the introduction; and
 - (iv) if the highest indicative risk for the introduction is determined, in whole or in part, on the basis of the absence of certain hazard characteristics—the information detailed in the Guidelines to demonstrate the absence of the hazard characteristics.

Note: See section 31 for requirements regarding information that cannot be used to demonstrate categorisation.

31 Restriction on using animal test data for determining category of introduction for industrial chemicals with multiple end uses including an end use in cosmetics

- (1) This section applies if:
 - (a) an industrial chemical is to be introduced for multiple end uses; and
 - (b) one of those end uses is in cosmetics.
- (2) For the purposes of paragraph 102(1)(b) of the Act, a person who introduces the industrial chemical during a registration year must not, in determining the

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category of the introduction, have regard to animal test data obtained from tests conducted on or after 1 July 2020, other than:

- (a) animal test data that:
 - (i) demonstrates that the industrial chemical has a hazard characteristic; and
 - (ii) if the person did not have regard to that data, the category of introduction would be a lower risk category; or
- (b) animal test data that is the only information that can demonstrate whether the industrial chemical has a particular environment hazard characteristic; or
- (c) animal test data that is derived from tests conducted on animals involving a chemical that:
 - (i) is not the industrial chemical; and
 - (ii) is not an industrial chemical introduced by the person for an end use in cosmetics; or
- (d) animal test data that the person is approved to have regard to under section 33 of this instrument.

Note 1: For paragraph (a), the category of introduction would be a lower risk category if, for example, the category of introduction would be exempted if the data were not had regard to but reported if the data were had regard to.

Note 2: For how to apply for Executive Director approval to have regard to animal test data in determining the category of introduction, see section 32.

32 Applying for approval to use animal test data for determining category of introduction for industrial chemicals with multiple end uses including an end use in cosmetics

- (1) For the purposes of paragraph 102(3)(b) of the Act, a person may apply, in writing, to the Executive Director for approval to have regard to animal test data in determining the category of introduction.

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

Further information

- (2) The Executive Director may, by written notice given to an applicant, request further information to be provided for the purposes of considering the application.
- (3) The requested 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.
- (4) If the requested information is not provided within the period mentioned in subsection (3), the Executive Director may take the application to be withdrawn.

33 Decision on application

- (1) The Executive Director must:
-

- (a) consider the application under section 32 in accordance with this section;
and
 - (b) make a decision on the application within 10 working days after the day the application is made.
- (2) In considering the application, the Executive Director must have regard to the following:
- (a) if the animal test data is for the purpose of identifying a human health hazard characteristic of the industrial chemical—whether the non-cosmetic end use of the industrial chemical involves, or potentially involves, exposure of humans to the industrial chemical;
 - (b) if the animal test data is for the purpose of identifying an environment hazard characteristic of the industrial chemical—whether the non-cosmetic end use of the industrial chemical involves, or potentially involves, exposure of the environment to the industrial chemical;
 - (c) any further information provided by the applicant under subsection 32(3);
 - (d) any other information the Executive Director considers relevant.
- (3) After considering the application, the Executive Director must decide to:
- (a) approve the person having regard to the animal test data in determining the category of introduction; or
 - (b) not approve the person having regard to the animal test data in determining the category of introduction.
- (4) The Executive Director must give the applicant written notice of:
- (a) the decision; and
 - (b) if the decision is to refuse the application—the reasons for the decision.
- (5) If the Executive Director has requested further information under subsection 32(2), the 10 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 is given under subsection 32(2);
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 32(3); or
 - (ii) the last day of the period specified in the notice.

34 Ban on using animal test data for determining category of introduction for industrial chemical with end use solely in cosmetics

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

- (a) both:
 - (i) the person has animal test data that demonstrates that the industrial chemical has a hazard characteristic; and

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- (ii) if the person did not have regard to that data, the category of introduction would be a lower risk category; or
- (b) animal test data is the only information that can demonstrate whether the industrial chemical has a particular environment hazard characteristic; or
- (c) both:
 - (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.

Note: For paragraph (a), the category of introduction would be a lower risk category if, for example, the category of introduction would be exempted if the data were not had regard to but reported if the data were had regard to.

Chapter 3—Reporting

Part 1—Simplified outline of this Chapter

35 Simplified outline of this Chapter

If a person first introduces an industrial chemical in a registration year as an exempted introduction, under section 96A of the Act the person must generally make a post-introduction declaration about the introduction of the industrial chemical. Part 2 of this Chapter sets out what information must be included in that declaration and the circumstances in which such a declaration will not be required.

In order for an introduction to be authorised by section 27 of the Act, the introduction must be in accordance with the terms of the pre-introduction report for the industrial chemical. Part 3 of this Chapter sets out what information must be included in the pre-introduction report.

Part 4 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.

Part 2—Post-introduction declarations for exempted introductions

36 Post-introduction declarations for exempted introductions

- (1) This section applies for the purposes of paragraph 96A(2)(b) of the Act.

Introductions where highest indicative risk is very low risk

- (2) If the introduction is an exempted introduction in accordance with step 6 of the method statement in section 24, the information mentioned in an item of the following table is prescribed.

Post-introduction declarations for exempted introductions where highest indicative risk is very low

| Item | Prescribed information |
|------|---|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (b) the CAS number (if assigned) for the industrial chemical |
| 2 | If: (a) the proper name for the industrial chemical is not known to the person; and (b) the total volume of the industrial chemical introduced by the person during the registration year is 10 kg or less; then: (c) the names by which the industrial chemical is known to the person; and (d) the name of the chemical identity holder |
| 3 | If: (a) the proper name for the industrial chemical is not known to the person; and (b) the total volume of the industrial chemical introduced by the person during the registration year is greater than 10 kg; then: (c) the names by which the industrial chemical is known to the person; and (d) the name of the chemical identity holder who has provided to the Executive Director: (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (ii) the CAS number (if assigned) for the industrial chemical |
| 4 | The total volume of the industrial chemical introduced by the person during the registration year |
| 5 | The end use for the industrial chemical |
| 6 | The maximum concentration of the industrial chemical at end use |
| 7 | If the industrial chemical was introduced for an end use in cosmetics—a statement as to which |

Post-introduction declarations for exempted introductions where highest indicative risk is very low

Item Prescribed information

of the circumstances specified in subsection (3) applies to the introduction

Note: For the definition of *chemical identity holder*, see section 5.

- (3) For the purposes of item 7 of the table in subsection (2), the following circumstances are specified:
- (a) animal test data obtained from tests conducted on or after 1 July 2020 was not used to determine the highest indicative risk for the introduction;
 - (b) both:
 - (i) the industrial chemical was introduced for an end use solely in cosmetics; and
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction in the circumstances mentioned in paragraph 34(a), (b) or (c);
 - (c) all of the following apply:
 - (i) the industrial chemical was introduced for multiple end uses, including an end use in cosmetics;
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction;
 - (iii) the animal test data is of a kind mentioned in paragraph 31(2)(a), (b), (c) or (d).

Introductions of polymers of low concern or low concern biological polymers

- (4) If the introduction is covered by subsection 26(6) (polymers of low concern) or (7) (low concern biological polymers), the number of different polymers introduced is prescribed.

Note: If the introduction is covered by another subsection in section 26, a post-introduction declaration is not required: see section 37.

37 Circumstances in which a post-introduction declaration for exempted introductions is not required

For the purposes of subsection 96A(3) of the Act, the following circumstances are prescribed:

- (a) the introduction of the industrial chemical is covered by subsection 26(2) of this instrument (industrial chemicals that are imported and subsequently exported);
- (b) the introduction of the industrial chemical is covered by subsection 26(3) of this instrument (industrial chemicals that are solely for use in research and development);
- (c) the introduction of the industrial chemical is covered by subsection 26(4) of this instrument (polymers that are comparable to listed polymers);

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- (d) the introduction of the industrial chemical is covered by subsection 26(5) of this instrument (industrial chemicals that are comparable to listed industrial chemicals);
- (e) the introduction of the industrial chemical is covered by subsection 26(8) of this instrument (industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals).

Part 3—Pre-introduction reports for reported introductions

38 Introductions of industrial chemicals that are internationally-assessed for human health and 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 24; and
 - (b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health and for the environment

| Item | Prescribed information |
|------|---|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: <ul style="list-style-type: none">(a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and(b) any other names by which the industrial chemical is known to the person; and(c) the CAS number (if assigned) for the industrial chemical |
| 2 | If the proper name for the industrial chemical is not known to the person: <ul style="list-style-type: none">(a) the names by which the industrial chemical is known to the person; and(b) the name of the chemical identity holder who has provided to the Executive Director:<ul style="list-style-type: none">(i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and(ii) the CAS number (if assigned) for the industrial chemical |
| 3 | Whether the industrial chemical is: <ul style="list-style-type: none">(a) imported; or(b) manufactured in Australia |
| 4 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 5 | The end use for the industrial chemical |
| 6 | The maximum concentration of the industrial chemical at the end use |
| 7 | Any known hazard classification for the industrial chemical |
| 8 | The name of the international assessment body that assessed or evaluated the industrial chemical for: |

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Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health and for the environment

| Item | Prescribed information |
|-------------|---|
| | (a) human health; and (b) the environment |
| 9 | Both: (a) the reference number (however described) for the international assessment or evaluation; and (b) the name by which the industrial chemical is identified in the international assessment or evaluation |
| 10 | The year the international assessment or evaluation was completed |
| 11 | If the international assessment or evaluation included any parameters relating to end use, introduction volume or the maximum concentration of the industrial chemical at the end use—those parameters |
| 12 | If: (a) the international assessment or evaluation is of a kind mentioned in item 6 of the table in subsection 6(3); and (b) there are restrictions set out in Annex XVII of the REACH Regulation relating to the industrial chemical; what those restrictions are and how those restrictions will be complied with by the person in Australia |
| 13 | If: (a) the international assessment or evaluation is not of a kind mentioned in item 6 of the table in subsection 6(3); and (b) the international assessment body determined conditions that must be complied with in order to manage any risks to human health or the environment from the industrial chemical in the overseas jurisdiction; what those conditions are and how those conditions will be complied with by the person in Australia |
| 14 | A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report |
| 15 | A declaration that introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction |
| 16 | A declaration that the risk to human health and the environment from the introduction and use of the industrial chemical in Australia is no higher than in the overseas jurisdiction, as determined in accordance with the Guidelines |
| 17 | A declaration that no information has become available to the person after the international assessment or evaluation was completed about: (a) a hazard to human health or the environment from the industrial chemical that is not identified in the international assessment or evaluation; or (b) an increase in the severity of a hazard to human health or the environment from the industrial chemical that is identified in the international assessment or evaluation |

Note: For the definitions of *international assessment body* and *known hazard classification*, see section 5.

39 Introductions of industrial chemicals that are internationally-assessed for human health but not 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 24; and
 - (b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment

| Item | Prescribed information |
|-------------|---|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: <ol style="list-style-type: none"> (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (b) any other names by which the industrial chemical is known to the person; and (c) the CAS number (if assigned) for the industrial chemical |
| 2 | If the proper name for the industrial chemical is not known to the person: <ol style="list-style-type: none"> (a) the names by which the industrial chemical is known to the person; and (b) the name of the chemical identity holder who has provided to the Executive Director: <ol style="list-style-type: none"> (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (ii) the CAS number (if assigned) for the industrial chemical |
| 3 | Whether the industrial chemical is: <ol style="list-style-type: none"> (a) imported; or (b) manufactured in Australia |
| 4 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 5 | The end use for the industrial chemical |
| 6 | The maximum concentration of the industrial chemical at the end use |
| 7 | Whether the introduction of the industrial chemical involves a designated kind of release into the environment and, if so, which kind |
| 8 | The environment exposure band for the introduction, and the exposure band criteria on which the exposure band is based |
| 9 | Any known hazard classification for the industrial chemical |

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Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment

| Item | Prescribed information |
|-------------|--|
| 10 | Any environment hazard characteristics of the industrial chemical that are known to the person |
| 11 | A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv) |
| 12 | If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction |
| 13 | Whether the introduction is a specified class of introduction to which subsection 7(2) or (3) applies, and, if so, which such class |
| 14 | The name of the international assessment body that assessed or evaluated the industrial chemical for human health |
| 15 | Both: (a) the reference number (however described) for the international assessment or evaluation; and (b) the name by which the industrial chemical is identified in the international assessment or evaluation |
| 16 | The year the international assessment or evaluation was completed |
| 17 | If the international assessment or evaluation included any parameters relating to end use, introduction volume or the maximum concentration of the industrial chemical at the end use—those parameters |
| 18 | If: (a) the international assessment or evaluation is of a kind mentioned in item 6 of the table in subsection 6(3); and (b) there are restrictions set out in Annex XVII of the REACH Regulation relating to the industrial chemical; what those restrictions are and how those restrictions will be complied with by the person in Australia |
| 19 | If: (a) the international assessment or evaluation is not of a kind mentioned in item 6 of the table in subsection 6(3); and (b) the international assessment body determined conditions that must be complied with in order to manage any risks to human health from the industrial chemical in the overseas jurisdiction; what those conditions are and how those conditions will be complied with by the person in Australia |
| 20 | A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report |
| 21 | A declaration that introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction |
| 22 | A declaration that the risk to human health from the introduction and use of the industrial chemical in Australia is no higher than in the overseas jurisdiction, as determined in |

Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment

Item Prescribed information

accordance with the Guidelines

- 23 A declaration that no information has become available to the person after the international assessment or evaluation was completed about:
- (a) a hazard to human health from the industrial chemical that is not identified in the international assessment or evaluation; or
 - (b) an increase in the severity of a hazard to human health from the industrial chemical that is identified in the international assessment or evaluation
-

Note 1: For the definitions of *international assessment body* and *known hazard classification*, see section 5.

