



Western Australia

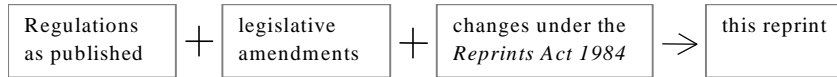
Health Act 1911

Health (Drugs and Allied Substances) Regulations 1961

Reprint 1: The regulations as at 6 December 2013

Guide for using this reprint

What the reprint includes



Endnotes, Compilation table, and Table of provisions that have not come into operation

1. Details about the original regulations and legislation that has amended its text are shown in the Compilation table in endnote 1, at the back of the reprint. The table also shows any previous reprint.
2. Transitional, savings, modifying or other provisions identified in the Compilation table may be important. The table may refer to another endnote setting out the text of these provisions in full.
3. A table of provisions that have not come into operation, to be found in endnote 1a if it is needed, lists any provisions of the regulations being reprinted that have not come into operation and any amendments that have not come into operation. The full text is set out in another endnote that is referred to in the table.

Notes amongst text (italicised and within square brackets)

1. If the reprint includes a regulation that was inserted, or has been amended, since the regulations being reprinted were made, editorial notes at the foot of the regulation give some history of how the regulation came to be as it is. If the regulation replaced an earlier regulation, no history of the earlier regulation is given (the full history of the regulations is in the Compilation table).

Notes of this kind may also be at the foot of Schedules or headings.

2. The other kind of editorial note shows something has been —
 - removed (because it was repealed or deleted from the law); or
 - omitted under the *Reprints Act 1984* s. 7(4) (because, although still technically part of the text, it no longer has any effect).

The text of anything removed or omitted can be found in an earlier reprint (if there is one) or one of the written laws identified in the Compilation table.

Reprint numbering and date

1. The reprint number (in the footer of each page of the document) shows how many times the regulations have been reprinted. For example, numbering a reprint as “Reprint 3” would mean that the reprint was the 3rd reprint since the regulations were published. Reprint numbering was implemented as from 1 January 2003.
2. The information in the reprint is current on the date shown as the date as at which the regulations are reprinted. That date is not the date when the reprint was published by the State Law Publisher and it is probably not the date when the most recent amendment had effect.

**Reprinted under the
Reprints Act 1984 as
at 6 December 2013**

Western Australia

Health (Drugs and Allied Substances) Regulations 1961

Contents

REPRINT 1: THE REGULATIONS AS AT 6 DECEMBER 2013.....	I
--	----------

1. Citation	1
Part A — Interpretation and labels	
A.01.001 Terms used.....	2
A.01.001A Application of Therapeutic Goods Act of Commonwealth.....	3
A.01.002 Labelling	4
A.01.003 Type, size and description	5
A.01.004 Prohibition	7
A.01.007 Exemptions	8
Part B — Sale and use of kits or systems for testing the presence of HIV	
B.01.001 Terms used.....	9
B.01.002 Prescription under s. 245 of Act.....	9
B.01.003 Persons to be authorised	9
B.01.004 Sale or supply of kits or systems prohibited unless to authorised person.....	10
Part R — Labelling and advertising of therapeutic substances, drugs and medicines	
R.01.001 Content of labels for therapeutic substances, drugs and medicines.....	11
R.01.002 Fictitious testimonials	19
R.01.003 Publication or display of offending advertisements	19
R.01.004 Exemption for trade journals and price lists.....	19
Part S — Substances for use as disinfectants, germicides, antiseptics, deodorants and the like	

S.01.002 Labelling of disinfectants and germicides.....	20
S.01.003 Labelling of antiseptics.....	20
S.01.005 Misleading labels.....	20
Part T — Sunscreen products	
T.01.001 Term used: Standard	21
T.01.002 Application.....	21
T.01.003 Determination of performance of sunscreen products	21
T.01.004 Labelling of sunscreen products	21
Part Z — Offences and penalties	
Z.01.001 Offences relating to sale or drugs etc.	22
Z.01.002 Offences generally	23
Z.01.003 Penalty	23

Notes

Defined terms



Reprinted under the
Reprints Act 1984 as
at 6 December 2013

Western Australia

Health Act 1911

Health (Drugs and Allied Substances) Regulations 1961

1. Citation

These regulations may be cited as the *Health (Drugs and Allied Substances) Regulations 1961*¹.

[Regulation 1 amended in Gazette 6 Mar 1987 p. 554.]

[2. Omitted under the Reprints Act 1984 s. 7(4)(f).]

