

# Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

made under section 10 of the

Therapeutic Goods Act 1989

## Compilation No. 3

**Compilation date:** 23 August 2025

**Includes amendments:** F2025L00955

Prepared by the Department of Health, Disability and Ageing, Canberra

## About this compilation

#### This compilation

This is a compilation of the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019* that shows the text of the law as amended and in force on 23 August 2025 (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. The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au).

#### Application, saving and transitional provisions

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.

#### **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. Any modifications affecting the law are accessible on the Register.

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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

## Contents

Part 1—Preliminary	1
1 Name	1
3 Authority	1
4 Definitions	1
5 Standard	
6 Application	
7 Requirements	4
Part 2—Requirements for disinfectants	5
Division 1—General requirements	5
9 Approved names for ingredients etc	
10 Stability data	
11 Shelf life	
12 Toxicity data	6
Division 2—Performance requirements	6
13 Performance requirements for hospital grade disinfectants	6
14 Performance requirements for household grade disinfectants	8
14A Performance requirements for hospital and household grade disinfectants— residual activity	10
Division 3—Packaging requirements	11
15 Packaging of disinfectants	11
Part 3—Requirements for disinfectants, sanitisers, sanitary fluids and	
sanitary powders	11
16 Labelling requirements	11
Part 4—Transitional	13
17 Transitional arrangements relating to the <i>Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021</i>	13
Schedule 1—Acceptable common names	14
Endnotes	16
Endnote 1—About the endnotes	16
Endnote 2—Abbreviation key	17
Endnote 3—Legislation history	18
Endnote 4—Amendment history	19



## Part 1—Preliminary

#### 1 Name

- (1) This instrument is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019.*
- (2) This instrument may also be cited as TGO 104.

#### 3 Authority

This instrument is made under section 10 of the Therapeutic Goods Act 1989.

#### 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) batch;
- (b) container;
- (c) current Poisons Standard;
- (d) label; and
- (e) primary pack.

In this instrument:

Act means the Therapeutic Goods Act 1989.

antibacterial clothes preparation means a disinfectant that is represented to be capable of reducing the number of viable micro-organisms in water in which clothes are soaked, washed or rinsed.

*approved name* means the name of an ingredient as included in the Australian Approved Names List.

Australian Approved Names List has the same meaning as in the Regulations.

**batch number** means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to identify uniquely that batch, and from which it is possible to trace that batch through all stages of manufacture and distribution.

*biocide* means a physical or chemical agent that kills some or all types of micro-organisms.

*common name*, in relation to the goods listed in column 2 of an item in the table in Schedule 1 to this instrument, means the name or names listed in column 3 of that item.

disinfectant has the same meaning as in the Regulations.

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

*disinfectant wipe or sponge* means a cloth, towel, towelette or sponge that is premoistened with a disinfectant and is recommended by its manufacturer for application of the disinfectant to an inanimate object to kill microorganisms.

expiry date has the same meaning as in the Regulations.

hospital grade disinfectant has the same meaning as in the Regulations.

household grade disinfectant has the same meaning as in the Regulations.

Note: Household grade disinfectants may be marketed and labelled as being for household and/or commercial use.

*Instructions* means the *TGA* instructions for disinfectant testing (Version 4.0, August 2025) published by the Therapeutic Goods Administration, as in force or existing on 11 August 2025.

Note: The Instructions are published at www.tga.gov.au.

#### main label means:

- (a) where there are two or more labels, or two or more portions of a single label—that label, or portion of the label, where the trade name (or, where there is no trade name, the name of the goods), is more or most prominent; or
- (b) where the trade name (or where there is no trade name, the name of the goods) is equally prominent on two or more labels, or portions of a label—either of such label or portion.

name and address, in relation to a manufacturer or sponsor, means:

- (a) if the manufacturer or sponsor has a registered name:
  - (i) that registered name; and
  - (ii) the city, town or locality in which the registered office or registered place of business is situated; or
- (b) if the manufacturer or sponsor does not have a registered name (and including a manufacturer whose place of business is outside Australia):
  - (i) the name of the manufacturer or sponsor; and
  - (ii) the address of the principal place of business of that manufacturer or sponsor including, where applicable, the street number, street name, the town or city, and the State or Territory in Australia or the name of the overseas country, as the case may be, but not including a post office, cable, telegraphic or code address.

