



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Disinfectant Claim Guide - specific claims and non-specific claims

Information on the different ways the Therapeutic Goods Administration (TGA) regulates disinfectants depending on the intended use and label claims.

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Disinfectant claim guide

The regulation of disinfectants depends on the claims made by the product on labels, packaging and product information leaflets including websites.

Virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as "**specific claims**". Products that make specific claims are required to be Listed in the ARTG prior to their supply. The testing set out in the [TGA instructions for disinfectant testing \(https://www.tga.gov.au/node/289689\)](https://www.tga.gov.au/node/289689) must be conducted to validate specific claims.

Claims of general antibacterial action or activity against vegetative bacteria (excluding mycobacteria) covered by the battery of test organisms included in the TGA Disinfectant test, or bacteria of the same genus, are known as "**non-specific claims**". If label claims are made for vegetative bacterial species in addition to or other than those covered by the required test organisms, the testing as set out in the [TGA instructions for disinfectant testing \(https://www.tga.gov.au/node/289689\)](https://www.tga.gov.au/node/289689) must be conducted using these additional organisms.

A claim of residual activity (such as "protects for up to 24 hours") is considered to be a specific claim which requires review by the TGA. All claims made about residual effectiveness must be substantiated with testing data that meets the requirements set out in the [TGA instructions for disinfectant testing](https://www.tga.gov.au/node/289689) (<https://www.tga.gov.au/node/289689>).

Note

The claim "antibacterial action is subject to an industry Code of Practice - contact your relevant industry association for more information.

Note

Products where claims are limited specifically to activity against "moulds" are excluded goods and are not regulated under the *Therapeutic Goods Act 1989* and TGO 104.

The following table provides a guide to commonly used claims for disinfectant products to assist sponsors in determining the regulatory pathway for a product, based on the claims made and the manufacturer's intended use for the product.

General cleaning products and sanitisers are only exempt in the absence of other listable claims. In addition, products that are intended exclusively for the destruction of moulds are excluded.

This guide is not intended to be an exhaustive list of allowable claims. Sponsors may use other wording for claims that do not contradict the table, for example, claims for 'germicidal' action may be labelled as 'bactericidal'.

Note

Sponsors of disinfectant products must comply with the [TGA Advertising Code \(https://www.tga.gov.au/node/288202\)](https://www.tga.gov.au/node/288202), at all times.

Product type	Claim	Definition	Regulatory pathway
Hospital grade disinfectant, Household / commercial grade disinfectant	Active against polio	Specific claim	Listable
	Active against TB/kills TB	Specific claim	Listable
	Active against mycobacteria/kills mycobacteria	Specific claim	Listable
	Kills/destroys mould	Specific claim	Listable*
	Kills fungi (yeast and mould)	Specific claim	Listable
	Kills spores	Specific claim	Listable
	Kills viruses	Specific claim	Listable
	Residual activity/efficacy	Specific claim	Listable
	Bacteriostatic action	Non-specific claim	Exempt*
	Active against gram + or gram - bacteria	Non-specific claim	Exempt
Controls/reduces/removes mould	Non-specific claim	Exempt*	
Effective against bacteria	Non-specific claim	Exempt	

Product type	Claim	Definition	Regulatory pathway
	Germicidal	Non-specific claim	Exempt
	Kills bacteria/germs	Non-specific claim	Exempt
	Kills bacterial growth	Non-specific claim	Exempt
	Kills E coli	Non-specific claim	Exempt
	Kills Pr vulgaris	Non-specific claim	Exempt
	Kills Ps aeruginosa	Non-specific claim	Exempt
	Kills S aureus	Non-specific claim	Exempt
	Kills S typhosa	Non-specific claim	Exempt, but testing must include S typhosa
	Kills/destroys salmonella	Non-specific claim	Exempt, Salmonella sp must be included in the test battery
Sanitiser - as defined in TGO 104	Antibacterial action	Non-specific claim	Exempt*
	Bacteriostatic action	Non-specific claim	Exempt*
	Inhibits bacteria	Non-specific claim	Exempt*

Product type	Claim	Definition	Regulatory pathway
	Removes/reduces bacteria	Non-specific claim	Exempt*
	Mildew control	Non-specific claim	Exempt*
General cleaner	Kills/destroys mould/mildew	Non-specific claim	Excluded
General cleaner - wipe/sponge	Anti-bacterial	Not a regulated claim	Not regulated by the TGA
A sanitiser that does not meet the definition in TGO 104 and that does not make disinfectant or specific claims	Reduces/removes bacteria	Not a regulated claim	Not regulated by the TGA
	Bacteriostatic/inhibits bacteria	Not a regulated claim	Not regulated by the TGA
	Deodorises	General consumer product	Not regulated by the TGA
	Kills/reduces bacteria within the wipe/sponge	General consumer product	Not regulated by the TGA

* Only in the absence of other listable claims. Products that are intended exclusively for the destruction of moulds are excluded.

Topics:

Disinfectants/Sterilants (<https://www.tga.gov.au/products/other-therapeutic-goods/disinfectantssterilants>)