Understanding Disinfectants in Practice: TGA Requirements, Contact Time and Efficacy Standards

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Overview

- Why this all matters
- Different efficacy tests including key requirements and considerations
- Limitations and future improvements

Hopefully, you will understand more about TGA requirements and what your products are claiming to do!

Why is disinfection important?

- Ability to kill/inactivate microorganisms
- Stop transmission of pathogens and decrease infection risk
- Keep patients and staff safe
- Various methods using both chemicals and more physical methods
- Detergents are not enough
- If you are using a disinfectant incorrectly you might as well not be using it at all!

Why is efficacy testing important?

- Performs as intended under expected usage conditions
- Provide reliable information to give end user assurance
- Keep updated with new testing methods
- Validation of claims and agreement of definitions
- Informs correct use of product
- Contact time and concentration key considerations

The TGA and ARTG

A disinfectant is classed as a *therapeutic good* in Australia when it is *intended to kill or remove harmful microorganisms*

Companies must:

1) Register or list the product on the ARTG
2) Provide evidence of efficacy
3) Demonstrate safety
4) Comply with labelling requirements
5) Maintain ongoing compliance

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

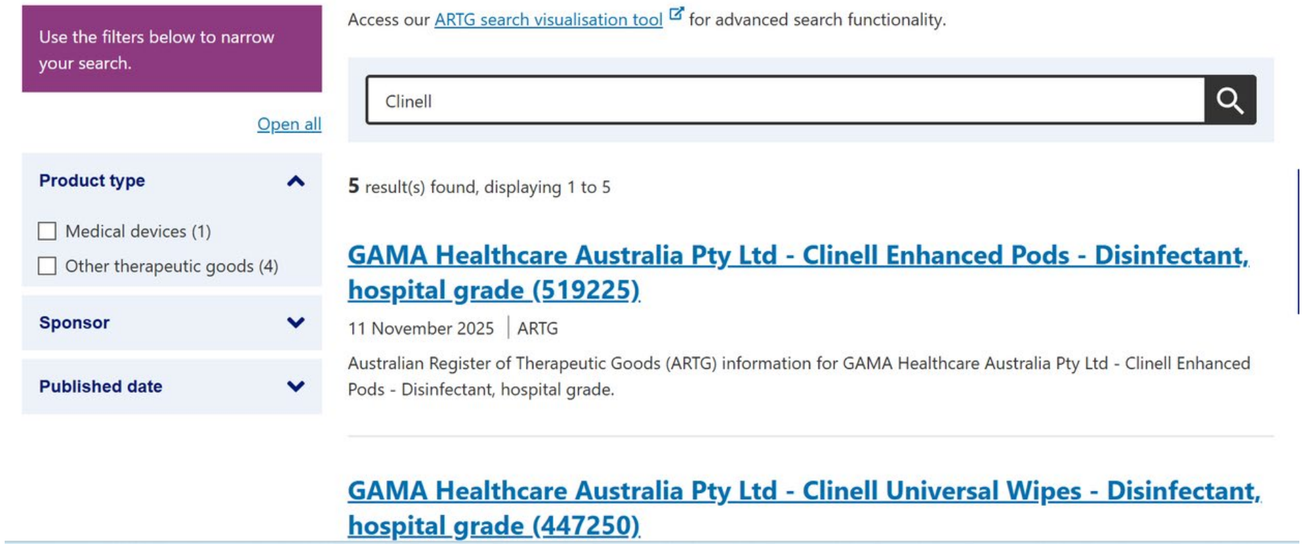
**Products that simply clean (remove dirt) are not regulated by TGA

The TGA and ARTG

Listed versus registered products - what's the difference?

You can look and verify products on https://www.tga.gov.au/resources/artg

Legally what can products claim? Antibacterial? Virucidal?



Label requirements

Products require correct mandatory labelling including:

- Active ingredients
- Contact time
- Direction for use
- Dilution

What is contact time?

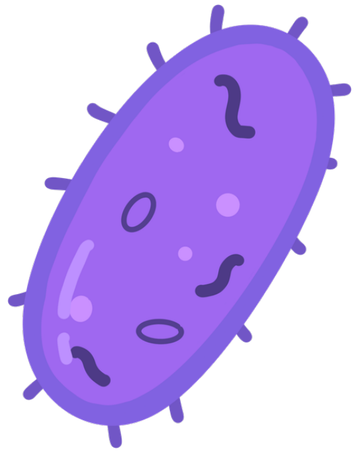
Duration a disinfectant must remain wet on a surface to effectively kill microorganisms

Factors affecting contact time:

- Surface type
- Organic load
- Temperature, humidity, product concentration
- Application method

Common mistakes include wiping too early and using incorrect dilutions!