[3. Deleted in Gazette 6 Mar 1987 p. 554.]

Part A — Interpretation and labels

[Heading amended in Gazette 21 Dec 1990 p. 6251.]

A.01.001 Terms used

In these regulations unless the context requires otherwise —

celsius (°C) means a measure of temperature;

common name means a name or description which indicates the true nature of the drug, ingredient or the constituent, as the case may be, to which it is applied, but does not include any word claiming or implying superior quality or purity and which is, where appropriate, a specific and not a generic name or description.

Where a regulation lays down a compositional standard and specifies the name of the product to which such standard applies, that name shall be deemed to be its common name. But nothing in this regulation shall prevent the use of a more specific name as a common name except where a precise designation is required by these regulations;

grams per kilogram (g/kg) means grams per kilogram by mass (mass in mass — m/m);

joule (j) means a metric measurement of energy and is the one-thousandth part of a kilojoule;

kilojoule (kj) means a metric measurement of energy;

label includes every tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on or attached to any drug;

litre (l) means a metric measurement of volume;

micrograms per kilogram (ug/kg) means micrograms per kilogram by mass (mass in mass — m/m);

milligrams per kilogram (mg/kg) means milligrams per kilogram by mass (mass in mass — m/m);

millilitre (ml) means a metric measurement of volume and is the one-thousandth part of a litre;

millimetre (mm) means a metric measurement of length and is the one-thousandth part of a metre (m);

package or **container** includes any form of enclosing or encasing a drug as a single item, whether by completely or partially enclosing the drug and includes wrappers, confining bands, jars, cans and boxes;

parts per million (p.p.m.) means parts per million by mass (mass in mass — m/m) unless otherwise indicated;

per centum means percent by mass (mass in mass — m/m) unless otherwise indicated;

the Act means the *Health Act 1911* (as amended); and

trade name in relation to a drug is a distinctive arbitrary, or fancy name which clearly distinguishes such drug from any other drug but shall not —

- (a) represent any single constituent of the drug; or
- (b) misrepresent the composition or any property or quality of a drug; or
- (c) give false indication of origin, character or place of manufacture.

[Regulation A.01.001 inserted in Gazette 19 Apr 1978 p. 1165-6; amended in Gazette 16 May 1980 p. 1508; 15 May 1981 p. 1485-8; 6 Mar 1987 p. 554.]

A.01.001A Application of Therapeutic Goods Act of Commonwealth

For the purposes of section 245 of the Act the substances contained in those therapeutic goods included in the Register of Therapeutic Goods maintained under section 17 of the *Therapeutic Goods Act 1989* of the Commonwealth are therapeutic substances for the purposes of these regulations.

[Regulation A.01.001A inserted in Gazette 9 Mar 1993 p. 1509.]

r. A.01.002

A.01.002 Labelling

- (a) Unless exempted by these regulations, every package in which any drug is enclosed for sale shall bear a label on or attached to it containing such information, in the English language as is required by the Act or by these regulations and such information shall appear conspicuously in a prominent position in the label and shall be clearly discernible to the purchaser under the customary conditions of purchase and use.
- (b) The contents of the label shall include —
- [(i) *deleted*]
- (ii) the name of the manufacturer, packer, importer or vendor and his address, not being a post office, cable, telegraphic or code address, but where a manufacturer, packer, importer or vendor is a company incorporated in accordance with the *Corporations Act 2001* (Commonwealth), or is a firm to which a business name is registered under the *Business Names Registration Act 2011* (Commonwealth), the inclusion in the label of the registered name of the company or firm and the city or town in which its registered office or address is situated shall be deemed to comply with this requirement;
- [(iii) *deleted*]
- (iv) the place of manufacture of the contents of the package or the country of origin, if required to be declared by these regulations.

[Regulation A.01.002 inserted in Gazette 19 Apr 1978 p. 1166; amended in Gazette 16 May 1980 p. 1508; 6 Mar 1987 p. 554; 27 Nov 2012 p. 5735.]

[A.01.002A, A.01.002B, A.01.002C, A.01.002D, A.01.002E, A.01.002F. Deleted in Gazette 6 Mar 1987 p. 554.]