Note 2: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

- (3) For the purposes of item 12 of the table in subsection (2), the following circumstances are specified:
- (a) animal test data obtained from tests conducted on or after 1 July 2020 was not used to determine the highest indicative risk for the introduction;
 - (b) both:
 - (i) the industrial chemical is to be introduced for an end use solely in cosmetics; and
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction in the circumstances mentioned in paragraph 34(a), (b) or (c);
 - (c) all of the following apply:
 - (i) the industrial chemical is to be introduced for multiple end uses, including an end use in cosmetics;
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction;
 - (iii) the animal test data is of a kind mentioned in paragraph 31(2)(a), (b), (c) or (d).

40 Introductions of industrial chemicals that are internationally-assessed for the environment but not 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 24; and
 - (b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.

Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.

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- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for the environment but not for human health

| Item | Prescribed information |
|-------------|--|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (b) any other names by which the industrial chemical is known to the person; and (c) the CAS number (if assigned) for the industrial chemical |
| 2 | If the proper name for the industrial chemical is not known to the person: (a) the names by which the industrial chemical is known to the person; and (b) the name of the chemical identity holder who has provided to the Executive Director: (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (ii) the CAS number (if assigned) for the industrial chemical |
| 3 | If: (a) the industrial chemical is a high molecular weight polymer; and (b) the human health exposure band for the introduction is 4; the polymer molecular weight details of the industrial chemical |
| 4 | Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia |
| 5 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 6 | The end use for the industrial chemical |
| 7 | The human health exposure band for the introduction, and the exposure band criteria on which the exposure band is based |
| 8 | Any known hazard classification for the industrial chemical |
| 9 | Any human health hazard characteristics of the industrial chemical that are known to the person |
| 10 | A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv) |
| 11 | If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction |
| 12 | Whether the introduction is a specified class of introduction to which subsection 7(3) or (4) applies and, if so, which such class |
| 13 | The name of the international assessment body that assessed or evaluated the industrial chemical for the environment |
| 14 | Both: (a) the reference number (however described) for the international assessment or evaluation; and |

Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for the environment but not for human health

| Item | Prescribed information |
|-------------|---|
| | (b) the name by which the industrial chemical is identified in the international assessment or evaluation |
| 15 | The year the international assessment or evaluation was completed |
| 16 | If the international assessment or evaluation included any parameters relating to end use or introduction volume—those parameters |
| 17 | If: (a) the international assessment or evaluation is of a kind mentioned in item 6 of the table in subsection 6(3); and (b) there are restrictions set out in Annex XVII of the REACH Regulation relating to the industrial chemical; what those restrictions are and how those restrictions will be complied with by the person in Australia |
| 18 | If: (a) the international assessment or evaluation is not of a kind mentioned in item 6 of the table in subsection 6(3); and (b) the international assessment body determined conditions that must be complied with in order to manage any risks to the environment from the industrial chemical in the overseas jurisdiction; what those conditions are and how those conditions will be complied with by the person in Australia |
| 19 | A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report |
| 20 | A declaration that introduction of the industrial chemical is not prohibited (however described) in the overseas jurisdiction |
| 21 | A declaration that the risk to the environment from the introduction and use of the industrial chemical in Australia is no higher than in the overseas jurisdiction, as determined in accordance with the Guidelines |
| 22 | A declaration that no information has become available to the person after the international assessment or evaluation was completed about: (a) a hazard to the environment from the industrial chemical that is not identified in the international assessment or evaluation; or (b) an increase in the severity of a hazard to the environment from the industrial chemical that is identified in the international assessment or evaluation |

Note: For the definitions of *international assessment body*, *known hazard classification* and *polymer molecular weight details*, see section 5.

- (3) For the purposes of item 11 of the table in subsection (2), the following circumstances are specified:
- (a) animal test data obtained from tests conducted on or after 1 July 2020 was not used to determine the highest indicative risk for the introduction;
 - (b) both:

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- (i) the industrial chemical is to be introduced for an end use solely in cosmetics; and
- (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction in the circumstances mentioned in paragraph 34(a), (b) or (c);
- (c) all of the following apply:
 - (i) the industrial chemical is to be introduced for multiple end uses, including an end use in cosmetics;
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction;
 - (iii) the animal test data is of a kind mentioned in paragraph 31(2)(a), (b), (c) or (d).

41 Introductions of industrial chemicals 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 27(2) or (3).

Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for reported introductions of industrial chemicals that are solely for use in research and development

| Item | Prescribed information |
|------|---|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: <ul style="list-style-type: none">(a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and(b) any other names by which the industrial chemical is known to the person; and(c) the CAS number (if assigned) for the industrial chemical |
| 2 | If the proper name for the industrial chemical is not known to the person: <ul style="list-style-type: none">(a) the names by which the industrial chemical is known to the person; and(b) the name of the chemical identity holder who has provided to the Executive Director:<ul style="list-style-type: none">(i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and(ii) the CAS number (if assigned) for the industrial chemical |
| 3 | Whether the industrial chemical is: <ul style="list-style-type: none">(a) imported; or(b) manufactured in Australia |
| 4 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 5 | Whether the industrial chemical is to be introduced as a solid, in a dispersion or neither |
| 5A | If the industrial chemical is introduced by the person as a solid or in a dispersion—whether |

Pre-introduction reports for reported introductions of industrial chemicals that are solely for use in research and development

| Item | Prescribed information |
|-------------|--|
| | the industrial chemical is known to the person to consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale |
| 6 | A declaration that the requirements of subsection 27(2) or (3) (as the case requires) are being met for the introduction |

42 Low-risk flavour or fragrance blend introductions

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(4).

Note: Subsection 27(4) deals with low-risk flavour blend introductions and fragrance blend introductions.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for low-risk flavour or fragrance blend introductions

| Item | Prescribed information |
|-------------|--|
| 1 | The name of the flavour blend or fragrance blend that the industrial chemical is to be introduced as part of |
| 2 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (b) any other names by which the industrial chemical is known to the person; and (c) the CAS number (if assigned) for the industrial chemical |
| 3 | If the proper name for the industrial chemical is not known to the person—the name of the chemical identity holder for the flavour blend or fragrance blend that the industrial chemical is to be introduced as part of |
| 4 | The number of industrial chemicals in the flavour blend or fragrance blend that are to be introduced by the person in accordance with subsection 27(4) |
| 5 | If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction |

Note: For the definition of *chemical identity holder*, see section 5.

- (3) For the purposes of item 5 of the table in subsection (2), the following circumstances are specified:
- (a) animal test data obtained from tests conducted on or after 1 July 2020 was not used to determine the highest indicative risk for the introduction;
 - (b) both:
 - (i) the industrial chemical is to be introduced for an end use solely in cosmetics; and
-

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- (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction in the circumstances mentioned in paragraph 34(a), (b) or (c);
- (c) all of the following apply:
 - (i) the industrial chemical is to be introduced for multiple end uses, including an end use in cosmetics;
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction;
 - (iii) the animal test data is of a kind mentioned in paragraph 31(2)(a), (b), (c) or (d).
- (4) A person may prepare a single pre-introduction report for all the industrial chemicals in a flavour blend or a fragrance blend that are to be introduced in accordance with subsection 27(4).

42A Introductions of 10 kg or less of an industrial chemical

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(6).

Note: Subsection 27(6) deals with introductions of an industrial chemical that do not exceed 10 kg in a registration year.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

Pre-introduction reports for introductions of 10 kg or less of an industrial chemical

| Item | Prescribed information |
|------|------------------------|
|------|------------------------|

- | | |
|---|--|
| 1 | If the CAS number for the industrial chemical is known to the person: <ul style="list-style-type: none">(a) the CAS number; and(b) the CAS name, IUPAC name or INCI name for the industrial chemical; and(c) any other names by which the industrial chemical is known to the person |
| 2 | If: <ul style="list-style-type: none">(a) a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person; and(b) the CAS name or IUPAC name for the industrial chemical is known to the person; all of the following information: <ul style="list-style-type: none">(c) the CAS name or IUPAC name for the industrial chemical;(d) any other names by which the industrial chemical is known to the person |
| 3 | If: <ul style="list-style-type: none">(a) a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person; and(b) neither the CAS name nor the IUPAC name for the industrial chemical is known to the person; and(c) the INCI name for the industrial chemical is known to the person; the INCI name for the industrial chemical |
| 4 | If: |
-

Pre-introduction reports for introductions of 10 kg or less of an industrial chemical

Item Prescribed information

| | |
|---|---|
| | <p>(a) a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person (the <i>introducer</i>); and</p> <p>(b) neither the CAS name, the IUPAC name nor the INCI name for the industrial chemical is known to the introducer;</p> <p>all of the following information:</p> <p>(c) the names by which the industrial chemical is known to the introducer;</p> <p>(d) the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give to the Executive Director:</p> <p style="padding-left: 20px;">(i) the CAS number (if assigned) for the industrial chemical; and</p> <p style="padding-left: 20px;">(ii) the CAS name, IUPAC name or INCI name for the industrial chemical</p> |
| 5 | <p>(a) if the person knows that the industrial chemical is to be introduced as a solid, or knows that the industrial chemical is to be introduced in dispersion—whether the industrial chemical is to be introduced as a solid or in dispersion; or</p> <p>(b) if the person knows that the industrial chemical is to be introduced neither as a solid nor in dispersion—that the industrial chemical is to be introduced neither as a solid nor in dispersion; or</p> <p>(c) otherwise—that the person does not know whether the industrial chemical is to be introduced as a solid, in dispersion, or neither</p> |
| 6 | The end use for the industrial chemical |
| 7 | Any known hazard classification for the industrial chemical |
| 8 | A declaration that the requirements of subsection 27(6) are being met for the introduction |

- (3) For the purposes of subsection (2), if:
- (a) a person does not know the CAS number, CAS name, IUPAC name or INCI name for an industrial chemical; but
 - (b) it would be reasonably practicable for the person to find out that number or name;
- the person is taken to know that number or name.

43 Other introductions where the highest indicative risk is low risk

- (1) This section applies if:
- (a) an introduction of an industrial chemical is a reported introduction by a person in accordance with step 6 of the method statement in section 24; and
 - (b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

- (2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.

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Pre-introduction reports for other reported introductions where the highest indicative risk is low risk

| Item | Prescribed information |
|-------------|--|
| 1 | If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person: (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (b) any other names by which the industrial chemical is known to the person; and (c) the CAS number (if assigned) for the industrial chemical |
| 2 | If the proper name for the industrial chemical is not known to the person: (a) the names by which the industrial chemical is known to the person; and (b) the name of the chemical identity holder who has provided to the Executive Director: (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); and (ii) the CAS number (if assigned) for the industrial chemical |
| 3 | If: (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the person; and (b) the industrial chemical is a UVCB substance; and (c) either: (i) the human health exposure band for the introduction is 4; or (ii) the environment exposure band for the introduction is 3 or 4; the UVCB substance description of the industrial chemical |
| 4 | If: (a) the proper name for the industrial chemical is not known to the person; and (b) the industrial chemical is a UVCB substance; and (c) either: (i) the human health exposure band for the introduction is 4; or (ii) the environment exposure band for the introduction is 3 or 4; the name of the chemical identity holder who has provided to the Executive Director the UVCB substance description of the industrial chemical |
| 5 | If: (a) the industrial chemical is a high molecular weight polymer; and (b) the human health exposure band for the introduction is 4; the polymer molecular weight details of the industrial chemical |
| 6 | Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia |
| 7 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 8 | The end use for the industrial chemical |
| 9 | Both: (a) the human health exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |

Pre-introduction reports for other reported introductions where the highest indicative risk is low risk

| Item | Prescribed information |
|------|---|
| 10 | Whether the introduction of the industrial chemical involves a designated kind of release into the environment and, if so, which kind |
| 11 | Both: (a) the environment exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |
| 12 | Any human health hazard characteristics of the industrial chemical that are known to the person |
| 13 | Any environment hazard characteristics of the industrial chemical that are known to the person |
| 14 | A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv) |
| 15 | If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction |
| 16 | Whether the introduction is a specified class of introduction to which subsection 7(2), (3) or (4) applies, and, if so, which such class |

Note 1: For the definitions of *polymer molecular weight details* and *UVCB substance description*, see section 5.

