Australian Government
Department of Health
Therapeutic Goods Administration

Introduction to the Poisons Standard

Version 1.0, December 2020

TGA Health Safety Regulation

Contents

Any substance (ingredient) can be a 'poison' and cause harm if used incorrectly or taken at the wrong dose. This guidance helps sponsors and manufacturers of therapeutic goods to understand and use the Poisons Standard to determine if any restrictions apply to their product.

The Poisons Standard has been developed to ensure the safe handling of substances in Australia. It provides a uniform approach to control the availability and accessibility of substances that can be used as ingredients in medicines as well as cosmetics, agricultural products or household cleaners. The Poisons Standard is given legal effect through State and Territory legislation.

The Poisons Standard also includes provisions about containers and labels with a view to promoting uniform labelling and packaging requirements throughout Australia.

The Poisons Standard is also known as the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). It is a legislative instrument made under the *Therapeutic Goods Act 1989* (paragraph 52D(2)(b)).

About the Poisons Standard

When the Poisons Standard applies

You need to refer to the Poisons Standard if you are a sponsor or manufacturer of:

- prescription medicines
- over-the-counter medicines
- complementary medicines
- medical devices that contain a medicine component

You must check the scheduling of the substances (ingredients) contained in your therapeutic good as this will determine if and how your therapeutic good can be supplied. For example, scheduled substances can only be used in registered medicines; they cannot be used in listed medicines.

In addition to therapeutic goods, the Poisons Standard also applies to:

- cosmetics
- agricultural and veterinary medicine products
- industrial and domestic chemicals

Scheduling of substances

The Poisons Standard groups substances into different categories called Schedules. The ten different Schedules are organised according to factors such as toxicity, intended use, potential for abuse, safety and need. Products are captured by the schedule of the highest risk ingredient.

The schedule of a substance determines:

- how your product may be sold or supplied
- what information needs to be included on your product's label
- what sort of container your product must be stored in

- how your product is stored and disposed of
- any requirements for record-keeping

Any additional unique restrictions or exemptions are covered by the 13 Appendices (A-M).

Various other Commonwealth, State and Territory legislation integrate with the Poisons Standard to ensure that poisons are appropriately handled.

For example, the Therapeutic Goods Order 80 – Child-Resistant Packaging Requirements for Medicines.

Enforcement of the Poisons Standard

The implementation and enforcement of the Poisons Standard is the responsibility of each State and Territory government.

State and Territory governments can choose to vary their own legislation to classify substances differently to the Poisons Standard. However, they classify the majority of substances in accordance with the Poisons Standard.

If you need advice on the interpretation and enforcement of the Poisons Standard, please contact your local State or Territory Health Department.

Where to find the Poisons Standard

The Poisons Standard is an electronic document located on the Federal Register of Legislation (FRL), which can be accessed via the TGA website.

The Poisons Standard is updated at least three times a year, so make sure the version you are looking at is labelled 'In force – Latest Version'.

Downloading the Poisons Standard as a PDF can make it easier to find your substance.

CTRL+F brings up the 'Find' function, allowing you to type in your substance. Any instance of that term will then be highlighted in the PDF.

Interpretation of the Schedules and Appendices

In scheduling substances, consideration is given to a standard set of factors such as proposed indications, dose, concentration, formulation type, pack size and the toxicity of the substance. A substance may therefore be included in more than one schedule.

For help reading the Schedules, search (Ctrl+F) 'READING THE SCHEDULES' in the Introduction part of the Poisons Standard.

Where a substance has been included in more than one schedule, the main entry is found in the most restrictive (highest) schedule. References to its entry in other schedule(s) will be outlined.

The Appendices found in Part 5 of the Poisons Standard contain further information on exceptions and additional restrictions that may also apply.

Description of each Schedule

Schedule 1 is not currently in use.

Substances for therapeutic use (ingredients in medicines) are mostly included in Schedules 2, 3, 4 and 8. As you progress through these schedules, the regulatory controls become increasingly restrictive.