A.01.003 Type, size and description

- (a) Any particulars, directions, statements, letters or words required by the Act or these regulations to be written in the label, shall —
- (i) be in durable characters; and
 - (ii) be in boldface *sans serif* capital letters of at least the prescribed size, but the name of the manufacturer, importer, vendor or packer may appear in letters other than *sans serif* capital letters; and
 - (iii) be in such colour or colours as to afford a distinct colour contrast to the ground; and
 - (iv) unless otherwise prescribed be of 1.5 mm face depth measurement, but when the package or container is of a size that prevents the use of the prescribed size, a proportionately reduced size consistent with legibility, may be used; and
 - (v) be in letters of uniform size, description and colour.

[(b) *deleted*]

- (c) Where in these regulations a reference is made to a size of type to be used that size shall be in accordance with the measurement made in millimetres (mm) in conformity with metrication requirements, but where the point system of type size is used in these regulations the following conversion schedule to the metric measurement system shall apply.

Conversion schedule

Point size	Millimetres (mm) size
6	1.5
8	2.0
10	2.5
12	3.0
18	4.5
24	6.0
36	9.0

r. A.01.003

Point size	Millimetres (mm) size
48	12.0
60	15.0
72	18.0

- (d) The size of type to be used shall be in accordance with the following scale —

1.5 mm —

ABCDEFGHIJKLMN**OP**QRSTUVWXYZ

2.0 mm —

ABCDEFGHIJKLMN**OP**QRSTUVWXYZ

2.5 mm —

ABCDEFGHIJKLMN**OP**QRSTUVWXYZ

3.0 mm —

ABCDEFGHIJKLMN**OP**QRSTUVWXYZ

4.5 mm —

ABCDEFGHIJKLMN**OP**QRSTUVWXYZ

6.0 mm —

ABCDEFGHIJKLMN**OP**

9.0 mm —

ABCDEFGHIJKLM

12.0 mm —

ABCDEFGH

15.0 mm —

ABCDEF

18.0 mm —

ABCDE

*[Regulation A.01.003 inserted in Gazette 19 Apr 1978
p. 1166-8; amended in Gazette 6 Mar 1987 p. 554.]*

A.01.004 Prohibition

- (a) The label on or attached to any package of a drug shall not contain —
 - (i) any statement, claim explicit or implicit, design, device, fancy name or abbreviation which either directly or by implication is false or misleading in any particular concerning the ingredients, or the quality, or the physiological or therapeutic action, or the place of origin of the drug; and
 - (ii) any comment on, reference to, or explanation of any statement required by the Act or these regulations which

r. A.01.007

directly or by implication, contradicts, qualifies or modifies such statement; and

- (iii) the word “pure” or the word “health” or any word of similar import used in conjunction with the common name or trade mark of the drug; and
- (iv) the word “imitation” or any word implying that the article is a substitute for any drug unless the use of the word is specifically permitted by these regulations.

[(b) deleted]

[Regulation A.01.004 inserted in Gazette 19 Apr 1978 p. 1168-9; amended in Gazette 6 Mar 1987 p. 554.]

[A.01.005 and A.01.006. Deleted in Gazette 6 Mar 1987 p. 554.]

A.01.007 Exemptions

- (a) Notwithstanding anything contained in these regulations, the Executive Director, Public Health may grant an exemption from any requirement regarding labelling in respect of any drug where he is satisfied that —
 - (i) the information required by these regulations is available from the label although not specifically contained thereon; and
 - (ii) for reasons beyond the control of the manufacturer, it is impractical to amend the label.

[(b) deleted]

[Regulation A.01.007 inserted in Gazette 19 Apr 1978 p. 1169; amended in Gazette 29 Jun 1984 p. 1781; 6 Mar 1987 p. 555.]

[A.02 - A.13. Deleted in Gazette 6 Mar 1987 p. 555.]

Part B — Sale and use of kits or systems for testing the presence of HIV

[Heading inserted in Gazette 21 Dec 1990 p. 6251.]

B.01.001 Terms used

In this Part, unless the contrary intention appears —

authorised means authorised in writing by the Executive Director, Public Health to use or direct the use of kits or systems for testing for the presence of human immunodeficiency virus, its antibodies and antigens;

HIV means human immunodeficiency virus, its antibodies and antigens.

[Regulation B.01.001 inserted in Gazette 21 Dec 1990 p. 6251.]

B.01.002 Prescription under s. 245 of Act

For the purposes of section 245 of the Act a substance or compound comprising a kit or system for testing for the presence of HIV is a therapeutic substance when the kit or system is used for the prescribed purpose of testing for the presence of HIV.

[Regulation B.01.002 inserted in Gazette 21 Dec 1990 p. 6251.]