Note 2: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

- (3) For the purposes of item 15 of the table in subsection (2), the following circumstances are specified:
- (a) animal test data obtained from tests conducted on or after 1 July 2020 was not used to determine the highest indicative risk for the introduction;
 - (b) both:
 - (i) the industrial chemical is to be introduced for an end use solely in cosmetics; and
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction in the circumstances mentioned in paragraph 34(a), (b) or (c);
 - (c) all of the following apply:
 - (i) the industrial chemical is to be introduced for multiple end uses, including an end use in cosmetics;
 - (ii) animal test data obtained from tests conducted on or after 1 July 2020 was used to determine the highest indicative risk for the introduction;
 - (iii) the animal test data is of a kind mentioned in paragraph 31(2)(a), (b), (c) or (d).

Part 4—Annual declaration for all introduction categories

44 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 one of 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.

Chapter 4—Record keeping

Part 1—Simplified outline of this Chapter

45 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 records relating to the introduction. This Chapter sets out the kinds of records 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

46 Listed introductions

- (1) For the purposes of paragraph 104(2)(b) of the Act, and subject to subsection (3) of this section, if a circumstance mentioned in column 1 of an item in the following table applies in relation to the listed introduction of an industrial chemical by a person, 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 | | |
|----------------------------------|--|---|
| | Column 1 | Column 2 |
| Item | If ... | the kinds of records that must be kept are ... |
| 1 | the CAS number for the industrial chemical is known to the person | (a) the CAS number for the industrial chemical; and (b) either the CAS name or the INCI name for the industrial chemical |
| 2 | a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person | (a) the CAS name for the industrial chemical; or (b) both: (i) the names by which the industrial chemical is known to the person, or the names of all products containing the industrial chemical that are imported into Australia by the person; and (ii) a written undertaking from the chemical identity holder that the CAS name and CAS number (if assigned) for the industrial chemical will be provided to the Executive Director, if requested, within 40 working days after the day the request is made |
| 3 | the terms of the Inventory listing for the industrial chemical include 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 | the terms of the Inventory listing for the industrial chemical include conditions relating to the introduction or use of the industrial chemical | records to demonstrate that the conditions are being complied with |
| 5 | the terms of the Inventory listing for the industrial chemical include specific requirements to provide information to the Executive Director in relation to the | records to demonstrate that those requirements are being met |

| Records that must be kept | |
|---|-----------------|
| Column 1 | Column 2 |
| Item | If ... |
| the kinds of records that must be kept are | |
| ... | |
| introduction of the industrial chemical | |

Note: For the definition of *chemical identity holder*, see section 5.

Alternative record keeping requirements for listed introductions of 10 kg or less of an industrial chemical

- (2) Subsection (3) applies to the listed introduction of an industrial chemical by a person in a registration year if the total volume of the industrial chemical introduced by the person in the registration year does not exceed 10 kg.
- (3) For the purposes of paragraph 104(2)(b) of the Act, the prescribed records in relation to the introduction are:
 - (a) records of the kind prescribed by subsection (1) of this section in relation to the introduction; or
 - (b) the following records:
 - (i) if a circumstance mentioned in column 1 of an item in the following table applies in relation to the introduction—records of the kind mentioned in column 2 of the item;
 - (ii) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (iii) records to demonstrate that the total volume of the industrial chemical introduced by the person in the registration year does not exceed 10 kg;
 - (iv) any known hazard classification for the industrial chemical.

| Records that must be kept—listed introductions of 10 kg or less of an industrial chemical | |
|--|---|
| Column 1 | Column 2 |
| Item | If ... |
| the kinds of records that must be kept are | |
| ... | |
| 1 | the CAS number for the industrial chemical is known to the person |
| (a) the CAS number for the industrial chemical; and | |
| (b) the CAS name, IUPAC name or INCI name for the industrial chemical | |
| 2 | (a) a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person; and (b) the CAS name, IUPAC name or INCI name for the industrial chemical is known to the person |
| (a) records that indicate that the industrial chemical is listed on the Inventory; and | |
| (b) the CAS name, IUPAC name or INCI name for the industrial chemical | |
| 3 | (a) a CAS number for the industrial chemical is not assigned, or the CAS number for |
| (a) records that indicate that the industrial chemical is listed on the Inventory; and | |

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Records that must be kept—listed introductions of 10 kg or less of an industrial chemical

| | Column 1 | Column 2 |
|-------------|---|--|
| Item | If ... | the kinds of records that must be kept are ... |
| | the industrial chemical is not known to the person (the <i>introducer</i>); and (b) neither the CAS name, IUPAC name nor INCI name for the industrial chemical is known to the introducer | (b) the names by which the industrial chemical is known to the introducer; and (c) the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give to the Executive Director: (i) the CAS number (if assigned) for the industrial chemical; and (ii) the CAS name, IUPAC name or INCI name for the industrial chemical |

- (4) For the purposes of subsection (3), if:
- (a) a person does not know the CAS number, CAS name, IUPAC name or INCI name for an industrial chemical; but
 - (b) it would be reasonably practicable for the person to find out that number or name;
- the person is taken to know that number or name.

Part 3—Record keeping for exempted introductions

47 Certain introductions of industrial chemicals under section 26

- (1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(2), (5), (6) or (7) of this instrument.

Note 1: Subsection 26(2) deals with introductions of industrial chemicals that are imported and subsequently exported.

Note 2: Subsection 26(5) deals with introductions of industrial chemicals that are comparable to listed industrial chemicals.

Note 3: Subsection 26(6) deals with introductions of polymers of low concern; and subsection 26(7) deals with introductions of low concern biological polymers.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;
 - (d) records to demonstrate which of subsections 26(2), (5), (6) and (7) of this instrument applies to the introduction;
 - (e) records to demonstrate that the requirements of subsection 26(2), (5), (6) or (7) of this instrument (as the case requires) are being met.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) the names by which the industrial chemical is known to the person;
 - (b) a written undertaking from the chemical identity holder that the following will be provided to the Executive Director if requested:
 - (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (ii) the CAS number (if assigned) for the industrial chemical;
 - (c) a written undertaking from the chemical identity holder that:

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- (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;
- (d) records to demonstrate which of subsections 26(2), (5), (6) and (7) of this instrument applies to the introduction;
- (e) if subsection 26(2) of this instrument applies to the introduction—records to demonstrate that the requirements of that subsection are being met;
- (f) if subsection 26(5), (6) or (7) of this instrument applies to the introduction—a written undertaking from the chemical identity holder that:
 - (i) the requirements of subsection 26(5), (6) or (7) of this instrument (as the case requires) are being met; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested.

Note: For the definition of *chemical identity holder*, see section 5.

48 Introductions of industrial chemicals that are solely for use in research and development

- (1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(3).

Note: Subsection 26(3) deals with introductions of industrial chemicals that are solely for use in research and development.

Proper name for industrial chemical known to person

- (2) If the person knows the proper name for the industrial chemical, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
 - (a) if the total volume of the industrial chemical introduced by the person in a registration year is 10 kg or less—the number of industrial chemicals that are introduced by the person in accordance with subsection 26(3) of this instrument where the total volume introduced by the person in a registration year is 10 kg or less;
 - (b) if:
 - (i) the total volume of the industrial chemical introduced by the person in a registration year is greater than 10 kg; and
 - (ii) a CAS number for the industrial chemical is assigned;
the CAS number for the industrial chemical and either the CAS name or the INCI name for the industrial chemical;
 - (c) if:
 - (i) the total volume of the industrial chemical introduced by the person in a registration year is greater than 10 kg; and
 - (ii) a CAS number for the industrial chemical is not assigned;
the proper name for the industrial chemical (including the CAS name or the IUPAC name);

- (d) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;
- (da) if the industrial chemical is a solid, or is in a dispersion, at the time of introduction and the total volume of the industrial chemical introduced by the person in a registration year is greater than 10 kg—records to demonstrate that the industrial chemical does not consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale;
- (e) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
 - (a) if the total volume of the industrial chemical introduced by the person in a registration year is 10 kg or less—the number of industrial chemicals that are introduced by the person in accordance with subsection 26(3) of this instrument where the total volume introduced by the person in a registration year is 10 kg or less;
 - (b) if the total volume of the industrial chemical introduced by the person in a registration year is greater than 10 kg;
 - (i) the names 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 provided to the Executive Director if requested;
 - (c) a written undertaking from the chemical identity holder that:
 - (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (ca) if the industrial chemical is a solid, or is in a dispersion, at the time of introduction and the total volume of the industrial chemical introduced by the person in a registration year is greater than 10 kg—a written undertaking from the chemical identity holder that:
 - (i) the industrial chemical does not consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;

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- (d) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.

Note: For the definition of *chemical identity holder*, see section 5.

49 Introductions of polymers that are comparable to listed polymers

- (1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(4).

Note: Subsection 26(4) deals with introductions of polymers that are comparable to polymers listed on the Inventory.

- (2) For the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:

- (a) if the person first introduces the industrial chemical before 1 July 2020:
- (i) the CAS name and CAS number for the listed polymer (within the meaning of subsection 26(4) of this instrument); or
 - (ii) if the person does not know the CAS name and CAS number for the listed polymer (within the meaning of subsection 26(4) of this instrument)—the name by which the listed polymer is known to the person, and a written undertaking from the chemical identity holder that the CAS name and CAS number (if assigned) will be provided to the Executive Director if requested; or
- (b) if the person first introduces the industrial chemical on or after 1 July 2020 and the proper name for the industrial chemical is known to the person—records of a kind specified in subsection (3); or
- (c) if the person first introduces the industrial chemical on or after 1 July 2020 and the proper name for the industrial chemical is not known to the person—records of a kind specified in subsection (4).

Note: For the definition of *chemical identity holder*, see section 5.

Proper name for industrial chemical known to person

- (3) For the purposes of paragraph (2)(b), the following kinds of record are specified:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) records to demonstrate that none of subsections 25(2) to (4) apply to the introduction;
 - (d) records to demonstrate that the requirements of subsection 26(4) are being met.

Proper name for industrial chemical not known to person

- (4) For the purposes of paragraph (2)(c), the following kinds of record are specified:

- (a) the names by which the industrial chemical is known to the person;
- (b) a written undertaking from the chemical identity holder that:
 - (i) none of subsections 25(2) to (4) apply to the introduction; and
 - (ii) the requirements of subsection 26(4) are being met;
- (c) a written undertaking from the chemical identity holder that the following will be provided to the Executive Director if requested:
 - (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (ii) the CAS number (if assigned) for the industrial chemical;
 - (iii) records to demonstrate that none of subsections 25(2) to (4) apply to the introduction;
 - (iv) records to demonstrate that the requirements of subsection 26(4) are being met.

Note: For the definition of *chemical identity holder*, see section 5.

50 Introductions of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals

- (1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(8).

Note: Subsection 26(8) deals with introductions of industrial chemicals that result from the reaction between multiple chemicals where the reaction occurs at the surface of one of those chemicals.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) the CAS numbers and CAS names for the substrate chemical (within the meaning of paragraph 26(8)(a) of this instrument) and all other industrial chemicals involved in the reaction at the surface of the substrate chemical;
 - (d) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;
 - (e) records to demonstrate that the requirements of paragraphs 26(8)(c) and (d) of this instrument are being met.

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Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) the names by which the industrial chemical is known to the person;
 - (b) a written undertaking from the chemical identity holder that the following will be provided to the Executive Director if requested:
 - (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (ii) the CAS number (if assigned) for the industrial chemical;
 - (c) a written undertaking from the chemical identity holder that the CAS numbers and CAS names for the substrate chemical (within the meaning of paragraph 26(8)(a) of this instrument) and all other industrial chemicals involved in the reaction at the surface of the substrate chemical will be provided to the Executive Director if requested;
 - (d) a written undertaking from the chemical identity holder that:
 - (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (e) a written undertaking from the chemical identity holder that:
 - (i) the requirements of paragraphs 26(8)(c) and (d) of this instrument are being met; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested.

Note: For the definition of *chemical identity holder*, see section 5.

51 Other introductions where the highest indicative risk is very low risk

- (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 24.

Note: An introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 24 if the highest indicative risk for the introduction is very low.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the kinds of record mentioned in an item of the following table are prescribed.