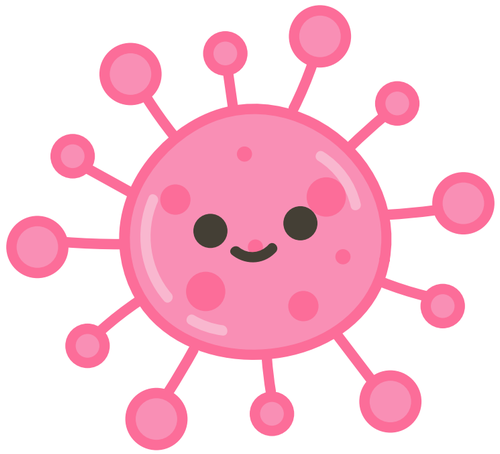
Hardest to kill



Bacterial spores

Mycobacteria

Non-enveloped viruses



Fungi

Vegetative bacteria

Enveloped viruses

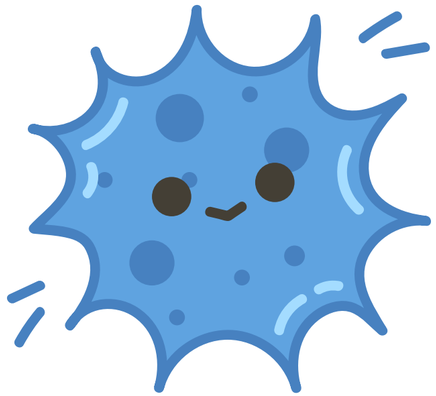
Easiest to kill

Key considerations for standard testing procedures

Neutralisation

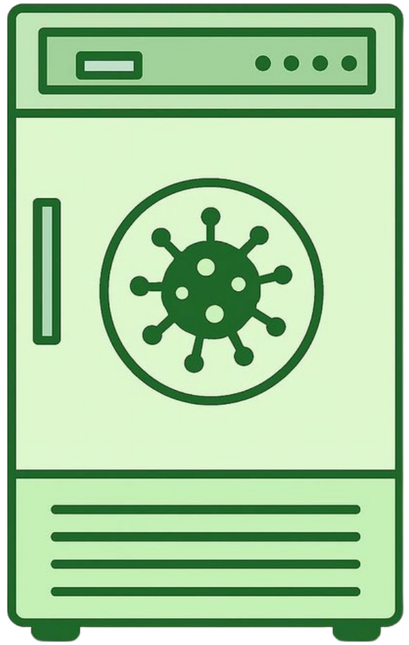
Level of Soiling

Test Organisms



Contact Time

Other conditions to be aware of

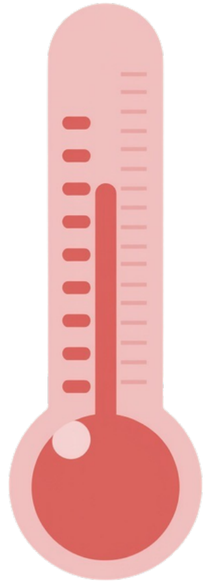


Media and storage

Sterile hard water - diluent

Dilutions - temperature

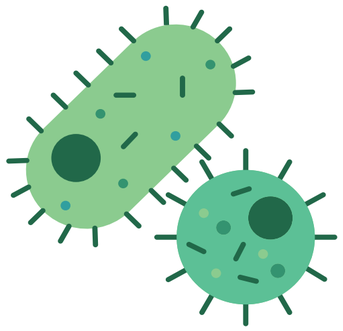
Controls - validation claims



The TGA disinfectant test

All hospital disinfectants must pass at least pass under dirty conditions

Pseudomonas aeruginosa	*Proteus vulgaris*	*Staphylococcus aureus*	*Escherichia coli*



