



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**Summary of regulation of disinfectants and sterilants**

Product Category		ARTG Status	Requirements	GMP Licensing
A	Sterilant	<i>Registrable</i> (Schedule 3 Part 2)  [ <i>Now Included Medical Devices Class IIb</i> ]	TGOs54, 54A & 54B +AUST R  [ <b>New Medical Device Standard Order based on TGO 54 drafted</b> ]	Manufacturer Licensing Required  <b>Conformity Assessment Certification required</b>
B	Instrument grade disinfectants - high level - intermediate level - low level			
C	Hospital grade disinfectants - with specific claims	<i>Registrable</i> (Schedule 3 Part 2)  [ <b>Proposed to be Listable</b> ]	TGOs54, 54A 54B +AUST R  [ <b>Updated TGO 54 &amp; Guidelines</b> ]	Not Required
D	Household/commercial grade disinfectants - with specific claims			
E	Hospital grade disinfectants - without specific claims	<i>Listable</i>	TGOs54, 54A & 54B + AUST L [ <b>Updated TGO 54 &amp; Guidelines</b> ]	Not Required
F	Household /commercial grade disinfectants - without specific claims - <b>new chemical entity</b>	<i>Exempt</i>  [ <b>Proposed to be Listable</b> ]	TGOs54, 54A & 54B [ <b>Updated TGO 54 &amp; Guidelines</b> ]	Not Required
G	Household /commercial grade disinfectants - without specific claims	<i>Exempt</i>	TGOs54, 54A & 54B [ <b>Updated TGO 54 &amp; Guidelines</b> ]	Not Required
H	Sanitisers *	<i>Exempt</i>  [ <b>Proposed to be Excluded</b> ]	TGOs54 & 54A & 54B  [ <b>Not Required if Excluded</b> ]	Not Required
I	Sanitary fluid *			
J	Antibacterial clothes preparation *			

The term ‘**specific claim**’ is currently defined in the TGA document ‘Guidelines for the Evaluation of Sterilants and 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.

\* Proposed to be excluded from TGA’s controls under Section 7 of the Therapeutic Goods (Excluded Goods) Order.