Record keeping for other introductions where the highest indicative risk is very low risk—proper name known to person

| Item | Prescribed kinds of record |
|------|----------------------------|
|------|----------------------------|

| | |
|---|--|
| 1 | If a CAS number for the industrial chemical is assigned: |
|---|--|

Record keeping for other introductions where the highest indicative risk is very low risk—proper name known to person

| Item | Prescribed kinds of record |
|-------------|---|
| | (a) the CAS number for the industrial chemical; and (b) either the CAS name or the INCI name for the industrial chemical |
| 2 | If a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name) |
| 3 | The names of any products containing the industrial chemical that are imported into Australia by the person |
| 4 | If: (a) the industrial chemical is a UVCB substance; and (b) the human health exposure band for the introduction is 4 or the environment exposure band for the introduction is 3 or 4; the UVCB substance description of the industrial chemical |
| 5 | If: (a) the industrial chemical is a high molecular weight polymer; and (b) the human health exposure band for the introduction is 4; records to demonstrate the polymer molecular weight details of the industrial chemical |
| 6 | Both: (a) the indicative human health risk for the introduction; and (b) the indicative environment risk for the introduction |
| 7 | Records to demonstrate that the introduction is not covered by any of the following provisions of this instrument: (a) section 25; (b) items 1, 2, 3, 7 or 8 of the table in subsection 28(1); (c) items 1, 2, 3, 4, 5, 10 or 11 of the table in subsection 29(1) |
| 8 | Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia |
| 9 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |
| 10 | Records to demonstrate the end use for the industrial chemical |
| 11 | If item 1, 3 or 5 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction—the maximum concentration of the industrial chemical at introduction and at each end use |
| 12 | Both: (a) the human health exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |
| 13 | If item 2 or 4 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction: (a) the human health categorisation volume for the industrial chemical; and (b) records to demonstrate that that volume does not exceed the human health categorisation volume specified in item 2 or 4 of the table (as the case requires) |

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Record keeping for other introductions where the highest indicative risk is very low risk—proper name known to person

| Item | Prescribed kinds of record |
|-------------|--|
| 14 | Whether the introduction of the industrial chemical involves a designated kind of release into the environment and, if so, which kind |
| 15 | Both: (a) the environment exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |
| 16 | If item 1, 2 or 3 of the table in subclause 3(1) of Schedule 1 to this instrument applies to the introduction: (a) the environment categorisation volume for the industrial chemical; and (b) records to demonstrate that that volume does not exceed the environment categorisation volume specified in item 1, 2 or 3 of the table (as the case requires) |
| 17 | Records to demonstrate any known hazard classification for the industrial chemical |
| 18 | Any human health hazard characteristics of the industrial chemical that are known to the person |
| 19 | Any environment hazard characteristics of the industrial chemical that are known to the person |
| 20 | If: (a) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and (b) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics; that detailed information |
| 21 | If: (a) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and (b) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics; the following: (c) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics; (d) a written undertaking from the person who has the detailed information that: (i) the detailed information is of the kind specified in the Guidelines; and (ii) the detailed information will be provided to the Executive Director if requested |
| 22 | Whether the introduction is a specified class of introduction and, if so: (a) which such class; and (b) if the specified class of introduction is of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item |
| Note 1: | For the definitions of <i>known hazard classification</i> , <i>polymer molecular weight details</i> and <i>UVCB substance description</i> , see section 5. |
| Note 2: | For when the introduction of an industrial chemical involves a <i>designated kind of release into the environment</i> , see subclause 3(2) of Schedule 1. |

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Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the kinds of record mentioned in an item of the following table are prescribed.

Record keeping for other introductions where the highest indicative risk is very low risk—proper name not known to person

| Item | Prescribed kinds of records |
|------|---|
| 1 | The names by which the industrial chemical is known to the person |
| 2 | A written undertaking from the chemical identity holder that the following will be provided to the Executive Director if requested: <ul style="list-style-type: none"> (a) the proper name for the industrial chemical (including the CAS name or the IUPAC name); (b) the CAS number (if assigned) for the industrial chemical |
| 3 | The names of any products containing the industrial chemical that are imported into Australia by the person |
| 4 | If: <ul style="list-style-type: none"> (a) the industrial chemical is a UVCB substance; and (b) either: <ul style="list-style-type: none"> (i) the human health exposure band for the introduction is 4; or (ii) the environment exposure band for the introduction is 3 or 4; a written undertaking from the chemical identity holder that the UVCB substance description of the industrial chemical will be provided to the Executive Director if requested |
| 5 | If: <ul style="list-style-type: none"> (a) the industrial chemical is a high molecular weight polymer; and (b) the human health exposure band for the introduction is 4; a written undertaking from the chemical identity holder that: <ul style="list-style-type: none"> (c) the introduction is of a high molecular weight polymer; and (d) records to demonstrate the polymer molecular weight details of the industrial chemical will be provided to the Executive Director if requested |
| 6 | Both: <ul style="list-style-type: none"> (a) the indicative human health risk for the introduction; and (b) the indicative environment risk for the introduction |
| 7 | A written undertaking from the chemical identity holder that: <ul style="list-style-type: none"> (a) the introduction is not covered by any of the following provisions <ul style="list-style-type: none"> (i) section 25; (ii) items 1, 2, 3, 7 or 8 of the table in subsection 28(1); (iii) items 1, 2, 3, 4, 5, 10 or 11 of the table in subsection 29(1); and (b) records to demonstrate this will be provided to the Executive Director if requested |
| 8 | Whether the industrial chemical is: <ul style="list-style-type: none"> (a) imported; or (b) manufactured in Australia |
| 9 | The maximum total volume of the industrial chemical the person intends to introduce in a registration year |

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Record keeping for other introductions where the highest indicative risk is very low risk—proper name not known to person

| Item | Prescribed kinds of records |
|-------------|---|
| 10 | Records to demonstrate the end use for the industrial chemical |
| 11 | If item 1, 3 or 5 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction—the maximum concentration of the industrial chemical at introduction and at each end use |
| 12 | Both: (a) the human health exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |
| 13 | If item 2 or 4 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction: (a) the human health categorisation volume for the industrial chemical; and (b) records to demonstrate that that volume does not exceed the human health categorisation volume specified in item 2 or 4 of the table (as the case requires) |
| 14 | Whether the introduction of the industrial chemical involves a designated kind of release into the environment and, if so, which kind |
| 15 | Both: (a) the environment exposure band for the introduction; and (b) the exposure band criteria on which the exposure band is based |
| 16 | If item 1, 2 or 3 of the table in subclause 3(1) of Schedule 1 to this instrument applies to the introduction: (a) the environment categorisation volume for the industrial chemical; and (b) records to demonstrate that that volume does not exceed the environment categorisation volume specified in item 1, 2 or 3 of the table (as the case requires) |
| 17 | Records to demonstrate any known hazard classification for the industrial chemical |
| 18 | Any human health hazard characteristics of the industrial chemical that are known to the person |
| 19 | Any environment hazard characteristics of the industrial chemical that are known to the person |
| 20 | If: (a) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and (b) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics; that detailed information |
| 21 | If: (a) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and (b) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics; the following: (c) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics; |

Record keeping for other introductions where the highest indicative risk is very low risk—proper name not known to person

| Item | Prescribed kinds of records |
|------|--|
| | (d) a written undertaking from the person who has the detailed information that: <ul style="list-style-type: none"> (i) the detailed information is of the kind specified in the Guidelines; and (ii) the detailed information will be provided to the Executive Director if requested |
| 22 | Whether the introduction is a specified class of introduction and, if so: <ul style="list-style-type: none"> (a) which such class; and (b) if the specified class of introduction is of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item |

Note 1: For the definitions of *known hazard classification*, *polymer molecular weight details* and *UVCB substance description*, see section 5.

Note 2: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

Additional record keeping requirements for specified classes of introduction

(4) For the purposes of item 22 of the table in subsections (2) and (3) and subject to subsection (5), the following table has effect.

Additional record keeping requirements for specified classes of introductions

| Item | Column 1 If ... | Column 2 the kinds of 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) | if practicable, 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; and (c) the quantity of the industrial chemical released to 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)(b) (GM product) | <ul style="list-style-type: none"> (a) the name of 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 |

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Additional record keeping requirements for specified classes of introductions

| | Column 1 | Column 2 |
|-------------|--|---|
| Item | If ... | the kinds of records that must be kept are ... |
| 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 in another country by an agency or authority of that country— 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) |
| 5 | the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product) | (a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines) |

Note 1: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of *children's care product* and *end use in an article with food contact*, see section 5.

(5) If:

- (a) the person is required to keep records of the information (the *relevant information*) mentioned in column 2 of item 2, 3 or 4 of the table in subsection (4), or paragraph (b) of column 2 of item 5 of that table; and
- (b) the person does not know the relevant information;

the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

Part 4—Record keeping for reported introductions

52 Introductions of industrial chemicals that are internationally-assessed for human health and 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 24; and
 - (b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (d) records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument;
 - (e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year:
 - (i) does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year; and
 - (ii) does not exceed the volume of the industrial chemical assessed in the international assessment or evaluation;
 - (f) records to demonstrate any known hazard classifications for the industrial chemical;
 - (g) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;

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- (h) records to demonstrate how it was determined that the risks to human health and the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
 - (a) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (b) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (c) a written undertaking from the chemical identity holder that:
 - (i) the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (d) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year:
 - (i) does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year; and
 - (ii) does not exceed the volume of the industrial chemical assessed in the international assessment or evaluation;
 - (e) records to demonstrate any known hazard classifications for the industrial chemical;
 - (f) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;
 - (g) records to demonstrate how it was determined that the risks to human health and the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction.

Note: For the definition of *chemical identity holder*, see section 5.

53 Introductions of industrial chemicals that are internationally-assessed for human health but not 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 24; and
 - (b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number is not assigned for the industrial chemical—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (d) records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument;
 - (e) if item 1, 2 or 3 of the table in subclause 3(1) of Schedule 1 to this instrument applies to the introduction:
 - (i) the environment categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume has not exceeded the environment categorisation volume specified in item 1, 2 or 3 of the table (as the case requires);
 - (f) if the introduction of the industrial chemical involves a designated kind of release into the environment—which designated kind of release into the environment;
 - (g) records to demonstrate any known hazard classification for the industrial chemical;
 - (h) if:
 - (i) the indicative environment risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;that detailed information;
 - (i) if:
 - (i) the indicative environment risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;the following:

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- (iii) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- (iv) a written undertaking from the person who has the detailed information that the detailed information is of the kind specified in the Guidelines and will be provided to the Executive Director if requested;
- (j) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;
- (k) records to demonstrate how it was determined that the risks to human health from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction;
- (l) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item.

Note: For when the introduction of an industrial chemical involves a designated kind of release into the environment, see subclause 3(2) of Schedule 1.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
 - (a) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (b) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (c) a written undertaking from the chemical identity holder that:
 - (i) the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (d) if item 1, 2 or 3 of the table in subclause 3(1) of Schedule 1 to this instrument applies to the introduction:
 - (i) the environment categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume has not exceeded the environment categorisation volume specified in item 1, 2 or 3 of the table (as the case requires);
 - (e) if the introduction of the industrial chemical involves a designated kind of release into the environment—which designated kind of release into the environment;
 - (f) records to demonstrate any known hazard classification for the industrial chemical;

- (g) if:
- (i) the indicative environment risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- that detailed information;
- (h) if:
- (i) the indicative environment risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- the following:
- (iii) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics;
 - (iv) a written undertaking from the person who has the detailed information that the detailed information is of the kind specified in the Guidelines and will be provided to the Executive Director if requested;
- (i) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;
 - (j) records to demonstrate how it was determined that the risks to human health from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction;
 - (k) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item.

Note: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

- (4) For the purposes of paragraphs (2)(l) and (3)(k) and subject to subsection (5), the following table has effect.

| Additional record keeping requirements for specified classes of introductions | | |
|--|---|--|
| Column 1 | Column 2 | |
| Item | If ... | the kinds of 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) | if practicable, 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 |

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Additional record keeping requirements for specified classes of introductions

| Column 1 | | Column 2 |
|----------|--|--|
| Item | If ... | the kinds of records that must be kept are ... |
| | | environment; and (c) the quantity of the industrial chemical released to 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)(b) (GM product) | (a) the name of 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 subclause 3(2) of Schedule 1.

(5) If:

- (a) the person is required to keep records of the information (the *relevant information*) mentioned in column 2 of item 2 or 3 of the table in subsection (4); and
- (b) the person does not know the relevant information;

the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

54 Introductions of industrial chemicals that are internationally-assessed for the environment but not 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 24; and
- (b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.

Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (d) records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument;
 - (e) if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 4—records to demonstrate the polymer molecular weight details of the industrial chemical;
 - (f) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year:
 - (i) does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year; and
 - (ii) does not exceed the volume of the industrial chemical assessed in the international assessment or evaluation;
 - (g) if item 2 or 4 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction:
 - (i) the human health categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume does not exceed the human health categorisation volume specified in item 2 or 4 of the table (as the case requires);
 - (h) records to demonstrate any known hazard classification for the industrial chemical;
 - (i) if:
 - (i) the indicative human health risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;that detailed information;
 - (j) if:
 - (i) the indicative human health risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and

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- (ii) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;
the following:
 - (iii) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics;
 - (iv) a written undertaking from the person who has the detailed information that the detailed information is of the kind specified in the Guidelines and will be provided to the Executive Director if requested;
- (k) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;
- (l) records to demonstrate how it was determined that the risks to the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction;
- (m) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
 - (a) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (b) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (c) a written undertaking from the chemical identity holder that:
 - (i) the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (d) if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 4—a written undertaking from the chemical identity holder that:
 - (i) the introduction is of a high molecular weight polymer; and
 - (ii) the records to demonstrate the polymer molecular weight details will be provided to the Executive Director if requested;
 - (e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year:

- (i) does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year; and
 - (ii) does not exceed the volume of the industrial chemical assessed in the international assessment or evaluation;
- (f) if item 2 or 4 of the table in subclause 1(1) of Schedule 1 to this instrument applies to the introduction:
- (i) the human health categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume does not exceed the human health categorisation volume specified in item 2 or 4 of the table (as the case requires);
- (g) records to demonstrate any known hazard classification for the industrial chemical;
- (h) if:
- (i) the indicative human health risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- that detailed information;
- (i) if:
- (i) the indicative human health risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- the following:
- (iii) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics;
 - (iv) a written undertaking from the person who has the detailed information that the detailed information is of the kind specified in the Guidelines and will be provided to the Executive Director if requested;
- (j) if the international assessment or evaluation applied any restrictions or conditions on the introduction or use of the industrial chemical in the overseas jurisdiction—records to demonstrate that those restrictions or conditions are being met by the person in Australia;
- (k) records to demonstrate how it was determined that the risks to the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction;
- (l) if the introduction is a specified class of introduction of a kind mentioned in column 1 of an item in the table in subsection (4)—records of the kind mentioned in column 2 of the item.

