

STERI-7[®]



S-7XTRA

**CLEANER / DISINFECTANT FOR
NON-INVASIVE MEDICAL DEVICES AND
ENVIRONMENTAL SURFACES**

TECHNICAL INFORMATION AND INSTRUCTIONS FOR USE

AUST R 463988 | AUST L 232011 | AUST L 232014

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Technical Information

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.

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.

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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

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

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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.

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.

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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>.

Microbiocidal Activity

S-7XTRA® has been rigorously tested for use in medical, institutional (e.g., offices), food, and domestic environments using industry-standard testing methodologies to simulate real-world use. Refer to the tables below for targeted pathogens and required contact times for different areas of use.

Table 1: Non-Invasive Medical Devices

S-7XTRA® is proven bactericidal, virucidal, fungicidal and yeasticidal in dirty conditions and is intended for use on non-invasive medical devices (excluding 'FRESH') against pathogens in the formats indicated by the table below.

Pathogen	Contact Time	RTU 5L & Squeeze	RTU Trigger Spray	Wipes
Bacteria				
Enterococcus hirae	5 mins	✓	✓	✓
Escherichia coli (E. coli)	5 mins	✓	✓	✓
Pseudomonas aeruginosa	5 mins	✓	✓	✓
Staphylococcus aureus	5 mins	✓	✓	✓
Methicillin-Resistant Staphylococcus aureus (MRSA)	5 mins	✓		✓
Proteus vulgaris	5 mins	✓		✓
Salmonella typhimurium	5 mins	✓		✓
Fungi & Yeast				
Candida albicans	5 mins	✓	✓	✓
Aspergillus brasiliensis	20 mins	✓		✓
Viruses				
Vaccina Virus Ankara (MVA)	5 mins	✓	✓	✓
SARS-CoV-2 (COVID-19) (Murine hepatitis virus surrogate)	5 mins	✓	✓	✓
Poliovirus (Murine norovirus S99 surrogate)	5 mins	✓	✓	
Adenovirus	5 mins	✓	✓	
Norovirus (Murine norovirus S99 surrogate)	5 mins	✓	✓	
Spores				
Bacillus subtilis	5 mins	✓	✓	

Notes:

- a) ✓ indicates the format has been proven effective and is intended for use against the target pathogen.
- b) RTU 5L and squeeze includes use of S-7XTRA® by flooding, mopping, or pouring.
- c) S-7XTRA® Concentrate must be diluted in accordance with the instructions for "Intermediate-high risk environments including non-invasive medical devices" in Table 5.1 S-7XTRA® Concentrate to achieve the results indicated by Table 1.



Table 2.1: Environmental Surfaces

All formats of S-7XTRA®, including 'FRESH', are bactericidal, virucidal, fungicidal, yeasticidal, mycobactericidal (including tuberculocidal) and sporicidal against pathogens on environmental surfaces in accordance with the table below.

Pathogen	Contact Time
Bacteria	
Acinetobacter baumannii	1 min
Campylobacter jejuni	5 min
Enterococcus faecium	1 min
Enterococcus hirae	45 sec
Escherichia coli (E. coli)	30 sec
Klebsiella pneumoniae (CRE)	1 min
Listeria monocytogene	30 sec
Methicillin-Resistant Staphylococcus Aureus (MRSA)	45 sec
Pseudomonas aeruginosa	45 sec
Rhodococcus equi	1 min
Salmonella choleraesuis	1 min
Salmonella enteritidis	1 min
Salmonella typhimurium	30 sec
Staphylococcus aureus	45 sec
Fungi & Yeast	
Aspergillus brasiliensis	5 mins
Aspergillus fumigatus	5 mins
Candida albicans	5 mins
Penicillium	5 mins
Trycophyton species (Atheletes foot, Tinea)	5 mins
Viruses	
Vaccina Virus Ankara (MVA)	5 mins
SARS-CoV-2 (COVID-19) (Murine hepatitis virus surrogate)	5 mins
Norovirus (Murine norovirus S99 surrogate)	5 mins
Adenovirus	5 mins
Poliovirus (Murine norovirus S99 surrogate)	5 mins

Pathogen	Contact Time
Influenza A (H1N1)	5 mins
Parvovirus	30 mins
Mycobacteria	
Mycobacterium avium	5 mins
Mycobacterium terrae (tuberculosis)	5 mins
Bacterial Spores	
Clostridium difficile	1 min
Clostridium perfringens	5 mins
Bacillus subtilis	5 mins

Table 2.2: Residual Activity

S-7XTRA® Reactive Barrier Technology™ provides residual surface protection against bacteria, yeast, and SARS-CoV-2 (COVID-19) on environmental surfaces *only* for up to 24 hours.