**Poisons Standard** means the current Poisons Standard.

**Regulations** means the *Therapeutic Goods Regulations 1990*.

**residual activity** means the capability of a disinfectant to continue to reduce the number of viable cells of relevant test organisms on a surface, when the disinfectant is used in accordance with the information provided on the label of the disinfectant.

2 Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order
2019

**sanitary fluid** means a fluid that is a chemical agent that is represented to be suitable for use in the charging of sanitary units used for the storage or disposal of human waste and which is not represented to be suitable for any other use.

**sanitary powder** means a powder that is a chemical agent that is represented to be suitable for use in the charging of sanitary units used for the storage or disposal of human waste and which is not represented to be suitable for any other use.

**sanitiser** means a chemical agent that is represented to be suitable for use on surfaces with which food for human consumption may come in contact, for the purposes of reducing pathogenic or food-spoilage micro-organisms to a sanitary level on such a surface.

*sporicide* has the same meaning as in the Regulations.

sterilant has the same meaning as in the Regulations.

*surface spray disinfectant* means a disinfectant that is represented to be suitable for use undiluted as a spray and that is not represented to be suitable for any other method of use.

**TGA Disinfectant Test** means the test that is specified in Part 1 of the Instructions.

*Therapeutic Goods Administration* has the same meaning as in the Regulations.

trade name has the same meaning as in the Regulations.

tuberculocide has the same meaning as in the Regulations.

virucide has the same meaning as in the Regulations.

#### 5 Standard

This instrument constitutes a standard for disinfectants, sanitisers, sanitary fluids and sanitary powders.

#### 6 Application

- (1) Subject to subsection (2), this instrument applies to therapeutic goods that are disinfectants, sanitisers, sanitary fluids and sanitary powders.
- (2) This instrument does not apply to the rapeutic goods that are:
  - (a) sterilants:
  - (b) sterilant gases;
  - (c) antiseptics and skin disinfectants;
  - (d) antibiotics;
  - (e) a disinfectant that is represented to be for antifungal use only;

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

J

- (f) a disinfectant or sanitiser registered under the *Agricultural and Veterinary Chemicals Code Act 1994* for which no claim or representation for disinfectant use is made, other than a use for which the disinfectant is registered under that Act;
- (g) a disinfectant or sanitiser that is represented to be for the treatment of water only;
- (h) contact lens care products.

Note:

A standard under section 10 of the Act does not apply to a medical device unless Part 3-2 of the Act (Registration and listing of therapeutic goods) applies to the device: see section 10A of the Act.

#### 7 Requirements

- (1) The requirements in relation to disinfectants are those requirements specified in Parts 2 and 3 of this instrument.
- (2) The requirements in relation to sanitisers, sanitary fluids and sanitary powders are those requirements specified in Part 3 of this instrument.

## Part 2—Requirements for disinfectants

### **Division 1—General requirements**

#### 9 Approved names for ingredients etc

- (1) A disinfectant may only contain ingredients with an approved name.
- (2) The physical form of a disinfectant must be appropriate for its intended use.

#### 10 Stability data

- (1) Subject to subsections (2) and (3):
  - (a) the physical and chemical stability; and
  - (b) the microbial efficacy;

of a disinfectant must be established in accordance with the requirements in:

- (c) Division 1 of Part 2 of the Instructions; and
- (d) section 1 of Division 2 of Part 2 of the Instructions; using the final formulation of the disinfectant when stored in its proposed container and packaging material for supply.
- (2) Laboratory batches of a disinfectant may be used for the purposes of subsection (1), provided that those batches properly reflect the scaled-up production process for the manufacture of the disinfectant for supply.
- (3) If batches of a disinfectant have been stored in a container that is not the container that is intended for supply, that container may be used for the purposes of subsection (1), if:
  - (a) the container is composed of the same material as the proposed container for supply; and
  - (b) either:
    - (i) the ratio of surface area to volume of the container is the same as that of the proposed container for supply; or
    - (ii) the ratio of surface area to volume of the container is different to that of the proposed container for supply, but this difference is justified.
- (4) The physical and chemical stability of a production batch of a disinfectant must also be established in accordance with the requirements in Division 1 of Part 2 of the Instructions, including in relation to any changes made to the manufacturing process for the disinfectant, or the quality of a raw material used in its manufacture, after the establishment of the disinfectant's stability in accordance with subsections (1) to (3).

### 11 Shelf life

A disinfectant must not have a shelf life that is more than 5 years.