Dirty and clean conditions

Number of challenges = 2

This differs for household -based disinfectants

The TGA disinfectant test

Prepare bacterial inoculum

Check you have the current amount of bacteria

Dilute disinfectant

Mix diluted disinfectant with bacterial culture

After 8 minutes take out a sample and plate

After 10 minutes add more bacteria into disinfectant

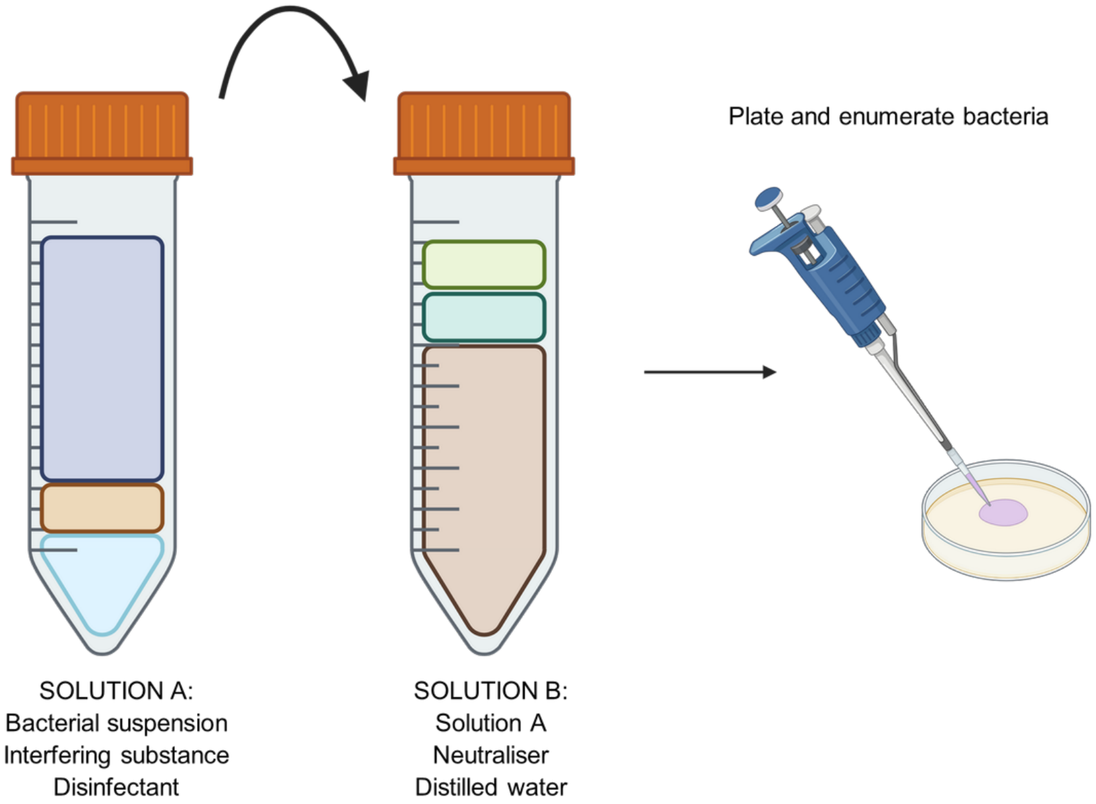
After 18 minutes take another sample and plate

No growth in 2/5 recovery broths = PASS

Suspension testing

Specific contact time claims

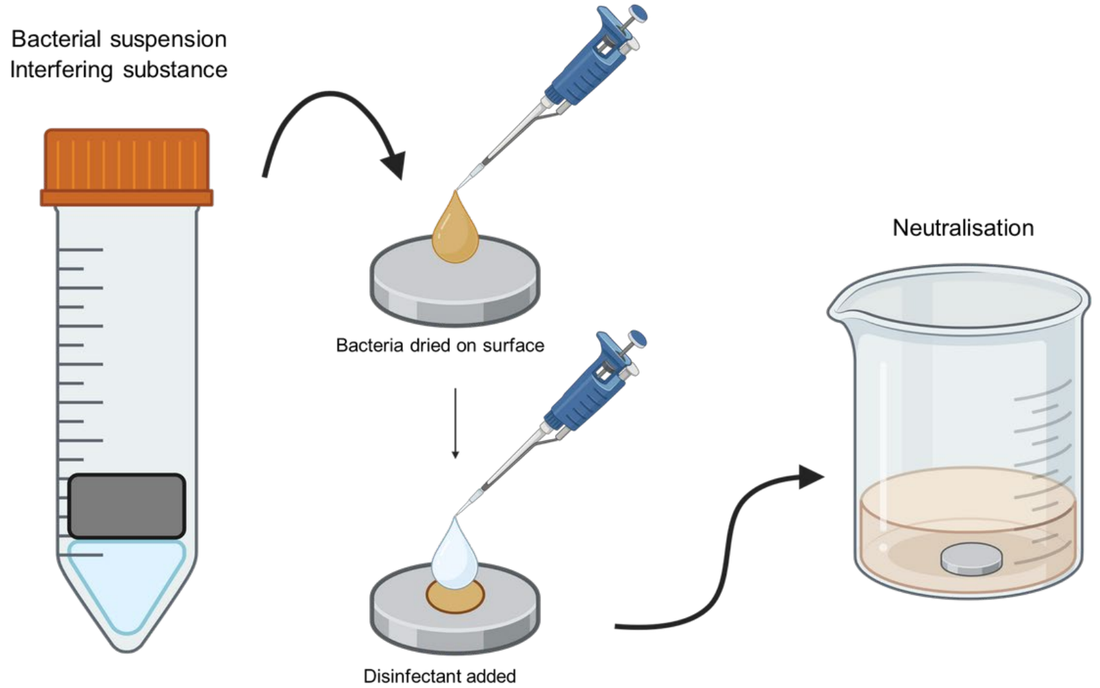
EN 13727
Planktonic liquid suspension
Disinfectant added directly to bacterial solution
5 log10 pass criteria