Note: For the definition of **chemical identity holder**, see section 5.

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- (4) For the purposes of paragraphs (2)(m) and (3)(l) and subject to subsection (5), the following table has effect.

| Additional record keeping requirements for specified classes of introductions | | |
|--|---|--|
| | Column 1 | Column 2 |
| Item | If ... | the kinds of 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)(b) (GM product) | (a) the name of 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 human health exposure band for the introduction is 4 | (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 |
| 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 in another country by an agency or authority of that country—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) |
| 5 | the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product) | (a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines) |

Note: For the definitions of *children's care product* and *end use in an article with food contact*, see section 5.

- (5) If:

(a) the person is required to keep records of the information (the **relevant information**) mentioned in column 2 of item 1, 2, 3 or 4 of the table in subsection (4), or paragraph (b) of column 2 of item 5 of that table; and

(b) the person does not know the relevant information;

the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

55 Introduction of industrial chemicals 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 27(2) or (3).

Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
- (a) if a CAS number for the industrial chemical is assigned:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned—the proper name for the industrial chemical (including the CAS name or the IUPAC name);
 - (c) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;
 - (d) if the industrial chemical is a solid, or is in a dispersion, at the time of introduction and the total volume of the industrial chemical introduced by the person in a registration year is greater than 100 kg—records to demonstrate that the industrial chemical does not consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale;
 - (e) records to demonstrate that the requirements of subsection 27(2) or (3) of this instrument (as the case requires) are being met.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
- (a) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (b) a written undertaking from the chemical identity holder that:

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- (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;
- (c) if the industrial chemical is a solid, or is in a dispersion, at the time of introduction and the total volume of the industrial chemical introduced by the person in a registration year is greater than 100 kg—a written undertaking from the chemical identity holder that:
 - (i) the industrial chemical does not consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
- (d) records to demonstrate that the requirements of subsection 27(2) or (3) of this instrument (as the case requires) are being met.

Note: For the definition of *chemical identity holder*, see section 5.

56 Low-risk flavour or fragrance blend introductions

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(4).

Note: Subsection 27(4) deals with low-risk flavour blend introductions and fragrance blend introductions.

Proper name for industrial chemical known to person

- (2) If the proper name for the industrial chemical is known by the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
 - (a) the name of the flavour blend or fragrance blend (as the case requires) that the industrial chemical is to be introduced as part of;
 - (b) the names of any products containing the flavour blend or the fragrance blend that are imported into Australia by the person;
 - (c) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;
 - (d) records to demonstrate that the requirements of subsection 27(4) of this instrument are being met;
 - (e) records to demonstrate either:
 - (i) the total volume of the flavour blend or fragrance blend introduced by the person in a registration year; or
 - (ii) the total volume of products that contain the flavour blend or fragrance blend introduced by the person in a registration year;
 - (f) records to demonstrate:
 - (i) each type of product at end use that is introduced by the person and contains the flavour blend or the fragrance blend; and

- (ii) the maximum concentration of the flavour blend or the fragrance blend in each type of product at end use.

Note: For paragraph (f), a type of product at end use is a reference to the specific kind of product at end use. For example, an industrial chemical might have an end use in cosmetics, but the type of product at end use may be shampoo.

Proper name for industrial chemical not known to person

- (3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
 - (a) the name of the flavour blend or fragrance blend (as the case requires) that the industrial chemical is to be introduced as part of;
 - (b) the names of any products containing the flavour blend or the fragrance blend that are imported into Australia by the person;
 - (c) a written undertaking from the chemical identity holder that:
 - (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
 - (ii) records to demonstrate this will be provided to the Executive Director if requested;
 - (d) a written undertaking from the chemical identity holder that:
 - (i) the requirements of paragraphs 27(4)(d) and (e) of this instrument have been met; and
 - (ii) the records to demonstrate this will be provided to the Executive Director if requested;
 - (e) records to demonstrate either:
 - (i) the total volume of the flavour blend or fragrance blend introduced by the person in a registration year; or
 - (ii) the total volume of products that contain the flavour blend or fragrance blend introduced by the person in a registration year;
 - (f) records to demonstrate:
 - (i) each type of product at end use that is introduced by the person and contains the flavour blend or the fragrance blend; and
 - (ii) the maximum concentration of the flavour blend or the fragrance blend in each type of product at end use.

Note 1: For paragraph (f), a type of product at end use is a reference to the specific kind of product at end use. For example, an industrial chemical might have an end use in cosmetics, but the type of product at end use may be shampoo.

Note 2: For the definition of *chemical identity holder*, see section 5.

56A Introductions of 10 kg or less of an industrial chemical

- (1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(6).

Note: Subsection 27(6) deals with introductions of an industrial chemical that do not exceed 10 kg in a registration year.

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- (2) For the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:
- (a) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (b) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (c) records to demonstrate that the requirements of subsection 27(6) are being met.

Note: For the names that must be included in the pre-introduction report, see section 42A of this instrument.

57 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 24; and
 - (b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

- (2) For the purposes of paragraph 104(2)(b) of the Act, the following kinds of record are prescribed:
- (a) if the CAS number for the industrial chemical is known to the person:
 - (i) the CAS number for the industrial chemical; and
 - (ii) either the CAS name or the INCI name for the industrial chemical;
 - (b) if a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person:
 - (i) the proper name for the industrial chemical (including the CAS name or the IUPAC name); or
 - (ii) the names by which the industrial chemical is known to the person (which must include the name included in the pre-introduction report for the industrial chemical);
 - (c) the names of any products containing the industrial chemical that are imported into Australia by the person;
 - (d) either:
 - (i) records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of this instrument; or
 - (ii) a written undertaking from the chemical identity holder that the introduction is not covered by any of the provisions mentioned in subparagraph (i) and that the records to demonstrate this will be provided to the Executive Director if requested;

- (e) if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 4:
 - (i) records to demonstrate the polymer molecular weight details of the industrial chemical; or
 - (ii) a written undertaking from the chemical identity holder that the introduction is of a high molecular weight polymer and that the records to demonstrate the polymer molecular weight details will be provided to the Executive Director if requested;
- (f) records to demonstrate the end use for the industrial chemical;
- (g) if item 1, 3 or 5 of the table in subclause 1(1) of Schedule 1 applies to the introduction—the maximum concentration of the industrial chemical at introduction and at end use;
- (h) if item 2 or 4 of the table in subclause 1(1) of Schedule 1 applies to the introduction:
 - (i) the human health categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume does not exceed the human health categorisation volume specified in item 2 or 4 of the table (as the case requires);
- (i) if item 1, 2 or 3 of the table in subclause 3(1) of Schedule 1 applies to the introduction:
 - (i) the environment categorisation volume for the industrial chemical; and
 - (ii) records to demonstrate that that volume does not exceed the environment categorisation volume specified in item 1, 2 or 3 of the table (as the case requires);
- (j) if the introduction of the industrial chemical involves a designated kind of release into the environment—which designated kind of release into the environment;
- (k) records to demonstrate any known hazard classification for the industrial chemical;
- (l) if:
 - (i) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person has detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;that information;
- (m) if:
 - (i) the highest indicative risk for the introduction is determined on the basis of the absence of certain hazard characteristics; and
 - (ii) the person does not have detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics;the following;

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- (iii) the outcomes of the information specified in the Guidelines to demonstrate the absence of the hazard characteristics;
- (iv) a written undertaking from the person who has the detailed information that the detailed information is of the kind specified in the Guidelines and will be provided to the Executive Director if requested;
- (n) 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.

Note 1: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

Note 2: For the definition of *chemical identity holder*, see section 5.

- (3) For the purposes of paragraph (2)(n) and subject to subsection (4), the following table has effect.

| Additional record keeping obligations for certain kinds of introductions | | |
|---|---|--|
| | Column 1 | Column 2 |
| Item | 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) | if practicable, 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; and (c) the quantity of the industrial chemical released to 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)(b) (GM product) | <ul style="list-style-type: none"> (a) the name of 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 human health exposure band for the introduction is 4 | <ul style="list-style-type: none"> (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 |

Additional record keeping obligations for certain kinds of introductions

| | Column 1 | Column 2 |
|-------------|--|---|
| Item | If ... | the records that must be kept are ... |
| | | the industrial chemical |
| 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 end use in an article with food contact in another country by an agency or authority of that country— 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) |
| 6 | the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children’s toy or a children’s care product) | (a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines) |

Note 1: For when the introduction of an industrial chemical involves a *designated kind of release into the environment*, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of *children’s care product* and *end use in an article with food contact*, see section 5.

(4) If:

- (a) the person is required to keep records of the information (the *relevant information*) mentioned in column 2 of item 2, 3, 4 or 5 of the table in subsection (3), or paragraph (b) of column 2 of item 6 of that table; and
- (b) the person does not know the relevant information;

the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

Part 5—Record keeping for assessed introductions**58 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 | | |
|----------------------------------|---|--|
| | Column 1 | Column 2 |
| Item | If ... | the kinds of 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 proper name for the industrial chemical is not known to the person | the AACN for the industrial chemical |
| 3 | the terms of the assessment certificate include a defined scope of assessment for the industrial chemical | records to demonstrate that the industrial chemical is being introduced and used in accordance with that defined scope |
| 4 | the terms of the assessment certificate include any conditions relating to the introduction or use of the industrial chemical | records to demonstrate that those conditions are being complied with |
| 5 | the terms of the assessment certificate include 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 6—Record keeping for commercial evaluation introductions

59 Commercial evaluation 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 commercial evaluation authorisation for the 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 | | |
|----------------------------------|--|--|
| | Column 1 | Column 2 |
| Item | If ... | the kinds of 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 proper name for the industrial chemical is not known to the person | the AACN for the industrial chemical |
| 3 | the terms of the commercial evaluation authorisation include any conditions relating to the introduction or use of the industrial chemical | records to demonstrate that those conditions are being complied with |
| 4 | the terms of the commercial evaluation authorisation include 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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Part 7—Record keeping for exceptional circumstances introductions

60 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 | | |
|----------------------------------|---|---|
| | Column 1 | Column 2 |
| Item | If the terms of the exceptional circumstances authorisation include ... | the kinds of 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 those 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 |
| 4 | a scope for the authorisation | records to demonstrate that the industrial chemical is being introduced or used in accordance with that scope |

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

61 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 | | |
|----------------------------------|---|--|
| | Column 1 | Column 2 |
| Item | If ... | the kinds of records that must be kept are ... |
| 1 | subsection 71(1) or 72(1) applies to the introduction of the industrial chemical | the name of the industrial chemical |
| 2 | subsection 73(1) applies to the export of the industrial chemical | the name of the industrial chemical |
| 3 | the approval includes conditions relating to the introduction or use of the industrial chemical | records to demonstrate that those conditions are being complied with |

Chapter 5—Confidentiality and disclosure

Part 1—Simplified outline of this Chapter

62 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 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 a 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.

Part 2—Publication of certain information

63 Publication of information relating to reported introductions

- (1) This section applies in relation to an introduction of an industrial chemical if:
- (a) the introduction is a reported introduction in accordance with step 6 of the method statement in section 24; and
 - (b) either or both of the following apply to the introduction:
 - (i) item 6 of the table in subsection 28(1);
 - (ii) item 9 of the table in subsection 29(1).

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

- (2) For the purposes of subsection 97(5) of the Act, the following kinds of information are prescribed:
- (a) the proper name for the industrial chemical;
 - (b) the end use for the industrial chemical;
 - (c) the name of the international assessment body that assessed or evaluated the industrial chemical.

Note 1: For the definition of *international assessment body*, see section 5.

Note 2: 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 a 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

64 Notice of proposed variations to Inventory listings

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

- (a) a holder of an assessment certificate has applied under subparagraph 87(1)(c)(ii) of the Act for a variation to the listing on the Inventory of an industrial chemical; and
- (b) the person is either:
 - (i) a confidence holder for an approval to treat an end use for the industrial chemical as confidential business information; or
 - (ii) a person specified in a notice under subsection 68(2) of this instrument by the holder of an approval to treat an end use for the industrial chemical as confidential business information.