#### 12 Toxicity data

The safety of a disinfectant in relation to its toxicity must be established, and toxicity data for the disinfectant must include the following:

- (a) potential hazards to the user through accidental body contact;
- (b) acute oral toxicity in concentrations equivalent to those likely to be encountered in use;
- (c) inhalation toxicity, skin irritation, sensitisation and eye irritation;
- (d) haemocompatibility, sub-chronic toxicity, mutagenicity and carcinogenicity;
- (e) any other forms of toxicity that are relevant in relation to the disinfectant and that may present a hazard.

#### **Division 2—Performance requirements**

#### 13 Performance requirements for hospital grade disinfectants

General requirements

- (1) A hospital grade disinfectant must comply with the minimum performance requirements specified in this section for each claim made in relation to the use of the disinfectant on the label, when tested:
  - (a) at the highest dilution recommended on the label for that use; and
  - (b) at the end of the shelf life for that use.

Hospital grade disinfectants for general purpose use on surfaces

- (2) If the disinfectant is for general purpose use on surfaces then, when tested in accordance with the conditions specified on the label (if any), the disinfectant must:
  - (a) pass either of the following tests:
    - (i) the TGA Disinfectant Test, under the conditions specified in Option A or Option B of that test; or
    - (ii) an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions; and
  - (b) pass an appropriate bactericidal carrier test as specified in Division 2 of Part 2 of the Instructions; and
  - (c) if it is a hospital grade disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Hospital grade disinfectants that are surface spray disinfectants

(3) If the disinfectant is a surface spray disinfectant then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order

- (a) pass an appropriate bactericidal carrier test as specified in Division 2 of Part 2 of the Instructions; and
- (b) if it is a surface spray disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Hospital grade disinfectant wipes or sponges for single use

- (4) Subject to subsection (6), if the disinfectant is a disinfectant wipe or sponge that is for single use then, following extraction from the wipe or sponge and when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:
  - (a) pass any of the following tests:
    - (i) the TGA Disinfectant Test under the conditions specified in Option A or Option B of that test;
    - (ii) an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions;
    - (iii) an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions; and
  - (b) if it is a disinfectant wipe or sponge that is for single use for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Hospital grade disinfectant wipes or sponges for multiple use

(5) Subject to subsection (7), if the disinfectant is a disinfectant wipe or sponge that is for multiple use then, following extraction from the wipe and when tested in accordance with the test conditions specified on the label (if any), the disinfectant must pass an appropriate test for multiple use as specified in Division 2 of Part 2 of the Instructions after the disinfectant has been subjected to a re-use protocol.

Hospital grade disinfectant wipes or sponges for single use where disinfectant cannot be expressed

- (6) If the disinfectant is a disinfectant wipe or sponge for single use and:
  - (a) the amount of disinfectant from such a wipe or sponge that is able to be expressed is not sufficient for testing; or
  - (b) the disinfectant in the wipe or sponge is too dry to be expressed from the wipe or sponge;

then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:

(c) pass an appropriate simulated in-use test for single use as specified in Division 2 of Part 2 of the Instructions; and

(d) if it is a disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Hospital grade disinfectant wipes or sponges for multiple use where disinfectant cannot be expressed

- (7) If the disinfectant is a disinfectant wipe or sponge for multiple use and:
  - (a) the amount of disinfectant from such a wipe or sponge that is able to be expressed is not sufficient for testing; or
  - (b) the disinfectant in the wipe or sponge is too dry to be expressed from the wipe or sponge;

then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:

- (c) pass an appropriate simulated in-use test for multiple use as specified in Division 2 of Part 2 of the Instructions after the disinfectant has been subjected to a re-use protocol; and
- (d) if it is a disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

#### 14 Performance requirements for household grade disinfectants

Note: Household grade disinfectants may be marketed and labelled as being for household and/or commercial use.

General requirements

- (1) A household grade disinfectant must comply with the minimum performance requirements specified in this section for each claim made in relation to the use of the disinfectant on the label, when tested:
  - (a) at the highest dilution recommended on the label for that use; and
  - (b) at the end of the shelf life for that use.

