



PrimeSafe

Primary Infection Control

OPA



HIGH-LEVEL INSTRUMENT DISINFECTANT

INTENDED USE/S

High-level disinfection of pre-cleaned thermo-sensitive instruments.
High-level disinfection of pre-cleaned instruments where a functional calibrated autoclave is unavailable.

ACTIVE INGREDIENTS

0.575% Ortho-phthalaldehyde; Corrosion Inhibitor;
Surfactant; Inert Ingredients

PACKAGING VARIANTS

5L, 4x5L with MEC Test Strips, 1L

PRODUCT CHARACTERISTICS

Recommended Dilution Factor: Ready to use
Physical Form: Pale yellow liquid
Odour: Strong Chemical Odour
pH: 7.0-8.0
Incompatibilities: Do not mix with other chemicals or product exposure to other chemical residues.
Environmental Concerns: Category 3 acute & chronic aquatic environmental hazard.
Optional Accessories: Minimum Effective Concentration Test Strips

REGULATORY INFORMATION

NRCS Registration: NRCS/8054/242613/186
SAHPRA Medical Device Registration: Awaiting Class Registration Call-up
Risk Classification: C / IIb
GMDN Code: 47631
GMDN Descriptor: Medical device disinfection agent.



SCAN THIS QR CODE FOR
ADDITIONAL INFORMATION OR
TO GIVE PRODUCT FEEDBACK
TO THE MANUFACTURER.

PPE REQUIREMENTS

Latex or nitrile gloves, protective aprons and chemical splash goggles. Use only in well-ventilated areas or wear respiratory protection.

Where access to an approved, regularly maintained and tested autoclave is available, the autoclave should always be considered the primary means of sterilisation.

INSTRUCTIONS FOR USE

Decant the required amount of undiluted (NEAT) PrimeSafe OPA into a clean, dry, covered stainless steel or HDPE receptacle. Completely immerse thoroughly disassembled, pre-cleaned, rinsed & dried instruments / devices in the liquid, ensuring that any hinges or joints are in the open position. Allow a contact time as per the below efficacy table (30 minutes is recommended). Remove the instruments / devices from the liquid using sterile forceps and follow the post-sterilisation procedure of the facility. Tray-life of the liquid should be tested weekly using M.E.C. strips. As soon as the test indicates that the active level has fallen below the minimum effective level, the liquid should be discarded. The product should have a minimum tray-life of 14 days, should the strips prove a shorter life, check your instrument cleaning process. For best results, replace the liquid every 14 days, **or** as soon as an MEC Test Strip reads less than 0.5% active ingredient, **or** immediately if any change in liquid colour occurs. PrimeSafe OPA should not be subjected to heating under any circumstances, including use in an autoclave, statum, automated washer and or any other heat-generating equipment.

Note:

Rinsing should be thoroughly performed to remove all traces of other chemical residues prior to exposure to PrimeSafe OPA - brown discolouration will result if the product is exposed to other chemicals or chemical residues. Do not heat the product - fumes hazardous to the user will result from any such heating step, in addition amber to brown discolouration will result on items exposed to the heated product and or on surrounding surfaces on which fumes from the heated product may settle. Not to be used after vehicular transport where ambient temperature has exceeded 35°C.



EFFICACY TESTING:



| | Tested To: | Time: (mins) | Dilution: | Conditions: |
|---------------------------------|---|--------------|--------------------|-------------|
| Bactericidal Efficacy | SANS 53727 (EN 13727): Enterococcus hirae, Pseudomonas aeruginosa, Staphylococcus aureus, Klebsiella pneumoniae & Listeria monocytogenes. | 5 | NEAT | Clean |
| | EN 14561 (SANS 54561): Enterococcus hirae, Pseudomonas aeruginosa & Staphylococcus aureus | 15 | 50% | |
| Fungicidal & Yeastical Efficacy | SANS 51650 (EN 1650): Aspergillus brasiliensis & Candida albicans SANS 53624 (EN 13624): Aspergillus brasiliensis & Candida albicans EN 14562 (SANS 54562): Aspergillus brasiliensis & Candida albicans | 15 | 50% NEAT 50% | Clean |
| Sporocidal Efficacy | SANS 53704 (EN 13704): Bacillus subtilis & Clostridium difficile EN 17126: Bacillus cereus | 15 30 | NEAT | Clean |
| Mycobactericidal Efficacy | EN 14348 (SANS 54348): Mycobacterium terrae EN 14563 (SANS 54563): Mycobacterium terrae & Mycobacterium avium | 30 60 | NEAT | Clean |
| Corrosivity | SANS 636 (In-house): Non-corrosive. | | | |
| Dermal Irritation | OECD 439: Non-irritant. | | | |
| Cytotoxicity | ISO 10993-5: Cytotoxic potential. Do not apply to broken skin, open wounds or cell-culture containers. | | | |