Carrier testing

For products used on surfaces

ASTM E2111 | ASTM E2197 | EN 14561
Minimum 5 log10 required
Bacteria dried onto surface
AOAC = no growth in 59/60 carries per organism



Sporicidal testing

For products effective against *bacterial spores*

- Requires quantitative carrier or suspension test
- Must achieve 6 -log10 reduction
- Organisms include Clostridium sporogenes and Bacillus subtilis*
- EN16615 (4-field), EN 17126 (suspension), EN2197 (carrier)

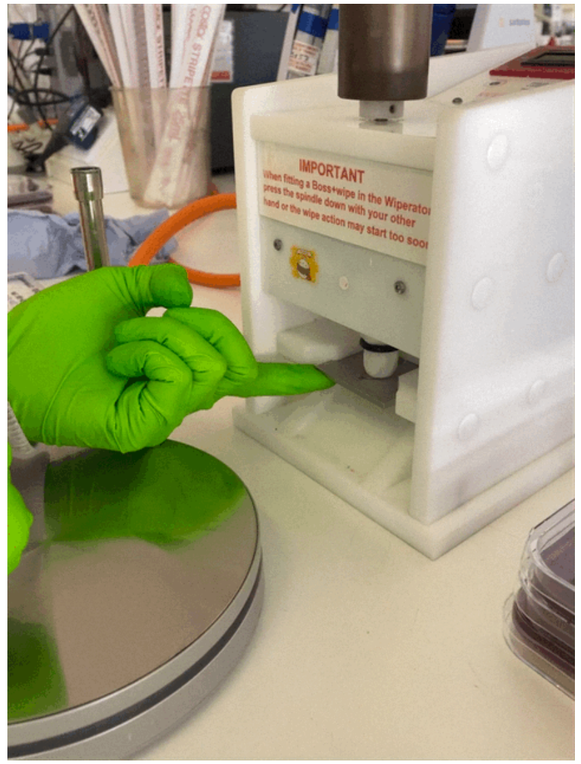
Disinfectant wipe testing

Products claiming surface disinfection *not* *solely activity of wipe itself*

Pass suspension test with wipe extract

Pass most stringent simulated in -use test (EN16615)

ASTM E2967-15 (Wiperator - **withdrawn**)



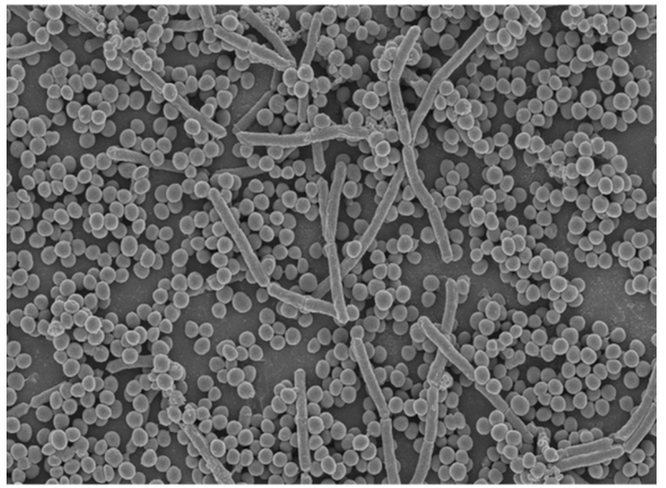
Residual activity

PAS 2424:2014

- Companies wanting to claim up to maximum 30 days residual activity
- Requires 3 log10 reduction
- Test suspension inoculated onto surface followed by disinfectant
- Dry and wet abrasion cycles
- Re-contamination of surface
- Repetition
- Enumeration when finished

Limitations of current standards

- Variance between geographical areas
- Australian TGA provide stringent and specific requirements
- How do they place in real world scenarios?
- Recontamination of surfaces - TGA improvements?
- Focus on log reduction only
- Limited test materials used
- Bacteria are typically found in biofilms in the environment



What to do in an outbreak?

Choose the right product and application!

High level disinfection must be used - sporicidal product

Increase normal concentrations used

PAA products are sustainable, non -toxic and eliminate resistant organisms

Bacteria in biofilm from outbreaks will not respond to chlorine -based products

Key takeaways

Verify listing with ARTG before purchase

Follow label instructions!

Match the appropriate product to task and risk level

Document disinfection practices

Thank you for listening!

Any questions?

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