Household grade disinfectants for general purpose use on surfaces

- (2) If the disinfectant is for general purpose use on surfaces then, when tested in accordance with the conditions specified on the label (if any), the disinfectant must:
  - (a) pass one of the following tests:
    - (i) the TGA Disinfectant Test under the conditions specified in Option C of that test; or
    - (ii) an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions; or

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order
2019

- (iii) an appropriate bactericidal carrier test as specified in Division 2 of Part 2 of the Instructions; and
- (b) if it is a household grade disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Household grade disinfectants that are surface spray disinfectants

- (3) If the disinfectant is a surface spray disinfectant then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:
  - (a) pass an appropriate bactericidal carrier test as specified in Division 2 of Part 2 of the Instructions; and
  - (b) if it is a surface spray disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Household grade disinfectant wipes or sponges for single use

- (4) Subject to paragraph (6), if the disinfectant is a disinfectant wipe or sponge that is for single use then, following extraction from the wipe or sponge and when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:
  - (a) pass either of the following tests:
    - (i) the TGA Disinfectant Test under the conditions specified in Option C of that test; or
    - (ii) an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions; and
  - (b) pass an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions; and
  - (c) if it is a disinfectant wipe or sponge that is for single use for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Household grade disinfectant wipes or sponges for multiple use

(5) Subject to paragraph (7), if the disinfectant is a disinfectant wipe or sponge that is for multiple use then, following extraction from the wipe or sponge and when tested in accordance with the test conditions specified on the label (if any), the disinfectant must pass an appropriate test for multiple use as specified in Division 2 of Part 2 of the Instructions after the disinfectant has been subjected to a re-use protocol.

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

Household grade disinfectant wipes or sponges for single use where disinfectant cannot be expressed

- (6) If the disinfectant is a disinfectant wipe or sponge for single use and:
  - (a) the amount of disinfectant from such a wipe or sponge that is able to be expressed is not sufficient for testing; or
  - (b) the disinfectant in the wipe or sponge is too dry to be expressed from the wipe or sponge;

then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:

- (c) pass an appropriate simulated in-use test for single use as specified in Division 2 of Part 2 of the Instructions; and
- (d) if it is a disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

Household grade disinfectant wipes or sponges for multiple use where disinfectant cannot be expressed

- (7) If the disinfectant is a disinfectant wipe or sponge for multiple use and:
  - (a) the amount of disinfectant from such a wipe or sponge that is able to be expressed is not sufficient for testing; or
  - (b) the disinfectant in the wipe or sponge is too dry to be expressed from the wipe or sponge;

then, when tested in accordance with the test conditions specified on the label (if any), the disinfectant must:

- (c) pass an appropriate simulated in-use test for multiple use as specified in Division 2 of Part 2 of the Instructions after the disinfectant has been subjected to a re-use protocol; and
- (d) if it is a disinfectant for which a claim for sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use is made—pass an appropriate sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal test as specified in Division 2 of Part 2 of the Instructions in relation to each such claim.

### 14A Performance requirements for hospital and household grade disinfectants—residual activity

If a claim of residual activity is made in relation to a disinfectant, the claim must:

- (a) only relate to bacteria, yeast or viruses; and
- (b) be based on residual activity that is established in accordance with the requirements in Division 2 of Part 2 of the Instructions.

Compilation date: 23/08/2025

## **Division 3—Packaging requirements**

#### 15 Packaging of disinfectants

- (1) A disinfectant must be enclosed in a container that is suitably designed to ensure that the disinfectant is adequately protected and contained.
- (2) If the disinfectant is, or contains a substance that is, included in a Schedule to the Poisons Standard, then the container for the disinfectant must comply with any applicable requirements in relation to such a container specified in the Poisons Standard.

# Part 3—Requirements for disinfectants, sanitisers, sanitary fluids and sanitary powders

#### 16 Labelling requirements

- (1) The label of a disinfectant, sanitiser, sanitary fluid or sanitary powder that is, or contains a substance that is, included in a Schedule to the Poisons Standard must comply with any applicable requirements in relation to such a label specified in the Poisons Standard.
- (2) Subject to subsections (3), (4) and (7), the container and any primary pack for a disinfectant, sanitiser, sanitary fluid or sanitary powder must be labelled with the following information:
  - (a) the trade name (or, if there is no trade name, the name) of the disinfectant, sanitiser, sanitary fluid or sanitary powder;
  - (b) the common name of the disinfectant, sanitiser, sanitary fluid or sanitary powder, located immediately above, below or adjacent to the trade name (or, if there is no trade name, the name);
  - (c) the approved name of each active ingredient of the disinfectant, sanitiser, sanitary fluid or sanitary powder;
  - (d) the quantity or proportion of each active ingredient of the disinfectant, sanitiser, sanitary fluid or sanitary powder together with, where applicable, a statement of the proportion of available chlorine, bromine or iodine in the disinfectant, sanitiser, sanitary fluid or sanitary powder, as a percentage of the total mass or volume of the disinfectant, sanitiser, sanitary fluid or sanitary powder;
  - (e) the quantity of disinfectant, sanitiser, sanitary fluid or sanitary powder;
  - (f) the batch number of the disinfectant, sanitiser, sanitary fluid or sanitary powder, immediately preceded by the words "Batch", "Batch Number", "Batch No.", "Lot", "Lot Number", "Lot No.", "Lot Code" or words with a similar meaning or the symbol "B", ® or "(B)";
  - (g) the expiry date of the disinfectant, sanitiser, sanitary fluid or sanitary powder immediately preceded by the words "Expiry date", "Expiry",