65 Protection of proper name or end use

Applying for protection for proper name

- (1) For the purposes of paragraph 105(1)(d) of the Act, the following circumstances are prescribed:
 - (a) that 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;
 - (b) that the Executive Director gives notice, under subsection 113(1) of the Act, to the person nominated in the notice mentioned in paragraph (a) of this subsection of a proposal to publish the proper name for the industrial chemical.

Applying for protection for end use

- (2) For the purposes of paragraph 105(2)(f) of the Act, the following circumstances are prescribed:
 - (a) that:
 - (i) 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
 - (ii) the Executive Director gives notice, under subsection 113(1) of the Act, to the person nominated in the notice mentioned in subparagraph (i) of this paragraph of a proposal to publish the end use for that industrial chemical;
 - (b) that the person makes an application under section 62 of the Act to vary the end use specified in a commercial evaluation authorisation.

Time for making applications

- (3) For the purposes of paragraph 105(4)(b) of the Act, if:
- (a) a circumstance mentioned in subsection (1) or paragraph (2)(a) of this section applies—the time for giving an application is within 20 working days after the day notice is given as mentioned in paragraph (1)(b) or subparagraph (2)(a)(ii) of this section (as the case requires); or
 - (b) all of the following apply:
 - (i) an applicant gives information to the Executive Director under subsection 167(4) of the Act before the decision on an application (the **original application**) is made;
 - (ii) the information includes an end use for the industrial chemical that was not included in the original application;
 - (iii) the application for protection under subsection 105(2) of the Act relates to that end use;

the time for giving the application for protection is at the same time as the information referred to in subparagraph (i) of this paragraph is given.

Note: If information that is relevant to an applicant becomes available to an applicant before a decision is made on the application, subsection 167(4) of the Act requires the applicant to give that information to the Executive Director as soon as practicable after it becomes available to the person.

66 When an AACN or a 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 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 72(1) (which deals with providing draft evaluation statements);
 - (d) subsection 73(3) (which deals with publishing evaluation statements of introductions authorised by assessment certificates);
 - (e) subsection 74(3) (which deals with publishing information about evaluations of other introductions or matters);
 - (f) paragraph 75(b) (which deals with conducting a public consultation process);
 - (g) subsection 78(3) (which deals with publishing evaluation statements of other introductions or matters);
 - (ga) subsection 80(2) (which deals with making the Inventory publicly available);

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- (gb) subsection 82(1) (which deals with listing on the Inventory after 5 years);
- (h) section 83 (which deals with listing on the Inventory before 5 years);
- (i) section 87 (which deals with variations to the Inventory relating to subsequent assessment certificates);
- (j) subsection 97(5) (which deals with publishing certain information relating to reported introductions).

67 Circumstances in which notice of review of protection of proper name or end use must be given

- (1) For the purposes of paragraph 110(1)(c) of the Act, the circumstances mentioned in any of subsections (2) to (5) of this section are prescribed.

Protection of proper name or end use

- (2) For the purposes of subsection (1), a circumstance is 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.

Protection of proper name only

- (3) For the purposes of subsection (1), a circumstance is that:
- (a) an application for the proper name for an industrial chemical to be treated as confidential business information has been approved (other than an application made under paragraph 105(1)(a) of the Act); and
 - (b) after that application has been approved, an application is made under subsection 31(1) of the Act for an assessment certificate for the introduction of the industrial chemical.

Protection of end use only

- (4) For the purposes of subsection (1), a circumstance is that:
- (a) an application for the end use for an industrial chemical to be treated as confidential business information has been approved (other than an application made under paragraph 105(2)(a) of the Act); and
 - (b) after that application has been approved, an application is made under subsection 31(1) of the Act for an assessment certificate for the introduction of the industrial chemical for that end use.
- (5) For the purposes of subsection (1), a circumstance is that:
- (a) an application for the end use for an industrial chemical to be treated as confidential business information has been approved; and
 - (b) 5 years have passed since notice of the decision to approve that application was given under subsection 108(2) of the Act; and
 - (c) the Executive Director:

- (i) is proposing to vary a term of the Inventory listing for the industrial chemical in the circumstances mentioned in subparagraph 87(1)(c)(i) of the Act; or
- (ii) has varied a term of the Inventory listing for the industrial chemical following an application under subparagraph 87(1)(c)(ii) of the Act.

68 Persons to whom notice regarding protection of proper name or end use is to be given

- (1) For the purposes of paragraph 110(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an industrial chemical, the persons mentioned in column 2 of the item are prescribed for that circumstance.

| Persons to whom notice is to be given | | |
|--|--|--|
| | Column 1 | Column 2 |
| Item | Circumstance | Prescribed persons |
| 1 | The circumstances mentioned in subsection 67(2) of this instrument | <p>All of the following:</p> <ul style="list-style-type: none"> (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 (2) of this section by the holder of the approval; (c) for an approval to treat the proper name for the industrial chemical as confidential business information: <ul style="list-style-type: none"> (i) each holder of any other approval to treat the proper name for 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: <ul style="list-style-type: none"> (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 |
| 2 | The circumstances mentioned in subsection 67(3) of this instrument | <p>All of the following:</p> <ul style="list-style-type: none"> (a) the person making the application mentioned in paragraph 67(3)(b); (b) any person specified in a notice under subsection (2) of this section by the holder of the approval; (c) each holder of any other approval to treat the proper name for the industrial chemical as confidential business information; |

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| Persons to whom notice is to be given | | |
|--|--|---|
| | Column 1 | Column 2 |
| Item | Circumstance | Prescribed persons |
| | | (d) a person to whom a commercial evaluation authorisation or evaluation statement was given with an AACN in lieu of the proper name for the industrial chemical |
| 3 | The circumstances mentioned in subsection 67(4) of this instrument | All of the following: (a) the person making the application mentioned in paragraph 67(4)(b); (b) any person specified in a notice under subsection (2) of this section by the holder of the approval; (c) each holder of any other approval to treat the end use of the industrial chemical as confidential business information; (d) a person to whom a 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 mentioned in subsection 67(5) of this instrument | All of the following: (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 (2) of this section by the holder of the approval; (c) each holder of any other approval to treat the end use of the industrial chemical as confidential business information; (d) 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 |
| 5 | The holder of an assessment certificate for an industrial chemical applies to have the industrial chemical listed on the Inventory under section 83 of the Act | All of the following: (a) any person specified in a notice under subsection (2) of this section by the holder of the approval; (b) for an approval to treat the proper name for the industrial chemical as confidential business information: (i) each holder of any other approval to treat the proper name for 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; (c) 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 |

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| Persons to whom notice is to be given | | |
|--|--|---|
| | Column 1 | Column 2 |
| Item | Circumstance | Prescribed persons |
| | | use in lieu of the end use for the industrial chemical |
| 6 | The circumstances mentioned in paragraph 110(1)(a) or (b) of the Act | <p>All of the following:</p> <p>(a) a person to whom an entrusted person has disclosed protected information relating to the industrial chemical under subsection 120(1) of the Act;</p> <p>(b) any person specified in a notice under subsection (2) of this section by the holder of the approval;</p> <p>(c) for an approval to treat the proper name for the industrial chemical as confidential business information:</p> <p style="padding-left: 20px;">(i) each holder of any other approval to treat the proper name for the industrial chemical as confidential business information; and</p> <p style="padding-left: 20px;">(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;</p> <p>(d) for an approval to treat an end use of an industrial chemical as confidential business information:</p> <p style="padding-left: 20px;">(i) each holder of any other approval to treat the end use of the industrial chemical as confidential business information; and</p> <p style="padding-left: 20px;">(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</p> |

- (2) The holder of an approval may give written notice to the Executive Director to notify a person for the purposes of paragraph (1)(b) of item 1, 2, 3, 4 or 6, or paragraph (1)(a) of item 5, of the table in subsection (1).

69 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:

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- (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.

Chapter 6—International agreements and arrangements

Part 1—Simplified outline of this Chapter

70 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.

Part 1A—General

70A Definitions

In this Chapter:

mercury means elemental mercury (Hg(0), CAS No. 7439-97-6), and includes mixtures of mercury (including alloys of mercury) with a mercury concentration of at least 95% by weight, but does not include non-Minamata mercury.

non-Minamata mercury means any of the following:

- (a) mercury to be used for laboratory-scale research or as a reference standard;
- (b) naturally occurring trace quantities of mercury present in:
 - (i) products such as non-mercury metals, ores or mineral products (including coal); or
 - (ii) products derived from the products mentioned in subparagraph (i);
- (c) unintentional trace quantities of mercury in chemical products.

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

Division 1—Introduction and export of industrial chemicals other than mercury

71 Introduction of certain industrial chemicals subject to conditions

- (1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, introduction of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:
- (a) that the introduction has been approved by the Executive Director, in writing, before the industrial chemical is introduced;
 - (b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.

Note: Applications for approval must be made to the Executive Director in writing: see section 74.

- (1A) Subsection (1) does not apply to the introduction of an industrial chemical specified in subsection (2) by a person in a registration year if:
- (a) the industrial chemical is to be introduced solely for use in research or analysis; and
 - (b) the total volume of the industrial chemical introduced by the person in the registration year does not exceed 100 kg.
- (2) For the purposes of subsection (1), the industrial chemicals are the following (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;
 - (ba) decabromodiphenyl ether;
 - (c) hexabromocyclododecane;
 - (d) perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, including:
 - (i) potassium perfluorooctane sulfonate; and
 - (ii) lithium perfluorooctane sulfonate; and
 - (iii) ammonium perfluorooctane sulfonate; and
 - (iv) diethanolammonium perfluorooctane sulfonate; and
 - (v) tetraethylammonium perfluorooctane sulfonate; and
 - (vi) didecyldimethylammonium perfluorooctane sulfonate; and

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- (vii) N-ethylperfluorooctane sulfonamide; and
- (viii) N-methylperfluorooctane sulfonamide; and
- (ix) N-ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide; and
- (x) N-(2-hydroxyethyl)-N-methylperfluorooctane sulfonamide; and
- (xi) perfluorooctane sulfonyl fluoride;
- (da) perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;
- (e) polybrominated biphenyls, including:
 - (i) hexabromobiphenyl; and
 - (ii) octabromobiphenyl; and
 - (iii) decabromobiphenyl;
- (f) short chain chlorinated paraffins;
- (g) tetramethyl lead;
- (h) tributyl tin compounds.

72 Introduction of tetraethyl lead subject to conditions

- (1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, introduction of tetraethyl lead by a person is subject to the following conditions:
- (a) that the introduction 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 may only be introduced in aviation gasoline, or for use in the production of aviation gasoline;
 - (iii) the tetraethyl lead may only be introduced by a person in the circumstances set out in subsection (2);
 - (b) that the person keep the records relating to the introduction of the tetraethyl lead that are required by Part 8 of Chapter 4 of this instrument.

Note: Applications for approval must be made to the Executive Director in writing: see section 74.

- (1A) Subsection (1) does not apply to the introduction of tetraethyl lead by a person in a registration year if:
- (a) the tetraethyl lead is to be introduced solely for use in research or analysis; and
 - (b) the total volume of the tetraethyl lead introduced by the person in the registration year does not exceed 100 kg.
- (2) For the purposes of subparagraph (1)(a)(iii), tetraethyl lead may be introduced by the person if:
- (a) the tetraethyl lead is in leaded fuel; and
 - (b) both:
 - (i) the person has been granted an approval under subsection 13(1) of the *Fuel Quality Standards Act 2000* in relation to the fuel; and
 - (ii) the approval is in force on the day the tetraethyl lead is introduced; and

- (c) the introduction is for the purposes of a supply specified in the approval.

73 Export of certain industrial chemicals subject to conditions

- (1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, export of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:
- (a) that the export has been approved by the Executive Director, in writing, before the industrial chemical is exported;
 - (b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.

Note: Applications for approval must be made to the Executive Director in writing: see section 74.

- (1A) Subsection (1) does not apply to the export of an industrial chemical specified in subsection (2) by a person in a registration year if:
- (a) the industrial chemical is to be exported solely for use in research or analysis; and
 - (b) the total volume of the industrial chemical exported by the person in the registration year does not exceed 100 kg.
- (2) For the purposes of subsection (1), the industrial chemicals are the following (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;
 - (ba) decabromodiphenyl ether;
 - (c) hexabromocyclododecane;
 - (d) perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, including:
 - (i) potassium perfluorooctane sulfonate; and
 - (ii) lithium perfluorooctane sulfonate; and
 - (iii) ammonium perfluorooctane sulfonate; and
 - (iv) diethanolammonium perfluorooctane sulfonate; and
 - (v) tetraethylammonium perfluorooctane sulfonate; and
 - (vi) didecylmethylammonium perfluorooctane sulfonate; and
 - (vii) N-ethylperfluorooctane sulfonamide; and
 - (viii) N-methylperfluorooctane sulfonamide; and
 - (ix) N-ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide; and
 - (x) N-(2-hydroxyethyl)-N-methylperfluorooctane sulfonamide; and
 - (xi) perfluorooctane sulfonyl fluoride;
 - (da) perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;

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- (e) polybrominated biphenyls, including:
 - (i) hexabromobiphenyl; and
 - (ii) octabromobiphenyl; and
 - (iii) decabromobiphenyl;
- (f) polychlorinated biphenyls;
- (g) polychlorinated terphenyls;
- (h) short chain chlorinated paraffins;
 - (i) tetraethyl lead;
 - (j) tetramethyl lead;
- (k) tributyl tin compounds;
- (l) tris (2,3-dibromopropyl) phosphate.

