



Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020

I, Meryl Clarke, as delegate of the Minister for Health, make the following order.

Dated 17 December 2020

Meryl Clarke
Assistant Secretary
Medical Devices Authorisation Branch
Health Products Regulation Group
Department of Health

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Schedules.....	1
Schedule 1—Amendments	2
<i>Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104)</i> <i>Order 2019</i>	2

1 Name

This instrument is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020*.

2 Commencement

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

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Note: See section 4.

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

1 Section 4 (definition of *Instructions*)

Repeal the definition, substitute:

Instructions means the *TGA instructions for disinfectant testing* (Version 2.1, March 2020) published by the Therapeutic Goods Administration, as in force or existing at 31 March 2020.

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

2 Subsection 13(4) (heading)

Repeal the heading, substitute:

Hospital grade disinfectant wipes or sponges for single use

3 Subsection 13(5) (heading)

Repeal the heading, substitute:

Hospital grade disinfectant wipes or sponges for multiple use

4 Subsection 13(6) (heading)

Repeal the heading, substitute:

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

5 Subsection 13(7) (heading)

Repeal the heading, substitute:

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

6 Subsection 14(2)

Repeal the subsection, substitute:

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 test 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

-
- (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.

7 Subsection 14(3) (heading)

Repeal the heading, substitute:

Household grade disinfectants that are surface spray disinfectants

8 Subsection 14(4) (heading)

Repeal the heading, substitute:

Household grade disinfectant wipes or sponges for single use

9 Subparagraph 14(4)(a)(i)

Omit “Option A or Option B”, substitute “Option C”.

10 Subsection 14(5) (heading)

Repeal the heading, substitute:

Household grade disinfectant wipes or sponges for multiple use

11 Subsection 14(6) (heading)

Repeal the heading, substitute:

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

12 Subsection 14(7) (heading)

Repeal the heading, substitute:

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

13 Subsection 16(2)

Omit “subsections (3) and (4),” substitute “subsections (3), (4) and (7),”.

14 Subparagraph 16(2)(i)(vii)

Repeal the subparagraph, substitute:

- (vii) for a disinfectant that contains chlorhexidine as an active ingredient—the words “Not to be used on skin”;

15 Subsection 16(4)

Repeal the subsection, substitute:

- (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.

16 Schedule 1 (item 2)

Repeal the item, substitute:

- | | | |
|---|-----------------------------|---|
| 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 |

17 Schedule 1 (item 8)

Repeal the item, substitute:

- | | | |
|---|----------------------------|---|
| 8 | surface spray disinfectant | (a) commercial grade – surface spray disinfectant |
| | | (b) hospital grade – surface spray – disinfectant |
| | | (c) household grade – surface spray disinfectant |
| | | (d) surface spray disinfectant – commercial grade |
| | | (e) surface spray disinfectant – hospital grade |
| | | (f) surface spray disinfectant – household grade |