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

11

- "Exp." or "Use by" or words with a similar meaning or an internationally recognisable symbol (such as the hour glass) with the same meaning;
- (h) the name and address of the manufacturer or sponsor of the disinfectant, sanitiser, sanitary fluid or sanitary powder;
- (i) clear and adequate instructions for each of the manufacturer's intended uses of the disinfectant, sanitiser, sanitary fluid or sanitary powder including:
  - (i) the method of use of the goods and a clear warning in any case where a danger exists if an incorrect method of use is employed;
  - (ii) for a hospital grade disinfectant—instructions indicating that the disinfectant is not to be used on medical devices or other therapeutic goods;
  - (iii) except for disinfectants that are surface spray disinfectants or disinfectant wipes or sponges—the words "Do not mix with detergents or other chemicals" or, where relevant, "Do not mix with detergents or other chemicals except [name of detergent or chemical] as directed below", together with directions in relation to the safe use of such a mix;
  - (iv) except for disinfectants that are liquids—a statement of the recommended dilution of the goods in water or other diluent or, where relevant, the words "Use undiluted";
  - (v) for disinfectants that are liquids—a statement of the recommended dilution of the goods in water or other diluent, expressed as either "1 in N" meaning that 1 part of the disinfectant is made up with water or other diluent to a total volume of N parts, or "1: N" meaning that 1 part of the disinfectant is added to N parts of water or other diluent;
  - (vi) for a disinfectant requiring preparation before use—instructions for the correct preparation, use and storage conditions of the preparation;
  - (vii) for a disinfectant that contains chlorhexidine as an active ingredient—the words "Not to be used on skin";
  - (viii) the details, clearly identified, of potential hazards that may occur through accidental body contact with the disinfectant, sanitiser, sanitary fluid or sanitary powder.
- (3) Subject to subsection (4), the information required to be included on a container and primary pack of a disinfectant, sanitiser, sanitary fluid or sanitary powder referred to in paragraphs (2)(a) to (g) must be set out on the main label.
- (4) Information in relation to the batch number and the expiry date required by paragraphs (2)(f) and (g) may be engraved or embossed on:
  - (a) the container or primary pack; or
  - (b) a label attached to, or on, the container or primary pack; instead of being set out on the main label.
- (5) A disinfectant that is a household grade disinfectant must not be labelled as "hospital grade disinfectant".

- (6) A statement of dilution in the label of a hospital grade disinfectant must not contain directions for the preparation of a dilution of the disinfectant from another such dilution.
- (7) The information referred to in subsection (2) must be clearly visible and written:
  - (a) in English; and
  - (b) on the outer face of the label; and
  - (c) in durable and legible characters with a letter height of at least 1.0 millimetre; and
  - (d) in metric units of measurement; and
  - (e) in a colour or colours that will provide a distinct contrast to the background colour.
- (8) For a hospital grade disinfectant that complies with subsections 13(2) or (4) on the basis of passing the TGA Disinfectant Test under the conditions specified in Option A of that test, the container and primary pack of the disinfectant must clearly indicate that the surface on which the disinfectant is to be used must be pre-cleaned before the disinfectant is used, for the disinfectant to be effective.
- (9) For a hospital grade disinfectant that is a surface spray disinfectant that complies with subsection 13(3) on the basis of passing a bactericidal carrier test under clean conditions, the container and primary pack of the disinfectant must clearly indicate that the surface on which the disinfectant is to be used must be precleaned before the disinfectant is used, for the disinfectant to be effective.