Reactive Barrier Technology™ also provides additional biostatic activity inhibiting pathogen growth on treated environmental surfaces *only* for bacteria and SARS CoV-2 (COVID-19) for up to 72 hours.

Pathogen	Residual Protection	Biostatic Activity
Bacteria		
Enterococcus hirae		
Escherichia coli (E. coli)	24 hours	72 hours
Pseudomonas aeruginosa		
Staphylococcus aureus		
Yeast		
Candida albicans	24 hours	72 hours
Viruses		
SARS-CoV-2 (COVID-19) (Murine hepatitis virus surrogate)	24 hours	72 hours

Materials Compatibility

S-7XTRA® has been meticulously tested for materials compatibility with a range of surface types using industry-standardised and customised laboratory testing methodologies and long-range studies.

S-7XTRA® is found safe and effective for use on non-porous surfaces, and some porous materials.

Table 3: Approved Medical Device Compatibility

OEMs of reusable medical devices are responsible for developing instructions for reprocessing, including approval of cleaning and disinfection products.

The table below contains current approved compatibility from OEMs as at the Issue Date of this document.

Before using S-7XTRA®, users should refer to the Instructions For Use (IFU) provided by the relevant medical device OEM for cleaning and disinfection instructions.

S-7XTRA® is intended for use on non-invasive medical devices.

Manufacturer	Types of Medical Device / Equipment Approved
Braun	Temperature scanners – Thermoscans.
Canon Toshiba^{vii}	– Ultrasound equipment and probes – Aplio Series, Viamo Series, Xario Series.
Carrflex	Specialist chairs and exam beds.
GE Healthcare^{vii}	Extensive range of medical devices and equipment including neonatal care equipment, ultrasound equipment and probes, and patient monitoring equipment – Carestation 620/650/650c/750/750c, MAC 7, MAC VU360, KISS plus, MAC2000, MAC5, Sonographe, Crystal Nova, Essential, Pristina, Crystal, Giraffe Carestation Incubator, Giraffe Omnibed, Carescape One Monitor, Patient Monitoring B105/B125/B105P/B125P/B105M/B155M, Carescape Canvas 1000, Canvas D19, Canvas Smart Display, Parameter SpO2, Patient Monitoring Oxinox Trunk Cables, Trusignal SpO2 Sensors (interconnect cables & finger/wrap/ear sensors), soft sensors, Tec 820/850, Ultrasound LOGIQ E10/E10s, E9, Fortis P10, P9, P8, P7, Vivid E9, LOGIQ S7 R3, S7 xdclear LOGIQ S8 R4, Venue, Voluson SWIFT, SWIFT+, Voluson P6/P8, BT15/16/18/22, Vscan Extend, Invenia ABUS, ABUS 2.0 .
Fujifilm SonoSite	Ultrasound Equipment – including Edge II, S-Series, SII, M-Turbo, Mini-Dock. Ultrasound Probes – C10-3, C11n, C11x, C11xp, C35x, C35xp, C5-1, C60, C60x, C60f, C60xi, C60xp, C8x, ECG Cable (Grey), HFL38, HFL38xi, HFL38xp, HFL50, HFL50x, HSL25x, HSL25xp, IC10-3, ICTn, ICTx Rev 80 and below, ICTx Rev 81 and above, ICTx Rev 21 and below, ICTx Rev 22 and above, L25n, L25v, L25x, L25xp, L38m, L38x, L38xi, L38xp, L52n, L52x, P10x, P10xp, P21n, P21v, P21x, P21xp, P5-1, rC60xi, rP19x, rP19xp, SLAx.
Fresenius Kabi^{vii}	Infusion pumps – Agilia range.
Mindray^{vii}	Ultrasound monitors, equipment, and probes.
Philips^{vii}	Ultrasound equipment and probes.
Verathon Medical	Ultrasound equipment – BladderScan i10, BVI 9400.

Table 4: General Materials Compatibility

S-7XTRA® has been tested for compatibility with a range of materials used in environmental surfaces.

The table below is non-exhaustive and may be used to assist in making compatibility decisions based on material of construction.

