3M Science. Applied to Life.™

Prepping with Confidence …

What Really Counts.

Quality and Efficacy of the Formulation

3M™ SoluPrep™ Antiseptic Solutions

2% w/v chlorhexidine gluconate and 70% v/v isopropyl alcohol

Quality: A Priority for 3M

Patient safety and the manufacture of high quality and safe products meeting Good Manufacturing Practices are a priority for 3M. 3M follows validated analytical methods that are used for all antiseptic product testing according to international requirements.

Our registered release and stability specifications comply with Microbiological Standards for Medicines:

- ✓ Total Aerobic Microbial Count (TAMC) and Total Combined Yeasts and Moulds Count (TYMC) levels less than 10 cfu/mL (if growth detected, perform ID and investigation),
- ✓ with an absence of *Staph aureus* and *Pseudomonas aeruginosa* and of *Pseudomonads* (if presence observed, perform ID and investigation)

These specifications ensure the safety and efficacy of each manufactured batch before it is made available for use.

> **“Continuous monitoring of our products throughout their registered 3-year shelf life, at various time points required by our health authority, ensures these specifications are met and maintained.”**

Efficacy: Proven through clinical results

Skin antiseptics registered for use in healthcare facilities must meet rigorous standards in order to be registered as a medicine. This rigour provides optimal protection for patients who are exposed to high-risk environments and organisms, and for whom the safety risk is highest. Antiseptic products for professional healthcare use are those indicated to reduce transient and/or resident organisms on the skin in a healthcare setting such as hospitals, nursing homes and clinics.

> **“3M has performed comprehensive in vitro and in vivo studies to support the efficacy of the 3M™ SoluPrep™ Antiseptic Products. All of these studies were conducted for 3M by independent and different clinical research organisations.”**

Clinical studies supporting the efficacy of 3M™ SoluPrep™ 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA) products.

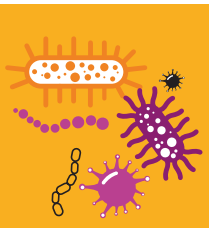
Study 100633-201: In vitro study following the EN 13727 test method to evaluate the bacterial activity of a 2% CHG in 70% IPA skin preparation.

This study was consistent with the European Standard method EN13727. As well as the test bacteria nominated in EN13727 (*E.coli K12, Ps aeruginosa, Enterococcus hirae and Staph aureus*) 17 other bacteria were also tested. The study was validated for each of the test bacteria, and with a 60 minute contact time the test product produced a mean $\log_{10}$ reduction for each of the tested strains of >5.00 $\log_{10}$ at both full strength and ¾ strength. The proposed product meets the acceptance criteria for EN13727.

Study 100934-201: In vitro study following the EN 13624 test method to evaluate the fungicidal activity of a 2% CHG in 70% IPA skin preparation.

This study was consistent with the European Standard method EN13624. The two nominated test fungi (*Candida albicans, Aspergillus brasiliensis*) were tested. The study was validated for each of the test organisms, and with a 60 minute contact time the test product produced a mean $\log_{10}$ reduction of >4.00 $\log_{10}$ at full strength and at ¾ strength for *Candida albicans* and *A brasiliensis*. The proposed product meets the acceptance criteria for EN13624.

Test



Test Organism

Test Specifications

Quality

3M™ SoluPrep™ Antiseptic Solutions

2% w/v chlorhexidine gluconate and 70% v/v isopropyl alcohol

For Hospital and Healthcare Professional use only.

Antiseptic for preparation of the patient's skin prior to invasive procedure on dry skin sites only. Helps reduce bacteria that potentially can cause skin infection. Please refer to product package for complete instructions for use.

Precautions:

- Do not use on patients with known allergies to chlorhexidine or isopropyl alcohol.
- Tuck towels as needed under the area to be prepped to absorb excess solution.
- Not recommended for use on infants less than two months of age.
- Avoid contact with meninges, eyes, inner ears and mucous membranes as this may cause serious or permanent injury.
- Mild skin irritation may occur, stop use if it becomes more severe.
- Caution should be exercised with using the product on children's skin.
- Keep out of reach of children. If swallowed, seek medical help.
- Chlorhexidine can cause severe allergic reactions. Seek immediate medical assistance if this occurs.

Warnings:

- For external use only.
- The product is non-sterile and should not be introduced into the sterile field without appropriate precautions.
- Do not use on open skin wounds.
- Flammable, keep away from fire or flame.
- To reduce the risk of fire, apply prep carefully.
- Solution contains alcohol and gives off flammable vapours.
- Allow product to evaporate completely prior to use in electrocautery procedures.
- Do not drape or use ignition source until solution is completely dry.
- Avoid getting solution into hairy areas.
- Wet hair is flammable.
- Hair may take up to one (1) hour to dry.
- Do not allow solution to drip or pool.
- Remove any antiseptic soaked material prior to draping.

Catalogue Code	Description	Volume	Unit of Measure (UOM)	Each per UOM	Minimum Order Qty
100.27	3M™ SoluPrep™ 2-Sponge Packs, 2% w/v CHG/70% v/v IPA, 30 Packs/Box, 4 Boxes/Case	50mL tinted solution (each sponge has a treatment area 40cm x 40cm)	Case	120 packs	1 case

For clinical and sales information, contact your 3M Sales Representative on 1300 363 878 (Australia) or 0800 80 81 82 (New Zealand).

3M

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