B.01.003 Persons to be authorised

A person shall not use a kit or system for testing for the presence of HIV unless the person —

- (a) is authorised; or
- (b) acts under the direction of a person who is authorised.

[Regulation B.01.003 inserted in Gazette 21 Dec 1990 p. 6251.]

r. B.01.004

B.01.004 Sale or supply of kits or systems prohibited unless to authorised person

A person who sells or supplies a kit or system for testing for the presence of HIV shall ensure that the person to whom the kit or system is sold or supplied is authorised.

[Regulation B.01.004 inserted in Gazette 21 Dec 1990 p. 6251.]

[Parts C-Q (r. C.01-Q.05.005) deleted in Gazette 6 Mar 1987 p. 555.]

Part R — Labelling and advertising of therapeutic substances, drugs and medicines

[Heading inserted in Gazette 6 Mar 1987 p. 555; amended in Gazette 9 Mar 1993 p. 1514.]

R.01.001 Content of labels for therapeutic substances, drugs and medicines

The label on or attached to a package containing therapeutic substances, drugs or medicines or any advertisement relating to therapeutic substances, drugs or medicines shall not contain a statement, claim or representation, pictorial or otherwise, which directly or by implication —

- (a) indicates or suggests any matter or thing with respect to the use of those therapeutic substances, drugs or medicines for the purpose of or in connection with —
 - (i) abortifacient action;
 - (ii) AIDS — see immune system diseases;
 - (iii) alcoholism;
 - (iv) anaemia;
 - (v) arthritis (all forms including rheumatoid arthritis) — other than the temporary relief of pain;
 - (vi) asthma;
 - (vii) baldness, including hair growth, hair loss or hair thinning;
 - (viii) blindness;
 - (ix) boils — other than treatment by topical application;
 - (x) breast development;
 - (xi) bronchitis — other than relief of cough;
 - (xii) carbuncles — other than treatment by topical application;

r. R.01.001

- (xiii) cardiovascular system diseases ailments or defects (including high or low blood pressure) other than —
 - (A) the advertising of blood pressure appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded blood pressure; or
 - (B) the advertising of cholesterol measurement appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded cholesterol levels; or
 - (C) the advertising of purpose specific bandages for the relief or treatment of circulation related ailments; or
 - (D) a statement to the effect of “aids or assists in the maintenance of peripheral circulation”, other than a statement to the effect of “aids or assists in the treatment of fluid retention” provided the advertisement carries a warning to the effect of —
 - “
 - If fluid retention persists, seek medical advice.
 - ”.
 - ”;
- (xiv) cataract;
- (xv) catarrh, other than temporary relief;
- (xvi) chilblains, other than temporary relief of symptoms;

- (xvii) colds, other than temporary relief;
- (xviii) coughs, other than temporary relief;
- (xix) croup;
- (xx) deafness, other than relief by an appliance;
- (xxi) diabetes, other than the advertising of urine testing or blood glucose monitoring products or insulin syringes;
- (xxii) diphtheria;
- (xxiii) eczema, other than temporary relief of symptoms;
- (xxiv) endocrine system diseases, ailments or defects;
- (xxv) erysipelas;
- (xxvi) fertility;
- (xxvii) fungus infections, including tinea (athlete's foot), other than for relief or treatment by topical application;
- (xxviii) gall bladder diseases, ailments or defects;
- (xxix) gastric, peptic or duodenal ulcer;
- (xxx) genito-urinary system diseases, ailments or defects — other than for products offering temporary relief of the pain and burning sensation associated with cystitis provided the advertisement carries a warning to the effect —

“

If pain or irritation persists for more than
48 hours, consult your doctor.

”;

and

“

The presence of blood in the urine warrants
immediate medical attention.

”;

Health (Drugs and Allied Substances) Regulations 1961

Part R Labelling and advertising of therapeutic substances, drugs and medicines

r. R.01.001

- (xxxix) glandular diseases, ailments or defects (including glandular enlargement);
- (xxxvii) glaucoma;
- (xxxviii) goitre;
- (xxxix) gout;
- (xl) haemorrhoids, other than —
 - (A) temporary relief of discomfort by local application and where the directions for use include the statement that sufferers should consult a medical practitioner if the symptoms persist; or
 - (B) reference to bulk producing laxatives being of indirect benefit to people suffering from haemorrhoids;
- (xli) hair and scalp — see baldness;
- (xlii) headaches, other than temporary relief;
- (xliiii) height increase;
- (xliv) hernia or rupture, other than advertising hernia appliances;
- (xlv) herpes virus infections, other than —
 - (A) the relief of symptoms of cold sores; or
 - (B) reduction of risk of the transmission of genital herpes by the use of condoms;
- (xlvi) hormonal disease, ailments or defects;
- (xlvii) immune system diseases, ailments or defects, including HIV induced diseases or ailments, such as Acquired Immune Deficiency Syndrome (AIDS), other than the reduction in the risk of the transmission of disease by the use of condoms;
- (xlviii) impetigo, other than treatment by topical application;
- (xlix) impotence;