Material / Group	Commonly used in
Carbon graphite	Most manufactured goods – ultrasound machines, patient monitoring equipment, aircraft.
Ceramics, tile, grout	Bathrooms, kitchens, floors, dental prosthesis.
Closed cell foam	Air filters, specialty sponges, protective covers, helmets.
Dartex® – polyurethane (PU) textile	Mattresses, mattress covers, wearable healthcare products, drapes.
Gas permeable cellulose acetate butyrate (CAB)	Contact lenses.
Textiles	Cotton, wool, nylon.
Glass and fiberglass	Windows, vials.
Laminate	Floors, fixtures, furniture.
Leather (incl. synthetic)	Chairs, furniture, specialist chairs, exam beds.
Metal	Soft and hard metals including stainless steel, copper, aluminum, brass, titanium, nickel, chrome, chrome plate.
Painted surfaces	Walls, equipment, furnishings.
Plastics <ul style="list-style-type: none"> • Polypropylene • Polyurethane • Polyethylene • Polycarbonate • PVC acrylic 	Most manufactured goods – hard, flexible, transparent plastics.
Tedlar® – polyvinyl fluoride (PVF)	Surface film coating used in internal and external aircraft surfaces.
Rubber	Most manufactured goods – rubber seals, hoses, tubes
Vinyl	Furnishings, equipment, floors.
Wood	Raw and varnished – furniture, floors.

To enquire on materials compatibility for specific materials and non-invasive medical devices, please contact our team.

S-7XTRA® Instructions for Use

The instructions for use in Tables 5.1 – 5.3 apply to non-invasive medical devices and environmental surfaces.

When using S-7XTRA® to reprocess reusable, non-invasive medical devices under an AS 5369:2023 compliant cleaning and disinfection protocol, users should refer to and comply with:

- the IFU for the relevant medical device provided by the OEM,
- the procedures and work instructions of the relevant health facility, and
- these IFU for S-7XTRA®.

Table 5.1 S-7XTRA® Concentrate

Instructions for Dilution

S-7XTRA® Concentrate MUST BE DILUTED before further use.

Intermediate-high risk environments including non-invasive medical devices

For non-invasive medical devices and environmental surfaces in hospitals, aged care, healthcare, and other intermediate-high risk environments:

1. dilute 1 part S-7XTRA® Concentrate to 9 parts clean tap or filtered water in a trigger spray bottle, squeeze bottle, bucket, or other suitable container,
2. mix until fully combined by stirring or shaking bottles vigorously, and
3. once S-7XTRA® Concentrate and water is combined, refer to Table 5.2 below for further directions.

For Reactive Barrier Technology™ providing residual activity of up to 24 hours on environmental surfaces, S-7XTRA® Concentrate must be diluted using the instructions above.

At a ratio of 1:9, diluted S-7XTRA® Concentrate is equivalent in concentration to S-7XTRA® Ready to Use (RTU).

Low risk environments

For use in offices, non-healthcare, and other low risk environments *without* Reactive Barrier Technology™:

1. dilute 1 part S-7XTRA® Concentrate to 49 parts clean tap water in a trigger spray bottle, squeeze bottle, bucket, or other suitable container,
2. mix until fully combined by stirring or shaking bottles vigorously, and
3. once S-7XTRA® Concentrate and water is combined, refer to Table 5.2 below for further instructions.

At a ratio of 1:49, S-7XTRA® achieves bactericidal and limited spectrum virucidal activity *only*.

Table 5.2 S-7XTRA® Ready to Use

Instructions for Use

S-7XTRA® RTU is multi-use unless decanted from the original container.

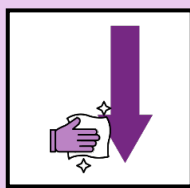
DO NOT DILUTE S-7XTRA® RTU (including Concentrate that has been diluted using the directions in Table 5.1).

S-7XTRA® RTU should be used at ambient room temperature (approx. 20°C).