74 Applying for approval to introduce or export restricted industrial chemicals

- (1) A person may apply, in writing, to the Executive Director for approval:
 - (a) to introduce an industrial chemical to which subsection 71(1) or 72(1) applies; or
 - (b) to export an industrial chemical to which subsection 73(1) applies.
- (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 requested 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.

75 Decision on application

- (1) The Executive Director must:
 - (a) consider the application in accordance with this section; and
 - (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 74(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

- (ba) Australia's obligations under relevant prescribed international agreements or prescribed international arrangements; 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 refuse the application—the reasons for the decision.
- (4A) If the decision is to approve the introduction or export of the industrial chemical, the notice under subsection (4):
- (a) must also include the following terms of the approval:
 - (i) the proper name for the industrial chemical;
 - (ii) the period for which the approval is in force;
 - (iii) any conditions relating to the introduction or export of the industrial chemical that are necessary to manage risks to human health or the environment from the introduction or export of the industrial chemical; and
 - (b) may include any other terms the Executive Director considers appropriate.
- (5) If the Executive Director has requested further information under subsection 74(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 is given under subsection 74(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 74(4); or
 - (ii) the last day of the period specified in the notice.

Section 75A

Division 2—Importation and export of an industrial chemical that is mercury

75A Importation of an industrial chemical that is mercury must be approved by the Executive Director

- (1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (2) of this section, the importation of an industrial chemical that is mercury by a person is subject to the condition that the importation has been approved by the Executive Director, in writing, before the mercury is imported.

Note: Applications for approval must be made to the Executive Director in writing: see section 75C.

- (2) Subsection (1) does not apply to the importation of mercury from a country that is a Party to the Minamata Convention.

75B Export of an industrial chemical that is mercury must be approved by the Executive Director

For the purposes of paragraph 163(1)(b) of the Act, the export of an industrial chemical that is mercury by a person is subject to the condition that the export has been approved by the Executive Director, in writing, before the mercury is exported.

Note: Applications for approval must be made to the Executive Director in writing: see section 75C.

75C Applying for approval to import or export an industrial chemical that is mercury

- (1) A person may apply, in writing, to the Executive Director for approval to import, or export, an industrial chemical that is mercury.

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

- (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 requested 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.

75D Decision on application to import an industrial chemical that is mercury

- (1) The Executive Director must:
 - (a) consider an application for approval to import an industrial chemical that is mercury in accordance with this section; and
 - (b) make a decision on the application as soon as is reasonably practicable after the day the application is made.
- (2) In considering the application, the Executive Director must have regard to any further information provided by the applicant under subsection 75C(4).
- (3) After considering the application, the Executive Director must decide to:
 - (a) approve the importation of the mercury; or
 - (b) not approve the importation of the mercury.
- (4) The Executive Director must not approve the importation of the mercury from a non-Party (the **exporting Party**) to the Minamata Convention unless the Executive Director is satisfied that:
 - (a) either:
 - (i) Australia has provided the exporting Party with written consent to the importation; or
 - (ii) a general notification of consent is in force for Australia in accordance with paragraph 7 of Article 3 of the Minamata Convention; and
 - (b) the exporting Party has provided certification that the mercury is not:
 - (i) sourced from primary mercury mining; or
 - (ii) excess mercury from the decommissioning of chlor-alkali facilities.
- (5) The Executive Director must give the applicant written notice of:
 - (a) the decision; and
 - (b) if the decision is to refuse the application—the reasons for the decision.

75E Decision on application to export an industrial chemical that is mercury

- (1) The Executive Director must:
 - (a) consider an application for approval to export an industrial chemical that is mercury in accordance with this section; and
 - (b) make a decision on the application as soon as is reasonably practicable after the day the application is made.
- (2) In considering the application, the Executive Director must have regard to any further information provided by the applicant under subsection 75C(4).
- (3) After considering the application, the Executive Director must decide to:
 - (a) approve the export of the mercury; or
 - (b) not approve the export of the mercury.

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Export to a Party to the Minamata Convention

- (4) The Executive Director must not approve the export of the mercury to a Party (the **importing Party**) to the Minamata Convention unless the Executive Director is satisfied that:
- (a) the importing Party has provided its written consent to the export; and
 - (b) the mercury is being exported:
 - (i) for a use allowed to the importing Party under the Minamata Convention; or
 - (ii) for environmentally sound interim storage as set out in Article 10 of the Minamata Convention.

Export to a country that is not a Party to the Minamata Convention

- (5) The Executive Director must not approve the export of the mercury to a non-Party (the **importing Party**) to the Minamata Convention unless the Executive Director is satisfied that:
- (a) the importing Party has provided its written consent to the export; and
 - (b) the importing Party has provided written certification demonstrating that:
 - (i) it has measures in place to ensure the protection of human health and the environment, and to ensure compliance with Articles 10 and 11 of the Minamata Convention; and
 - (ii) the mercury will be used only for a use allowed to the importing Party under the Minamata Convention, or for environmentally sound interim storage as set out in Article 10 of the Minamata Convention.

Notice of decision

- (6) The Executive Director must give the applicant written notice of:
- (a) the decision; and
 - (b) if the decision is to refuse the application—the reasons for the decision.

Chapter 7—Miscellaneous

Part 1—Simplified outline of this Chapter

76 Simplified outline of this Chapter

This Chapter contains miscellaneous provisions, including provisions about prescribing additional functions for the Executive Director and provisions about reconsideration and review of decisions under this instrument.

Section 77

Part 2—Miscellaneous

77 Additional function of Executive Director

For the purposes of paragraph 142(1)(c) of the Act, the Executive Director has the function of providing advice, on the Executive Director's initiative, about how to manage the risks (if any) that arise from the introduction or use of industrial chemicals to any of the following:

- (a) a prescribed body mentioned in section 16;
- (b) any other person.

78 Reconsideration and review of decisions

For the purposes of item 20 of the table in subsection 166(1) of the Act, each of the following is a decision that is reviewable under section 166 of the Act:

- (a) a decision under section 21 of this instrument to not approve the inclusion of animal test data in an application;
- (b) a decision under section 33 of this instrument to not approve a person having regard to animal test data in determining a category of introduction;
- (c) a decision under section 75 of this instrument to not approve an introduction or export;
- (d) a decision under section 75D of this instrument to not approve the importation of mercury;
- (e) a decision under section 75E of this instrument to not approve the export of mercury.

79 Calculating the consideration period for an application

For the purposes of item 12 of the table in subsection 169(1) of the Act:

- (a) the circumstances mentioned in column 1 of an item in the following table are prescribed; and
- (b) the days mentioned in columns 2 and 3 of an item in the following table are prescribed in relation to the circumstance mentioned in column 1 of the item.

| Calculating excluded periods | | | |
|-------------------------------------|---|--|--|
| | Column 1 | Column 2 | Column 3 |
| Item | If this circumstance applies: | exclude the period beginning on this day: | and ending on this day: |
| 1 | Advice is sought from a prescribed body under section 91 of the Act | The day notice of the request is given | The earlier of: (a) the day a complete response is given to the Executive Director; and (b) the last day of the period |

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| Calculating excluded periods | | |
|-------------------------------------|--|---|
| Column 1 | Column 2 | Column 3 |
| Item | If this circumstance applies: | exclude the period beginning on this day: |
| | | specified in the notice in accordance with subsection 91(4) of the Act |
| 2 | Advice is sought from the Gene Technology Regulator under section 92 of the Act | The day notice of the request is given |
| | | The earlier of: (a) the day a complete response is given to the Executive Director; and (b) the last day of the period specified in the notice in accordance with subsection 92(3) of the Act |
| 3 | A notice is given to a person under subsection 113(1) of the Act in relation to information included in an application under section 31, 43, 53, 62 or 88 of the Act | The day the notice is given |
| | | The earlier of: (a) the day a complete application in response to the notice is made under subsection 113(2) of the Act; and (b) the last day of the period specified in the notice in accordance with subsection 113(3) of the Act |

Chapter 8—Application, saving and transitional provisions

Part 1—Application provisions relating to the Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021

80 Record keeping for listed introductions

Item 2 of the table in section 46, as amended by Part 4 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, applies in relation to an undertaking mentioned in that item that is given on or after the commencement of that Part.

81 Pre-introduction reports for reported introductions

- (1) Subsection 41(2), as amended by Part 2 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, applies in relation to a report given under subsection 97(1) of the Act, or varied under section 98 of the Act, on or after the commencement of that Part.
- (2) Subsections 38(2), 39(2) and 40(2), as amended by Part 3 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, apply in relation to a report given under subsection 97(1) of the Act, or varied under section 98 of the Act, on or after the commencement of that Part.

Schedule 1—Exposure bands and hazard bands

Note: See the definitions of *environment exposure band*, *environment hazard band*, *human health exposure band* and *human health hazard band* in section 5.

Part 1—Human health

1 Human health exposure band

- (1) The following table sets out the *human health exposure band* 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 does not involve a designated kind of human exposure; and (b) the introduction of the industrial chemical is not for any consumer end use; and (c) the concentration of the industrial chemical at introduction and at all the end uses is less than 0.1% | 1 |
| 2 | (a) the introduction of the industrial chemical does not involve a designated kind of human exposure; and (b) the human health categorisation volume for the industrial chemical does not exceed 25 kg; and (c) item 1 does not apply to the introduction | 2 |
| 3 | (a) the introduction of the industrial chemical does not involve a designated kind of human exposure; and (b) the introduction of the industrial chemical is either: (i) solely for a consumer end use; or (ii) for multiple end uses, including a consumer end use; and (c) the concentration of the industrial chemical at introduction and at all end uses is less than 0.1% | 2 |
| 4 | (a) the introduction of the industrial chemical does not involve a designated kind of human exposure; and (b) the human health categorisation volume for the industrial chemical does not exceed 100 kg; and (c) items 1, 2 and 3 do not apply to the introduction | 3 |
| 5 | (a) the introduction of the industrial chemical does not involve a designated kind of human exposure; and (b) the concentration of the industrial chemical at introduction and at all end uses is 1% or less; and (c) items 1, 2 and 3 do not apply to the introduction | 3 |
| 6 | (a) the introduction of the industrial chemical does not involve a | 4 |

Clause 2

Human health exposure band

| Item | If ... | the human health exposure band for the introduction is ... |
|------|---|--|
| | designated kind of human exposure; and (b) the human health categorisation volume for the industrial chemical is greater than 100 kg; and (c) items 1, 3 and 5 do not apply to the introduction | |
| 7 | the introduction of the industrial chemical involves a designated kind of human exposure | 4 |

Note: For the definitions of *consumer end use* and *human health categorisation volume*, see section 5.

- (2) For the purposes of the table in subclause (1), each of the following is a *designated kind of human exposure*:
- (a) exposure arising from an end use in a tattoo ink;
 - (b) exposure arising from an end use in a personal vaporiser.

2 Human health hazard band

The following table sets out the *human health hazard band* that applies to a hazard characteristic of an industrial chemical.

Human health hazard band

| Item | If the industrial chemical has this human health hazard characteristic ... | the human health hazard band that applies to the hazard characteristic is ... |
|----------------------|--|---|
| Hazard band C | | |
| 1 | carcinogenicity (within the meaning given by the Guidelines) | C |
| 2 | reproductive toxicity (within the meaning given by the Guidelines) | C |
| 3 | developmental toxicity (within the meaning given by the Guidelines) | C |
| 4 | adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines) | C |
| 5 | genetic toxicity (within the meaning given by the Guidelines) | C |
| Hazard band B | | |
| 6 | high molecular weight polymer that is water absorbing (within the meaning given by the Guidelines) | B |
| 7 | respiratory sensitisation (within the meaning given by the Guidelines) | B |
| 8 | corrosive to the respiratory tract (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 |

| Human health hazard band | | |
|---------------------------------|--|--|
| Item | If the industrial chemical has this human health hazard characteristic ... | the human health hazard band that applies to the hazard characteristic is ... |
| 10 | skin corrosion (within the meaning given by the Guidelines) | B |
| 11 | eye damage (within the meaning given by the Guidelines) | B |
| 12 | skin sensitisation (within the meaning given by the Guidelines) | B |
| 13 | acute toxicity (fatal or toxic) (within the meaning given by the Guidelines) | B |
| 14 | specific target organ toxicity after repeated exposure (within the meaning given by the Guidelines) | B |
| Hazard band A | | |
| 15 | high molecular weight polymer that has lung overloading potential (within the meaning given by the Guidelines) | A |
| 16 | aspiration hazard (within the meaning given by the Guidelines) | A |
| 17 | specific target organ toxicity after a single exposure (harmful or transient effects) (within the meaning given by the Guidelines) | A |
| 18 | skin irritation (within the meaning given by the Guidelines) | A |
| 19 | eye irritation (within the meaning given by the Guidelines) | A |
| 20 | acute toxicity (harmful) (within the meaning given by the Guidelines) | A |

Clause 3

Part 2—Environment

3 Environment exposure band

- (1) The following table sets out the *environment exposure band* 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 a designated kind of release into the environment; and (b) the environment categorisation volume for the industrial chemical does not exceed 25 kg | 1 |
| 2 | (a) the introduction of the industrial chemical does not involve a designated kind of release into the environment; and (b) the environment categorisation volume for the industrial chemical is greater than 25 kg but no more than 1,000 kg | 2 |
| 3 | (a) the introduction of the industrial chemical does not involve a designated kind of release into the environment; 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 a designated kind of release into the environment | 4 |
| 5 | the environment categorisation volume for the industrial chemical is greater than 10,000 kg | 4 |

Note: For the definition of *environment categorisation volume*, see section 5.