- (xiv) indigestion, other than temporary relief or treatment of digestive disorders, provided the advertisement carries a warning to the effect of —

“

If symptoms persist, seek medical advice.

”.

- (xlv) infertility;
- (xlvii) influenza, other than temporary relief of symptoms;
- (xlviii) liver diseases, ailments, defects or injuries;
- (xlix) lupus;
- (l) menopause or menopausal ailments or defects;
- (li) menstrual cycle diseases, ailments or defects other than the temporary relief of menstrual pain;
- (lii) pre-menstrual symptoms where the advertisement includes a statement to the effect of —

“

Use only as directed and consult your doctor if pain or symptoms persist.

”.

- (liii) mental diseases, ailments or defects;
- (liv) mouth ulcers, other than temporary relief;
- (lv) muscular aches and pains, other than temporary relief;
- (lvi) neoplastic diseases (including cancer and leukaemia), other than use of sunscreens as an aid in the prevention of skin cancer (being S.P.F. 4 or greater) and premature skin ageing (being a broad spectrum sunscreen as defined in the current Australian Standard) but

r. R.01.001

without implying that long hours of exposure in the sun are desirable;

- (lvii) nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits or paralysis);
- (lviii) obesity including the reduction of subcutaneous fat also referred to as “cellulite”;
- (lix) overweight, other than suppression of appetite in conjunction with a balanced low joule (calorie) diet;
- (lx) phlebitis;
- (lxi) pregnancy testing kits — see sexual intercourse;
- (lxii) prostate gland disease, ailments or defects;
- (lxiii) psoriasis, other than for the relief or treatment of the effects of psoriasis on the skin provided the advertisement carries a warning to the effect of —

“

Do not use for prolonged periods without consulting a medical practitioner.

”

and provided an advertisement for products which contain coal tar carries an additional warning to the effect of —

“

Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a medical practitioner.

”

- (lxiv) psychiatric disease, ailments or defects;
- (lxv) purpura;

- (lxvi) pyorrhoea;
 - (lxvii) rheumatism, other than temporary relief of pain;
 - (lxviii) scabies, other than relief by topical application;
 - (lxix) sexual intercourse, other than —
 - (A) reduction in the possibility of conception; or
 - (B) pregnancy test kits where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the test results;
 - (lxx) sexually transmissible diseases, other than the reduction of the risk of transmission of sexually transmissible disease by the use of condoms;
 - (lxxi) sexual function potency or virility;
 - (lxxii) short stature;
 - (lxxiii) sinus infection, other than temporary relief of sinusitis;
 - (lxxiv) sleeplessness, other than temporary relief;
 - (lxxv) sunscreens — see neoplastic diseases;
 - (lxxvi) thrombosis, other than for the relief or treatment of circulation related ailments by means of purpose specific bandages;
 - (lxxvii) tuberculosis;
 - (lxxviii) varicose ulcers or varicose veins, other than the temporary relief by the use of elastic hosiery;
 - (lxxix) whooping cough;
- or
- (b) with respect to the use or consumption of those therapeutic substances, drugs or medicines —
 - (i) depicts excessive pain or suffering; or

Health (Drugs and Allied Substances) Regulations 1961

Part R Labelling and advertising of therapeutic substances, drugs and medicines

r. R.01.001

- (ii) induces or is likely to induce persons to believe that they are suffering from a serious ailment; or
 - (iii) induces or is likely to induce persons to believe that harmful consequences will result if those therapeutic substances, drugs or medicines are not used or consumed; or
 - (iv) disparages any physical or mental affliction or deformity; or
 - (v) claims or implies or induces or is likely to induce persons to infer that those therapeutic substances, drugs or medicines or their sales are recommended or used generally by medical practitioners, pharmacists, dentists, nurses or physiotherapists or by other persons having or purporting to have a qualification in a health care field;
- or
- (c) indicates or suggests with respect to the use or consumption of those therapeutic substances, drugs or medicines that those therapeutic substances, drugs or medicines —
 - (i) are a universal panacea; or
 - (ii) possess infallible, unfailing, sure, magical or miraculous curing properties; or
 - (iii) possess unique or absolute properties; or
 - (iv) act immediately or rapidly; or
 - (v) are a natural remedy or nature's remedy; or
 - (vi) possess stimulant properties; or
 - (vii) promote vitality; or
 - (viii) must be used for the relief of symptoms of any disease, ailment, defect or injury.