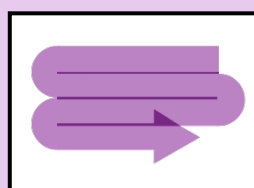
1. Where applicable, refer to any workplace procedure and / or IFU from a relevant medical device OEM in conjunction with these Instructions for Use.
2. Where gross soiling is evident, or if directed by a workplace procedure or IFU from a relevant medical device OEM, pre-clean the surface or non-invasive medical device using a clean cloth, neutral detergent, or S-7XTRA® wipe to remove visible soiling.
3. Apply S-7XTRA® RTU using one of the following methods:
 - pouring liquid directly onto device or surface (flooding, e.g., using 500ml squeeze bottle),
 - spraying (e.g., using 750ml or 500ml trigger spray), or
 - mopping or circulating liquid (e.g., using S-7XTRA® decanted from 5L container).
4. Disperse the liquid evenly in a downward motion or S-pattern using a clean, dry cloth, mop, or brush, unless flooding. Take care to not go over the same area and change cloth or rinse mops and brushes that become dirty or contaminated.



**SPRAY / POUR ON
RTU**



**CLEAN FROM HIGH TO
LOW**



USE AN S-PATTERN

5. Ensure the non-invasive medical device or environmental surface remains clean and wet for the minimum contact time for the most stringent target pathogen/s according to the appropriate table in the 'Microbiocidal Activity' section, for example:
 - 5 minutes for bacteria, viruses, and yeast on non-invasive medical devices.
 - 1 minute for *Klebsiella pneumoniae* (CRE) and *Clostridioides difficile* (C.diff) on environmental surfaces.
6. Once the minimum contact time has passed, allow the non-invasive medical device or surface to dry.
7. Once dry, use sufficient clean tap or filtered water to rinse and remove disinfectant residue if:
 - reprocessing a non-invasive medical device using an AS 5369:2023 cleaning and disinfection protocol, or
 - residual activity is not desired on environmental surfaces.

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- 8.** Perform appropriate clean-up according to the instructions in the 'Handling and Storage' section of the IFU by:
- disposing of dirty single-use cloths in general or clinical waste,
 - washing re-usable cloths, mops, brushes according to laundering instructions,
 - disposing of used bulk or decanted excess (in open / unsealed containers) S-7XTRA® RTU,
 - disposing of empty packaging in general waste or recycling, and / or
 - correctly storing unused and / or unopened bottles of S-7XTRA® RTU or Concentrate.

Table 5.3 S-7XTRA® Wipes

Instructions for Use

S-7XTRA® Wipes are single use.

S-7XTRA® Wipes should be used at ambient room temperature (approx. 20°C).

1. Open plastic lid on pillow pack or tub, pull back inner seal, remove required number of wipes, and close reusable seal^{viii} and / or plastic lid to prevent remaining wipes drying.

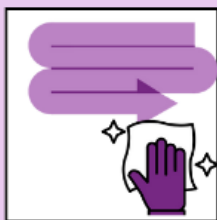


REMOVE ONE
WIPE



REMOVE ONE
WIPE

2. Where gross soiling is evident, or if directed by a workplace procedure or IFU from a relevant medical device OEM, pre-clean the surface or non-invasive medical device using a clean cloth, neutral detergent, or S-7XTRA® Wipe^{ix} to remove visible soiling.
3. Using a clean S-7XTRA® Wipe, disinfect the non-invasive medical device or environmental surface by wiping in one direction using an S-pattern taking care to pass over dirty sections once only.



WIPE IN
S-PATTERN

4. Ensure the non-invasive medical device or environmental surface remains clean and wet for the minimum contact time for the most stringent target pathogen/s according to the appropriate table in the 'Microbiocidal Activity' section, for example:
 - 5 minutes for bacteria, viruses, and yeast on non-invasive medical devices.
 - 1 minute for *Klebsiella pneumoniae* (CRE) and *Clostridioides difficile* (C.diff) on environmental surfaces.
5. Once the minimum contact time has passed, allow the non-invasive medical device or surface to dry.
6. Once dry, use sufficient clean tap or filtered water to rinse and remove disinfectant residue if:
 - reprocessing a non-invasive medical device using an AS 5369:2023 cleaning and disinfection protocol, or
 - residual activity is not desired on environmental surfaces.

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7. Perform appropriate clean-up according to the instructions in the 'Handling and Storage' section of the IFU by:

- disposing of used S-7XTRA® Wipes in general or clinical waste.
- disposing of empty packaging in general waste or recycling, and
- correctly storing open and unopened packets / tubs of S-7XTRA® Wipes.



**DISPOSE OF
USED WIPE SAFELY**

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.

^{vii} This Manufacturer approves disinfectants for use based on their own "approved chemical lists" and / or based on similar approved products or active ingredients.

^{viii} Pillow wipes only.

^{ix} Do not mix or use S-7XTRA with other disinfectants or chemicals other than neutral detergents.

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