#### Part 4—Transitional

# 17 Transitional arrangements relating to the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021*

Despite the amendments made by items 2 and 5 of Schedule 1 to the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104)*Amendment (Residual Activity) Order 2021, those amendments do not apply for the period from their commencement on 1 January 2022 to 30 June 2022 in relation to:

- (a) disinfectants included in the Register before 1 January 2022; and
- (b) disinfectants included in the Register on or after 1 January 2022, on the basis of an application for listing in the Register under section 26 of the Act made before 1 January 2022.

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

## Schedule 1—Acceptable common names

Note: See section 4, definition of *common name*.

Column 1	Column 2	Column 3  Common names  antibacterial (together with a word or words indicating the nature of the goods)		
Item	Descriptive name			
1	antibacterial clothes preparation			paration antibacterial (together with words indicating the natur
2	disinfectant wipe or sponge	(a)	commercial grade – disinfectant wipe or disinfectant sponge	
		(b)	disinfectant wipe or disinfectant sponge – commercial grade	
		(c)	disinfectant wipe or disinfectant sponge – hospital grade	
		(d)	disinfectant wipe or disinfectant sponge – household grade	
		(e)	hospital grade – disinfectant wipe or disinfectant sponge	
		(f)	household grade – disinfectant wipe or disinfectant sponge	
3	hospital grade disinfectant	(a)	disinfectant - hospital grade	
	Note: If the disinfectant is primarily for use as a spray—see item 8	(b)	hospital grade disinfectant	
4	household grade disinfectant	(a)	commercial grade disinfectant	
	Note 1: If the disinfectant is primarily for use	(b)	disinfectant - commercial grade	
	as a spray—see item 8	(c)	disinfectant - household grade	
	Note 2: Household grade disinfectants may be marketed and labelled as being for household and/or commercial use.	(d)	household grade disinfectant	
5	sanitary fluid	sani	sanitary fluid	
6	sanitary powder	sani	sanitary powder	
7	sanitiser	(a)	sanitiser	
		(b)	sanitising solution	
		(c)	antibacterial (together with a word or words indicating the nature of the goods)	
8	surface spray disinfectant	(a)	commercial grade – surface spray disinfectant	
		(b)	hospital grade – surface spray – disinfectant	
		(c)	household grade – surface spray disinfectant	

Column 1		Column 3
Item		Common names
		(d) surface spray disinfectant - commercial grade
		<ul><li>(e) surface spray disinfectant – hospital grade</li></ul>
		<ul><li>(f) surface spray disinfectant – household grade</li></ul>

15

#### 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.

#### 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 orig = original am = amendedp = page(s)para = paragraph(s)/subparagraph(s) amdt = amendment/sub-subparagraph(s) C[x] = Compilation No. xch = Chapter(s)pres = present cl = clause(s)prev = previous cont. = continued (prev...) = previouslydef = definition(s)pt = Part(s)Dict = Dictionary r = regulation(s)/Court rule(s) disallowed = disallowed by Parliament reloc = relocated div = Division(s)renum = renumbered exp = expires/expired or ceases/ceased to have rep = repealedrs = repealed and substituted gaz = gazettes = section(s)/subsection(s)/rule(s)/subrule(s)/order(s)/suborder(s) LA = Legislation Act 2003LIA = Legislative Instruments Act 2003 sch = Schedule(s)(md not incorp) = misdescribed amendment SLI = Select Legislative Instrument cannot be given effect SR = Statutory Rules mod = modified/modification sub ch = Sub-Chapter(s) No. = Number(s)sub div = Subdivision(s)

2019

sub pt = Subpart(s)

underlining = whole or part not

commenced or to be commenced

Ord = Ordinance

#### **Endnotes**

18

## Endnote 3—Legislation history

## **Endnote 3—Legislation history**

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019	29 Mar 2019 (F2019L00482)	31 Mar 2019	_
Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020	18 Dec 2020 (F2020L01650)	19 Dec 2020	_
Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021	1 Dec 2021 (F2021L01662)	1 Jan 2022	_
Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment Order 2025	22 Aug 2025 (F2025L00955)	23 Aug 2025	_

19

## **Endnote 4—Amendment history**

Provision affected	How affected
s 2	rep LA s 48D
s 4	am F2020L01650; F2021L01662; F2025L00955
s 8	rep LA s 48C
s 13	am F2020L01650; F2021L01662; F2025L00955
s 14	am F2020L01650; F2021L01662
s 14A	ad F2021L01662
s 16	am F2020L01650
Part 4	ad F2021L01662
s 17	ad F2021L01662
Schedule 1	am F2020L01650
Schedule 2	rep LA s 48C