[Regulation R.01.001 inserted in Gazette 6 Mar 1987 p. 555-6; amended in Gazette 9 Mar 1993 p. 1510-14.]

R.01.002 Fictitious testimonials

A fictitious testimonial or the name of a fictitious person shall not be included in the label on or attached to or in an advertisement relating to therapeutic substances, drugs or medicines.

[Regulation R.01.002 inserted in Gazette 6 Mar 1987 p. 556; amended in Gazette 9 Mar 1993 p. 1514.]

R.01.003 Publication or display of offending advertisements

A person shall not publish or display in any manner or cause to be published or displayed in any manner an advertisement that contravenes these regulations.

[Regulation R.01.003 inserted in Gazette 6 Mar 1987 p. 556.]

R.01.004 Exemption for trade journals and price lists

This regulation shall not be construed so as to prohibit the publication of advertisements relating to therapeutic substances, drugs or medicines in medical journals, *bona fide* trade journals or price lists for the use of the retail trade.

[Regulation R.01.004 inserted in Gazette 6 Mar 1987 p. 556; amended in Gazette 9 Mar 1993 p. 1514.]

r. S.01.002

**Part S — Substances for use as disinfectants,
germicides, antiseptics, deodorants and the like**

[Heading inserted in Gazette 21 Dec 1990 p. 6252.]

[S.01.001. Deleted in Gazette 6 Mar 1987 p. 557.]

S.01.002 Labelling of disinfectants and germicides

[(a) and (b) deleted]

- (c) No person shall sell any package on which the word DISINFECTANT, or the word GERMICIDE, is written in any label accompanying it which does not contain a substance or compound which, when used in the strength or proportion and for the time set forth in the label, is effective for the purpose of killing micro-organisms.

[Regulation S.01.002 amended in Gazette 6 Mar 1987 p. 557.]

S.01.003 Labelling of antiseptics

[(a) and (b) deleted]

- (c) No person shall sell any package on which the word “Antiseptic” is written in any label accompanying it which does not contain a substance or compound which when used in the strength or proportion set forth in the label is effective for the purpose of preventing the development of micro-organisms and the decomposition of animal or vegetable substances.

[Regulation S.01.003 amended in Gazette 6 Mar 1987 p. 557.]

[S.01.004. Deleted in Gazette 6 Mar 1987 p. 557.]

S.01.005 Misleading labels

No person shall pack a disinfectant or poisonous substance of any description in a package or container which bears upon it any brand, mark, or statement indicating the presence in that package or container of food, or which may be capable of misleading a purchaser into the belief that the contents of that package or container are for the purposes of human consumption.

Part T — Sunscreen products

[Heading inserted in Gazette 10 Oct 1986 p. 3837.]

T.01.001 Term used: Standard

In this Part —

Standard means Australian Standard AS 2604-1986 entitled “Sunscreen Products — Evaluation and Classification” published by the Standards Association of Australia².

[Regulation T.01.001 inserted in Gazette 10 Oct 1986 p. 3837; amended in Gazette 9 Mar 1993 p. 1514.]

T.01.002 Application

This Part applies to sunscreen products in accordance with clause 2 of the Standard.

[Regulation T.01.002 inserted in Gazette 10 Oct 1986 p. 3838.]

T.01.003 Determination of performance of sunscreen products

The performance of sunscreen products to which this Part applies shall be determined in accordance with the Standard.

[Regulation T.01.003 inserted in Gazette 10 Oct 1986 p. 3838.]

T.01.004 Labelling of sunscreen products

Sunscreen products to which this Part applies shall be labelled in accordance with the Standard.

[Regulation T.01.004 inserted in Gazette 10 Oct 1986 p. 3838.]

[Schedule to Part T. Deleted in Gazette 9 Mar 1993 p. 1514.]

[Y.01. Deleted in Gazette 6 Mar 1987 p. 557.]

Part Z — Offences and penalties

[Heading inserted in Gazette 21 Dec 1990 p. 6252.]

