



Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021

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

Dated 29 November 2021

Meryl Clarke
Assistant Secretary
Medical Devices Authorisation Branch
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021*.

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	1 January 2022.	1 January 2022

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

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 3.0, December 2021) published by the Therapeutic Goods Administration, as in force or existing at 1 January 2022.

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

2 Section 4

Insert:

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.

3 Subsection 13(2)

Omit “test” (first occurring).

4 Subsection 14(2)

Omit “test” (first occurring).

5 After section 14

Add:

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.

6 After Part 3

Add:

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.