



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

DRAFT ALLOWABLE CLAIMS GUIDE FOR HOSPITAL GRADE & HOUSEHOLD/COMMERCIAL GRADE DISINFECTANTS

Common Name	Action	Requirements for including in ARTG as listable product	TGO 54 Requirements	Guidelines Reference
Hospital Grade with specific claims	Sporicidal	Sponsors must ensure that they hold entire data to verify sporicidal claims made. This data must be submitted for safety evaluation with the application for listing.	3(1)(a), (b) or (c)	A.4, A.4.17 A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
	Tuberculocidal	Sponsors must ensure that they hold entire data to verify tuberculocidal claims made. This data must be submitted for safety evaluation with the application for listing.	3(1)(a), (b) or (c)	A.4, A.4.12 – 4.16, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
	Virucidal	Sponsors must ensure that they hold entire data to verify anti viral claims made and sponsors are required to present a certificate with application for listing to show acceptable test results when tested in accordance with TGO 54. Where claims are made in relation to activity against blood borne viruses eg HIV, HBV or HCV, supplementary data must be provided for safety evaluation with the application for listing.	3(1)(a), (b) or (c)	A.4, A.4.6 – 4.11, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
	Fungicidal	Sponsors must ensure that they hold entire data to verify anti fungal claims made and sponsors are required to present a certificate with application for listing to show acceptable test results when tested in accordance with TGO 54.	3(1)(a), (b) or (c)	A.4, A.4.5, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
Household/ Commercial Grade with specific claims	Sporicidal	Sponsors must ensure that they hold entire data to verify sporicidal claims made. This data must be submitted for safety evaluation with the application for listing.	3(2)(a), (b) or (c)	A.5, A.4.17, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
	Tuberculocidal	Sponsors must ensure that they hold entire data to verify tuberculocidal claims made. This data must be submitted for safety evaluation with the application for listing.	3(2)(a), (b) or (c)	A.5, A.4.4, A.4.12 - 4.16, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)

Common Name	Action	Requirements for including in ARTG as listable product	TGO 54 Requirements	Guidelines Reference
Household/ Commercial Grade with specific claims	Virucidal	Sponsors must ensure that they hold entire data to verify anti viral claims made and sponsors are required to present a certificate with application for listing to show acceptable test results when tested in accordance with TGO 54. Where claims are made in relation to activity against blood borne viruses eg HIV, HBV or HCV, supplementary data must be provided for safety evaluation with the application for listing.	3(2)(a), (b) or (c)	A.5, A.4.6 – 4.11, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
	Fungicidal	Sponsors must ensure that they hold entire data to verify anti fungal claims made and sponsors are required to present a certificate with application for listing to show acceptable test results when tested in accordance with TGO 54.	3(2)(a), (b) or (c)	A.5, A.4.5, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
Hospital Grade, with non-specific Claims	Bactericidal	Sponsors must ensure that they hold data to verify bactericidal claims made and sponsors are required to present a certificate with application for listing to show acceptable test results when tested in accordance with TGO 54. If labelling claims are made outside of the standard test battery, the test certificate should indicate which bacteria have been tested against.	3(1)(a), (b) or (c)	A.4.1 - 4.3, A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)
Exempt products household/commercial grade disinfectants without specific claims, sanitisers and sanitary products		Not required to be included in ARTG Sponsors/manufacturers are required to hold evidence of compliance with performance requirements	Labelling requirements (TGO 54) Performance 3(2)	A.5 A.6 (surface sprays) A.7 (cloth wipes – single use) A.8 (cloth wipes – multiple use)

The term ‘**specific claim**’ is currently defined in the TGA document *Guidelines for the Evaluation of Disinfectants* as **one which covers virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity**.

A ‘**non-specific claim**’, is a claim which includes general antibacterial action or activity against vegetative bacteria (excluding mycobacteria) covered by the battery of test organisms included in the specified test, or bacteria of the same genus. Claims for bacteria other than these are allowable, but the specific organism against which activity is claimed must be included as an extra organism in the test battery *eg E. coli 0157, Salmonella spp, Streptococcus spp etc*