Z.01.001 Offences relating to sale or drugs etc.

- (a) Where in relation to any drug a standard is appointed by any provision contained in these regulations, a person shall not have in his possession for sale or shall not, in the course of or for the purposes of sale, consign to any other person any quantity of such drug which does not in all respects conform with the standard appointed by these regulations in relation to such quantity of drug.
- (b) No person shall sell or offer or expose for sale any drug, disinfectant, antiseptic, deodorant, therapeutic good, drug or medicine, or sunscreen product which is not labelled as prescribed by these regulations.
- (c) No person shall use or shall attach or cause to be attached to any drug, disinfectant, antiseptic deodorant, therapeutic good, drug or medicine, or sunscreen product or to any package or container containing any drug, disinfectant, antiseptic deodorant, therapeutic good, drug or medicine, or sunscreen product any label which by reason of any matter contained therein or omitted therefrom contravenes, or is not in conformity with any provision of the regulations.
- (d) Provided that this regulation shall not apply so as to prohibit the offering for sale of any quantity of drug which does not in all respects conform with the standard appointed in relation thereto by these regulations when the Executive Director, Public Health expressly sanctions the sale of such quantity of drug upon and subject to any conditions which the Executive Director, Public Health may think fit to impose, and such quantity of drug is offered for sale strictly in compliance with such conditions.

[Regulation Z.01.001 amended in Gazette 29 Jun 1984 p. 1781; 6 Mar 1987 p. 557; 23 Dec 1988 p. 4971-2; 21 Dec 1990 p. 6252.]

Z.01.002 Offences generally

A person who contravenes regulation Z.01.001(a), (b) or (c) or a provision of the regulations specified in the Table to this regulation commits an offence.

Table

Regulations B.01.004, R.01.003, S.01.002(c), S.01.003(c) and S.01.005.

[Regulation Z.01.002 inserted in Gazette 23 Dec 1988 p. 4972; amended in Gazette 21 Dec 1990 p. 6252.]

Z.01.003 Penalty

A person who commits an offence under regulation Z.01.002 is liable to —

- (a) a penalty which is not more than \$1 000 and not less than —
 - (i) in the case of a first offence, \$100; and
 - (ii) in the case of a second offence, \$200; and
 - (iii) in the case of a third or subsequent offence, \$500;

and

- (b) if that offence is a continuing offence, a daily penalty which is not more than \$100 and not less than \$50.

[Regulation Z.01.003 inserted in Gazette 23 Dec 1988 p. 4972.]



Notes

- ¹ This reprint is a compilation as at 6 December 2013 of the *Health (Drugs and Allied Substances) Regulations 1961* and includes the amendments made by the other written laws referred to in the following table. The table also contains information about any reprint.

Compilation table

Citation	Gazettal	Commencement
<i>Food and Drug Regulations 1961</i> ³	4 Jan 1962 p. 1-67	4 Jan 1962
Untitled regulations	15 Feb 1962 p. 457	15 Feb 1962
Untitled regulations	2 Jun 1964 p. 2319-33	2 Jun 1964
Untitled regulations	10 Feb 1966 p. 393-410	10 Feb 1966
Untitled regulations	3 Oct 1967 p. 2578-89	3 Oct 1967
Untitled regulations	6 Nov 1970 p. 3420	6 Nov 1970
Untitled regulations	30 Nov 1971 p. 4938-40	30 Nov 1971
Untitled regulations	1 Dec 1972 p. 4570-81	1 Dec 1972
Untitled regulations	27 Apr 1973 p. 1077-86	27 Apr 1973
Untitled Regulations	20 Aug 1976 p. 3094-105	20 Aug 1976
Untitled regulations	10 Sep 1976 p. 3350	10 Sep 1976
Untitled regulations	10 Dec 1976 p. 4894	10 Dec 1976
Untitled regulations	19 Apr 1978 p. 1163-97	19 Apr 1978
Untitled regulations ⁴	9 Mar 1979 p. 634-5	9 Mar 1979
Untitled regulations ⁴	16 Mar 1979 p. 692-4	16 Mar 1979