- (2) For the purposes of the table in subclause (1), each of the following is 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, or end use in an air freshener);
 - (c) if the industrial chemical is introduced for an end use in firefighting—release (intentional or otherwise) into the environment;
 - (d) if the industrial chemical is introduced for an end use offshore—release (intentional or otherwise) into the ocean.

4 Environment hazard band

The following table sets out the *environment hazard band* that applies to the environment hazard characteristic of an industrial chemical.

| Environment hazard band | | |
|--------------------------------|--|---|
| Item | If the industrial chemical has this environment hazard characteristic ... | the environment hazard band that applies to the hazard characteristic is ... |
| Hazard band D | | |
| 1 | contains arsenic, cadmium, lead or mercury | D |
| 2 | ozone depleting chemical (within the meaning given by the Guidelines) | D |
| 3 | synthetic greenhouse gas (within the meaning given by the Guidelines) | D |
| 4 | adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines) | D |
| 5 | persistent, bioaccumulative and toxic (within the meaning given by the Guidelines) | D |
| Hazard band C | | |
| 6 | very toxic to any aquatic life (within the meaning given by the Guidelines) | C |
| 7 | persistent and bioaccumulative (within the meaning given by the Guidelines) | C |
| Hazard band B | | |
| 8 | toxic to any aquatic life (within the meaning given by the Guidelines) | B |
| Hazard band A | | |
| 9 | contains aluminium, chromium, copper, nickel, selenium, silver or zinc | A |
| 10 | polymer that does not have a low cationic density | A |
| 11 | polymer that is not stable (within the meaning given by the Guidelines) | A |
| 12 | bioaccumulation potential (within the meaning given by the Guidelines) | A |
| 13 | industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability (within the meaning given by the Guidelines) | A |
| 14 | harmful to any aquatic life (within the meaning given by the Guidelines) | A |

Note: For the definition of *low cationic density*, see section 5.

Schedule 2—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 solely from prescribed reactants 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 cationic 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 5; 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 6; 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 paragraphs 6(s) to (zc); 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 the definitions of *known hazard classification* and *low cationic density*, see section 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 set out in subclauses (2), (3) and (4) of this clause.

General

- (2) The polymer must:
- (a) have less than 10% (by mass) of molecules with a molecular weight that is less than 500 g/mol; and
 - (b) have less than 25% (by mass) of molecules with a 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).

Note: For the meaning of *reactive functional group*, see section 5.

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).

Note: For the meaning of *reactive functional group*, see section 5.

Reactive functional groups

- (5) 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;
 - (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;

Clause 2

(o) unsubstituted positions ortho or para to phenolic hydroxyl.

Note: For the meaning of *reactive functional group*, see section 5.

(6) For the purposes of subclauses (3) and (4), each of the following reactive functional groups is a **high concern reactive functional group**:

- (a) alkoxysilanes (with alkoxy of C₁- or C₂- alkoxysilane);
- (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) pendant acrylates;
- (o) pendant methacrylates;
- (p) trithiocarbonates;
- (q) vinyl sulfones;
- (r) any other reactive functional group that is not a low concern reactive functional group or a moderate concern reactive functional group.

Note: For the meaning of *reactive functional group*, see section 5.

(7) For the purposes of paragraph (6)(r), 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.

Note: For the meaning of *reactive functional group*, see section 5.

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:

- (a) have less than 2% (by mass) of molecules with a molecular weight that is less than 500 g/mol; and
- (b) have less than 5% (by mass) of molecules with a 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 7;
- (b) a modifier mentioned in the table in clause 8;
- (c) a monobasic acid or natural oil mentioned in clause 9;
- (d) a polyol mentioned in clause 10;
- (e) a derivative substance mentioned in clause 11.

5 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.

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

For the purposes of paragraphs 1(f) and (g), 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^- ;
- (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;

Schedule 2 Polymers of low concern

Part 1 Polymers of low concern

Clause 6

- (l) magnesium as the monatomic counterion Mg^{2+} ;
- (m) nitrogen;
- (n) oxygen;
- (o) potassium as the monatomic counterion K^+ ;
- (p) silicon;
- (q) sodium as the monatomic counterion Na^+ ;
- (r) sulfur;
- (s) boron;
- (t) copper;
- (u) iron;
- (v) lithium;
- (w) manganese;
- (x) nickel;
- (y) phosphorus;
- (z) tin;
- (za) titanium;
- (zb) zinc;
- (zc) zirconium.

Part 2—Prescribed reactants

7 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 |

Schedule 2 Polymers of low concern
Part 2 Prescribed reactants

Clause 8

| Dibasic and tribasic acids | | |
|-----------------------------------|---|----------------|
| Item | Substance | CAS no. |
| 32 | Pentanedioic acid, diethyl ester | 818-38-2 |
| 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 |

8 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 |

9 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.

| 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 | Cottonseed oil | 8001-29-4 |
| 10 | Dodecanoic acid | 143-07-7 |
| 11 | Fats and glyceridic oils, anchovy | 128952-11-4 |
| 12 | Fats and glyceridic oils, babassu | 91078-92-1 |
| 13 | Fats and glyceridic oils, herring | 68153-06-0 |
| 14 | Fats and glyceridic oils, menhaden | 8002-50-4 |
| 15 | Fats and glyceridic oils, sardine | 93334-41-9 |
| 16 | Fats and glyceridic oils, oiticica | 8016-35-1 |
| 17 | Fatty acids, C ₈₋₁₀ | 68937-75-7 |
| 18 | Fatty acids, C ₁₄₋₁₈ and C ₁₆₋₁₈ -unsaturated | 67701-06-8 |
| 19 | Fatty acids, C ₁₆₋₁₈ and C ₁₈ -unsaturated | 67701-08-0 |
| 20 | Fatty acids, castor-oil | 61789-44-4 |
| 21 | Fatty acids, coco | 61788-47-4 |
| 22 | Fatty acids, corn-oil | 68308-50-9 |
| 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 |

Schedule 2 Polymers of low concern
Part 2 Prescribed reactants

Clause 10

| Monobasic acids and natural oils | | |
|---|-------------------------------------|-------------------------|
| Item | Substance | CAS no. (if any) |
| 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 |
| 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 |

10 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 |

| Polyols | | |
|----------------|--|----------------|
| Item | Substance | CAS no. |
| 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 |
| 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 |

11 Derivatives

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

| Derivatives | |
|--------------------|---|
| Item | Substance |
| 1 | A diethyl or triethyl ester of a substance listed in clause 7 |
| 2 | A dimethyl or trimethyl ester of a substance listed in clause 7 |
| 3 | A methyl ester of a substance listed in clause 7 or 9 |
| 4 | An anhydride of a substance listed in clause 7 or 9 |
| 5 | An ethyl ester of a substance listed in clause 7 or 9 |

Endnotes

Endnote 1—About the endnotes

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

Endnote 2—Abbreviation key

| | |
|--|--|
| ad = added or inserted | o = order(s) |
| am = amended | Ord = Ordinance |
| amdt = amendment | orig = original |
| c = clause(s) | par = paragraph(s)/subparagraph(s) /sub-subparagraph(s) |
| C[x] = Compilation No. x | pres = present |
| Ch = Chapter(s) | prev = previous |
| def = definition(s) | (prev...) = previously |
| Dict = Dictionary | Pt = Part(s) |
| disallowed = disallowed by Parliament | r = regulation(s)/rule(s) |
| Div = Division(s) | reloc = relocated |
| ed = editorial change | renum = renumbered |
| exp = expires/expired or ceases/ceased to have effect | rep = repealed |
| F = Federal Register of Legislation | rs = repealed and substituted |
| gaz = gazette | s = section(s)/subsection(s) |
| LA = <i>Legislation Act 2003</i> | Sch = Schedule(s) |
| LIA = <i>Legislative Instruments Act 2003</i> | Sdiv = Subdivision(s) |
| (md) = misdescribed amendment can be given effect | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment cannot be given effect | SR = Statutory Rules |
| mod = modified/modification | Sub-Ch = Sub-Chapter(s) |
| No. = Number(s) | SubPt = Subpart(s) |
| | <u>underlining</u> = whole or part not commenced or to be commenced |

Endnotes

Endnote 3—Legislation history

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|---|---------------------------|---|---|
| Industrial Chemicals (General) Rules 2019 | 2 Dec 2019 (F2019L01543) | 1 July 2020 (s 2(1) item 1) | |
| Industrial Chemicals (General) Amendment (Minamata Convention on Mercury) Rules 2021 | 7 Oct 2021 (F2021L01411) | 7 Mar 2022 (s 2(1) item 1) | — |
| Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021 | 22 Nov 2021 (F2021L01584) | Sch 1 (items 1–19, 24–32, 36–57); 23 Nov 2021 (s 2(1) items 2, 4, 6, 7) Sch 1 (items 20–23, 33–35, 58); 10 Dec 2021 (s 2(1) items 3, 5, 8) | — |
| Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022 | 24 Nov 2022 (F2022L01502) | 25 Nov 2022 (s 2(1) item 1) | — |
| Industrial Chemicals (General) Amendment (Rotterdam Convention) Rules 2023 | 5 July 2023 (F2023L00966) | 21 July 2023 (s 2(1) item 1) | — |

Endnote 4—Amendment history

| Provision affected | How affected |
|---------------------------|-----------------------------|
| Chapter 1 | |
| Part 1 | |
| s 2 | rep LA s 48D |
| s 5 | am F2021L01411; F2022L01502 |
| s 6 | am F2021L01584 |
| s 7 | am F2021L01584 |
| Part 2 | |
| s 11 | am F2021L01411 |
| s 12A | ad F2021L01411 |
| Chapter 2 | |
| Part 2 | |
| s 25 | am F2021L01584 |
| s 26 | am F2021L01584 |
| s 27 | am F2021L01584; F2022L01502 |
| Part 3 | |
| s 28 | am F2021L01584 |
| s 29 | am F2021L01584 |
| Chapter 3 | |
| Part 3 | |
| s 38 | am F2021L01584 |
| s 39 | am F2021L01584 |
| s 40 | am F2021L01584 |
| s 41 | am F2021L01584; F2022L01502 |
| s 42A | ad F2022L01502 |
| Chapter 4 | |
| Part 2 | |
| s 46 | am F2021L01584; F2022L01502 |
| Part 3 | |
| s 48 | am F2021L01584 |
| s 51 | am F2021L01584 |
| Part 4 | |
| s 52 | am F2021L01584 |
| s 53 | am F2021L01584 |
| s 54 | am F2021L01584 |
| s 55 | am F2021L01584 |
| s 56A | ad F2022L01502 |
| s 57 | am F2021L01584 |

Endnotes

Endnote 4—Amendment history

| Provision affected | How affected |
|---------------------------|-----------------------------|
| Part 8 | |
| s 61 | am F2021L01584 |
| Chapter 5 | |
| Part 3 | |
| s 66 | am F2021L01584 |
| Chapter 6 | |
| Part 1A | |
| Part 1A | ad F2021L01411 |
| s 70A | ad F2021L01411 |
| Part 2 | |
| Division 1 | |
| Division 1 heading..... | ad F2021L01411 |
| s 71 | am F2021L01584; F2023L00966 |
| s 72 | am F2021L01584 |
| s 73 | am F2021L01584; F2023L00966 |
| s 74 | am F2021L01584 |
| s 75 | am F2021L01584 |
| Division 2 | |
| Division 2..... | ad F2021L01411 |
| s 75A | ad F2021L01411 |
| s 75B | ad F2021L01411 |
| s 75C | ad F2021L01411 |
| s 75D | ad F2021L01411 |
| s 75E..... | ad F2021L01411 |
| Chapter 7 | |
| Part 2 | |
| s 78 | am F2021L01411 |
| s 79 | am F2021L01584 |
| Chapter 8 | |
| Chapter 8..... | ad F2021L01584 |
| Part 1 | |
| s 80 | ad F2021L01584 |
| s 81 | ad F2021L01584 |
| Schedule 1 | |
| Part 2 | |
| c 3..... | am F2021L01584 |