Schedule	Description	Details
2	Pharmacy Medicine	Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.
3	Pharmacist Only Medicine	Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.
4	Prescription Only Medicine or Prescription Animal Remedy	Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.
8	Controlled Drug	Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedules 5, 6 and 7 are typically used for agricultural, domestic and industrial poisons and some medicines. These schedules have increasingly stricter container and labelling requirements, with special regulatory controls over the availability of the substances listed in Schedule 7.

Schedule	Description	Details
5	Caution	Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
6	Poison	Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
7	Dangerous Poison	Substances with a high potential for causing harm at low exposure and require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle it safely. Special regulations restricting its availability, possession, storage or use may apply.

Schedule 9 substances are prohibited, but can be used in specific circumstances (like clinical trials) with Government approval.

Schedule	Description	Details
9	Prohibited Substance	Substances which may be abused or misused. The manufacture, possession, sale or use should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

Schedule 10 substances are prohibited from sale, supply or use due to their dangerous properties. They cannot be used.

Schedule	Description	Details
10	Substances of such danger to health as to warrant prohibition of sale, supply and use	Substances which are prohibited for the purpose or purposes listed for each poison.

Further restrictions and exemptions

The appendices are found in Part 5 of the Poisons Standard. They give details of additional restrictions or exemptions, which apply to some substances under certain conditions. **Appendices D**, **H, K and M** are most relevant to medicines.

Appendix	Description
A	General exemptions
B	Substances considered not to require control by scheduling
C	Superseded by Schedule 10
D	Additional controls on possession or supply of poisons included in Schedules 4 or 8
E	First aid instructions for poisons
F	Warning statements and general safety directions for poisons
G	Dilute preparations
H	Schedule 3 medicines permitted to be advertised
I	(Intentionally Blank)
J	Conditions for availability and use of Schedule 7 poisons
K	Medicines required to be labelled with a sedation warning
L	Requirements for dispensing labels for human and veterinary medicines
M	Additional controls or supply requirements for Schedule 3 poisons to allow them to be provided by a pharmacist

Substances not found in the Poisons standard

If you can't find a substance in the Poisons Standard, don't presume that it is safe and can be used without restriction. You may not have searched the correct substance name or the substance may not yet have been considered for scheduling.

Substance name is different

Substances are scheduled using their approved names wherever practicable. However, some substances may be grouped together in a group entry or listed under a parent substance, which is a substance with a similar chemical structure or mode of action.

For more information on approved names, see the Interpretation in Part 1 of the Poisons Standard.

If you can't find the substance you're looking for, try other common names, in particular its International Nomenclature of Cosmetic Ingredients (INCI) name. You could also try searching the Ingredients table in TGA Business services, which includes the Australian Approved Names List for Therapeutic Substances.

Websites that will help find alternative names for a substance:

- PubChem
- ChemSpider
- The Australian Inventory of Industrial Chemicals (Inventory)

Group entry

If a substance is not found under its 'approved name' it may be shown under a group term:

Substance	Group term	Relationship
sodium oxalate	oxalic acid	the parent acid of salts
potassium chromate	chromates	the radical of a salt
arsenic trioxide	arsenic	the element
kerosene	hydrocarbons, liquid	A chemical group with similar toxicological or pharmacological activity
androsterone	anabolic steroidal agents	A pharmacological group

A Schedule entry includes preparations containing the substance in any concentration and all salts and derivatives of the substance unless it is specifically stated otherwise. (See Part 1, Interpretation, subparagraph 1(2) of the POISONS STANDARD).

Substances not yet scheduled

It may be that your substance has not yet been considered for scheduling and an application to amend the Poisons Standard is therefore required. Anyone can lodge an Application to amend the Poisons Standard and there is no fee charged.

Amendments to the Poisons Standard can include a new Schedule entry, rescheduling of a current entry, and/or inclusion in an Appendix.

Substances that don't require scheduling

Appendix B substances

Some substances are not included in the Poisons Standard because they are considered to be low risk. Appendix B of the Poisons Standard contains a list of substances for which the available information indicates that inclusion in the Poisons Standard is not necessary or not the most appropriate means of controlling the risk to public health. Inclusion of a substance in Appendix B does not prevent re-consideration of the scheduling of the substance where adverse information becomes available.