Health (Drugs and Allied Substances) Regulations 1961

Citation	Gazettal	Commencement
Untitled regulations	4 Oct 1979 p. 3045-78	4 Oct 1979
Untitled regulations	9 Nov 1979 p. 3504	9 Nov 1979
Untitled regulations ⁵	16 May 1980 p. 1508-11	16 May 1980
<i>Food and Drug Amendment Regulations 1981</i> ⁵	15 May 1981 p. 1484-8	r. 5: 15 May 1981 (see r. 2(2)); Regulations other than r. 5: 16 Nov 1981 (see r. 2(1))
<i>Food and Drug Amendment Regulations (No. 2) 1981</i>	9 Oct 1981 p. 4237	9 Oct 1981
<i>Food and Drug Amendment Regulations (No. 3) 1981</i>	20 Nov 1981 p. 4732-9	20 Nov 1981
<i>Food and Drug Amendment Regulations 1982</i>	2 Apr 1982 p. 1138-9	2 Apr 1982
<i>Food and Drug Amendment Regulations (No. 2) 1982</i>	21 May 1982 p. 1558-9	21 May 1982
<i>Food and Drug Amendment Regulations (No. 3) 1982</i>	30 Jul 1982 p. 2953-6	1 Jan 1983 (see r. 1(2))
<i>Food and Drug Amendment Regulations (No. 4) 1982</i>	10 Dec 1982 p. 4784	1 Jan 1983 (see r. 2)
<i>Food and Drug Amendment Regulations (No. 5) 1982</i>	31 Dec 1982 p. 4981-98	31 Dec 1982
<i>Food and Drug Amendment Regulations 1984</i>	30 Mar 1984 p. 814-25	Regulations other than r. 13: 27 Apr 1984 (see r. 2(1)); r. 13: 30 Mar 1985 (see r. 2(2))
<i>Health Legislation Amendment Regulations 1984 r. 4</i>	29 Jun 1984 p. 1780-4	1 Jul 1984 (see r. 2)
<i>Food and Drug Amendment Regulations 1986</i>	10 Oct 1986 p. 3837-44	10 Oct 1986 (see r. 2 ⁶)
<i>Food and Drug Amendment Regulations 1987</i>	6 Mar 1987 p. 554-7	13 Sep 1987 (see r. 3 and <i>Gazette</i> 13 Mar 1987 p. 681)
<i>Health (Offences and Penalties) Amendment Regulations (No. 2) 1988 Pt. 2</i>	23 Dec 1988 p. 4970-5	23 Dec 1988
<i>Health (Drugs and Allied Substances) Amendment Regulations 1990</i>	21 Dec 1990 p. 6251-2	21 Dec 1990
<i>Health (Drugs and Allied Substances) Amendment Regulations 1993</i>	9 Mar 1993 p. 1509-14	9 Mar 1993

Health (Drugs and Allied Substances) Regulations 1961

Citation	Gazettal	Commencement
<i>Health (Drugs and Allied Substances) Amendment Regulations 2012</i>	27 Nov 2012 p. 5735-6	27 Nov 2012 (see note under r. 1)

Reprint 1: The *Health (Drugs and Allied Substances) Substances Regulations 1961* as at 6 Dec 2013 (includes amendments as listed above)

- ² The Standards Association of Australia has changed its corporate status and its name. It is now Standards Australia International Limited (ACN 087 326 690). It also trades as Standards Australia.
- ³ Now known as the *Health (Drugs and Allied Substances) Regulations 1961*; citation changed (see note under r. 1).
- ⁴ The untitled amending regulations published in *Gazette* 19 Mar 1979 p. 634-5 have been superseded by the notice published in *Gazette* 16 Mar 1979 p. 692-4.
- ⁵ The untitled amending regulations published in *Gazette* 16 May 1980 p. 1508-11 did not come into operation and were repealed by the *Food and Drug Amendment Regulations 1981* r. 5.
- ⁶ The commencement date of 1 Oct 1986 that was specified was before the date of gazettal.

Defined terms

*[This is a list of terms defined and the provisions where they are defined.
The list is not part of the law.]*

Defined term	Provision(s)
authorised.....	B.01.001
celsius (°C).....	A.01.001
common name.....	A.01.001
container.....	A.01.001
grams per kilogram (g/kg).....	A.01.001
HIV.....	B.01.001
joule (j).....	A.01.001
kilojoule (kj).....	A.01.001
label.....	A.01.001
litre (l).....	A.01.001
micrograms per kilogram (ug/kg).....	A.01.001
milligrams per kilogram (mg/kg).....	A.01.001
millilitre (ml).....	A.01.001
millimetre (mm).....	A.01.001
package.....	A.01.001
parts per million (p.p.m.).....	A.01.001
per centum.....	A.01.001
trade name.....	A.01.001
the Act.....	A.01.001