



S-7XTRA® Label Compliance Information

AUST R 463988 | AUST L 232011 | AUST L 232014

Range of Use

S-7XTRA® is a dual-purpose, combined cleaner/disinfectant designed for its exceptional materials compatibility and the tri-effect of “Break, Treat, Prevent”.

In all environments where there is a risk of microbial contamination including healthcare, shared office spaces, transport, aged care, and early childhood education and schools, S-7XTRA® is suitable for use as a two-in-one step solution for environmental surface cleaning and disinfection or as part of a controlled cleaning and disinfection protocol for non-invasive medical devicesⁱ.

Therapeutic Goods Administration (TGA) assessed and registered as a Class IIb medical device, S-7XTRA® has undergone rigorous testing and is proven to be bactericidal, virucidal, fungicidal, yeasticidal, and sporicidal against bacillus subtilisⁱⁱ on non-invasive medical devices and environmental surfaces.

S-7XTRA® is also proven mycobactericidal (including tuberculocidal) and sporicidal (including against Clostridioides Difficile - also known as Clostridium Difficile or C. diff) on environmental surfaces *only*.

S-7XTRA® is the simpler, smarter, safer choice for best-practice infection prevention and control.

Features and Benefits

All Surface Types

- Two-in-one step cleaning and disinfection.
- Non-corrosive, non-viscous, and pH neutral – gentle on most skin typesⁱⁱⁱ.
- Triple-active ingredients reduce the risk of anti-microbial resistance.
- Works in dirty conditions (e.g., organic soiling, blood, proteins).
- Non-residual organoleptic effect on food.
- Low toxicity, low odour, and fragrance-free (unless FRESH).
- Excellent materials compatibility with non-porous and porous^{iv} materials – refer to 02-05-04.

Non-invasive Medical Device^{iv}

- Suitable for use in a user defined AS5369:2023 cleaning and disinfection protocol for reprocessing of reusable non-invasive medical devices and patient care equipment in conjunction with instructions from the relevant equipment or device Original Equipment Manufacturer (OEM).



Environmental Surfaces

- Liquid formats available in unscented and scented ginger and green tea 'FRESH' range (5L Concentrate and 5L Ready to Use).
- Reactive Barrier Technology™ – there is no need to maintain wet contact times.

Residual Activity on Environmental Surfaces

Formulated to have Reactive Barrier Technology™, S-7XTRA® keeps working after it dries so there's no need to maintain 'wetness' during the exposure phase to be fully effective on environmental surfaces.

S-7XTRA® provides residual surface protection for bacteria, SARS-CoV-2 (COVID-19) and yeast for 24 hours. When contact is made with water, S-7XTRA® reactivates to kill pathogens for superior protection.

In addition, S-7XTRA® has biostatic activity inhibiting pathogen growth on treated environmental surfaces for bacteria and SARS-CoV-2 (COVID-19) for up to 72 hours.

Formats

S-7XTRA® is available in three formats and in a range of sizes / quantities for use on non-invasive medical devices and environmental surfaces.

Refer to the tables on in the 'Microbiocidal Activity' section for the range of pathogens applicable to each format and type of use.

Format	Size	Product Code
S-7XTRA® Concentrate	5L container	S7XCON
S-7XTRA® FRESH Concentrate^v	5L container	S7XFCON
S-7XTRA® Ready-to-Use (RTU)	5L container	S7XRTU5L
	750ml trigger spray	S7XRTU750
	500ml squeeze bottle	S7XRTU500
	500ml trigger spray	S7XRTU500T
S-7XTRA® FRESH Ready-to-Use^v	5L container	S7XFRTU5L
S-7XTRA® Wipes	Pillow pack x80	S7XPW80
	Pillow pack x100	S7XPW100
	Tub x200	S7XW200

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Active Ingredients

Ingredient	Concentrate	Ready-to-use ^{vi} and Wipes
Benzalkonium chloride	0.90% w/w	0.09% w/w
Polyhexamethylene biguanide	0.90% w/w	0.09% w/w
Didecyldimethyl-ammonium chloride	1.47 % w/w	0.147% w/w

Regulatory Compliance

S-7XTRA® has been assessed separately by the TGA for the purpose of inclusion in the Australian Register of Therapeutic Goods (ARTG) as:

- **a hospital-grade disinfectant with claims** for use on environmental surfaces in accordance with Chapter 3 of the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990*, and *Therapeutic Goods (Standard for Disinfectants and Sanitary Products (TGO 104) Order 2019*, and
- **a class IIb medical device** intended for use as a disinfectant for non-invasive medical devices, including conformity assessment of the Quality Management System (QMS) for S-7XTRA®, in accordance with Chapter 4 of the *Therapeutic Goods Act 1989*, and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

S-7XTRA® has been authorised by the TGA and included in the ARTG as:

- a registered “class IIb medical device”, excluding ‘FRESH’, under entry AUST R 463988, and
- an “Other Therapeutic Good – Listed Disinfectant”, including ‘FRESH’, under entries:
 - AUST L 232014 – wipes and RTU, and
 - AUST L 232011 – Concentrate.

The public summaries for S-7XTRA® can be viewed and downloaded from the ARTG on the TGA website at <https://www.tga.gov.au/resources/artg>.

Handling and Storage

S-7XTRA® products should be stored in original containers between 4°C and 30°C in a dry place away from direct sunlight.

Avoid contact with eyes.

May cause skin irritation:

- S-7XTRA® Ready to Use and Wipes may cause skin irritation for people with sensitive skin types or with prolonged use. If irritation occurs, appropriate Personal Protective Equipment (PPE) should be worn.
- S-7XTRA® Concentrate may cause skin irritation. Appropriate PPE (e.g., gloves and eye protection) should be worn when diluting and handling.

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Keep out of reach of children and animals.

Do not mix with other chemicals.

Not intended for use on invasive or surgically invasive medical devices.

Disposal

Used, expired, or unwanted S-7XTRA® (all formats) must be disposed of in accordance with local waste management regulations.

Care must be taken to avoid release of S-7XTRA® into environment or waterways as some ingredients are toxic to aquatic life with long lasting effects.

Packaging may be disposed of or recycled in general waste.

All plastic packaging materials are made from High Density Polyethylene (HDPE) and can be recycled.

First Aid and Other Precautions

If skin irritation occurs, rinse with clean water and wear suitable PPE.

If eyes are exposed, flush immediately with clean water for several minutes.

If ingested, do not induce vomiting and seek medical advice.

For advice or information, contact a Poisons Information Centre: Australia 131 126; New Zealand - 0800 764 766

Refer to individual format Safety Data Sheets for further information on first aid, physical properties, and other relevant information.

Safety Data Sheet

The Safety Data Sheets (SDS) for S-7XTRA® can be viewed and downloaded from the Steri-7 website at <https://www.steri-7.com.au/biosecurity/td>.

Endnotes

ⁱ AS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*.

ⁱⁱ S-7XTRA® Concentrate and RTU only.

ⁱⁱⁱ Ready-to-use products only – S-7XTRA® Concentrate has higher pH and may cause corrosion with prolonged exposure. Refer to 'Handling and Storage' instructions for precautions.

^{iv} When using S-7XTRA as a Medical Device Disinfectant, it should not be applied to soft surfaces / textiles.

^v For environmental surfaces only.

^{vi} "Ready-to-Use" includes concentrate that has been diluted at a rate of 1:9 in accordance with the IFU.

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