Substances in lower amounts

For each substance in the Poisons Standard, there is usually a lower limit (dose or concentration) below which, the substance is no longer considered to be scheduled. These 'unscheduled' substances may be used in listed medicines.

For example, folic acid is found in Schedule 2 as a Pharmacy medicine:

FOLIC ACID for human therapeutic use **except**:

a) when included in Schedule 4; or

b) in preparations containing 500 micrograms or less of folic acid per recommended daily dose.

The entry above indicates that folic acid may be used in listed medicines in preparations containing 500 micrograms or less per recommended daily dose, as at this dose it becomes unscheduled and is no longer a Schedule 2 Pharmacy medicine.

Changes to the Poisons Standard

Sometimes the scheduling of a substance needs to be changed for various reasons. Availability of sufficient safety evidence may mean a substance can be down-scheduled and a therapeutic good becomes more widely available as a result.

Alternatively, new information about substance safety or evidence of abuse may indicate that tighter controls are necessary and a substance is placed in a more restrictive schedule to decrease availability.

Keep informed of any proposed scheduling changes by monitoring the public notices on the TGA website and subscribing to the Scheduling medicines and poisons (SMP) email list.

Applying for changes

If you would like to propose a change to the scheduling of a substance in the Poisons Standard, you can make a submission directly to the Medicines and Chemicals Scheduling Secretariat (Medicines.Scheduling@health.gov.au). Instructions on how to lodge an application are published on the TGA website. Detailed guidance for applicants and information regarding the scheduling process is provided in the Scheduling Handbook and the AHMAC Scheduling policy framework (SPF).

All proposed changes to the Poisons Standard are considered by a delegate of the Secretary of the Commonwealth Department of Health (the Delegate) who is the decision maker. The Delegate may refer the proposed changes to the Advisory Committee on Medicines Scheduling (ACMS), the Advisory Committee on Chemicals Scheduling (ACCS) or a joint sitting of these committees for advice. Where proposed changes are referred to a committee, public consultation is undertaken. The public submissions and committee advice inform the Delegate's decision.

Applying for a new substance

If you would like to make an application for a new substance in a new product, this will generally be assessed by the relevant regulator. Depending on the substance and use-pattern, the following Commonwealth agencies have regulatory oversight and may be able to assist you with your application:

- Therapeutic Goods Administration (TGA) – regulate therapeutic goods
- Australian Pesticides and Veterinary Medicines Authority (APVMA) - regulate all agricultural and veterinary chemical products
- Food Standards Australia New Zealand (FSANZ) – develop food standards for Australia and New Zealand
- Australian Industrial Chemicals Introduction Scheme (AICIS) - regulate the importation and manufacture of industrial chemicals from 1 July 2020 (previously the National Industrial Chemicals Notification and Assessment Scheme (NICNAS))

Case study: Rachel wants to supply omeprazole

Rachel wants to become a sponsor for a medicine used to treat gastrointestinal reflux disease.

The medicine contains the active ingredient omeprazole. She wants to supply packs containing 7or 14 tablets. The dosage unit is one 20 mg strength tablet per day.

Rachel consults the Poisons Standard, and looks up omeprazole in the index. She sees that omeprazole is included in Schedule 4 (Prescription Only Medicine), Schedule 3 (Pharmacist Only Medicine) and Schedule 2 (Pharmacy Medicine).

Schedule 4 (Prescription Only Medicine) entry example:

OMEPRAZOLE **except** when included in Schedule 2 or 3.

Schedule 3 (Pharmacist Only Medicine) entry example:

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply **except** when included in Schedule 2.

Schedule 2 (Pharmacy Medicine) entry example:

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

To fully understand the Schedule 4 requirement, Rachel must read Schedules 3 and 2 to gain full context.

The daily dose for Rachel's product is 20 mg of omeprazole, so the 7-tablet pack can be supplied as a Schedule 2 Pharmacy Medicine. The 14-tablet pack must be supplied as a Schedule 3 Pharmacist Only Medicine.

To supply her product, she will need to apply for market authorisation under the conditions of these schedules.

Note that the scheduling details for omeprazole are accurate at the time of publishing. Please refer to the current Poisons Standard for the most recent scheduling information.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement, Education & Planning Branch	December 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au