

## **GENERAL DESCRIPTION**

A unique powder system for the safe and rapid sterilisation of medical devices. The active agents, peracetyl ions, peracetic acid and hydrogen peroxide are formed by dissolving the powder in water giving an aqueous solution.

PeraSafe is proven effective against bacteria (including mycobacteria), viruses, spores and fungi is non-damaging to sensitive instruments and is compatible with automated endoscope reprocessors. PeraSafe is approved by suppliers and manufactures of associated instruments and equipment.

PeraSafe's unique formulation confers the benefit of user compatibility being virtually odour-free and non-sensitising whilst retaining the effectiveness of peracetic acid. A sophisticated corrosion-inhibition system allied to a near neutral pH allows sterilisation of stainless steel rigid endoscopes and other equipment through brief immersion in PeraSafe solution. PeraSafe does not fix protein and allow the growth of micro-organisms within the resulting protein matrix.

PeraSafe presents no long-term health risks to staff obviating the need for costly extraction equipment, disposal and occupational health monitoring associated with aldehyde and chlorine dioxide based disinfectants.

Relative to the volume of active sterilant, PeraSafe's powder format saves storage space and transportation costs.

PeraSafe addresses all the criteria for disinfection of medical devices for which autoclaving is neither possible nor practical. A rapid, broad spectrum sterilant, instrument and equipment compatible, PeraSafe is cost-effective and safe for users, patients and the environment.

No compromise - the perfect solution for infection Control

## **CHEMISTRY**

PeraSafe is a peroxygen system generating peracetyl ions in equilibrium at pH 8.0 equivalent to peracetic acid at 0.26% PeraSafe solution also contains hydrogen peroxide and acetic acid and decomposes to carbon dioxide and water

## **MODE OF ACTION**

By oxidation of proteins by hydrogen peroxide and peracetic acid.

## **PRESENTATION**

Paleblue/white powder supplied in 100x16.2gm, 24x81 gm, 12x162gm and 6 x 81 Ogm packs making 100 x 1.24 x 5, 12 x 10 and 6 x 50 litres of working solution respectively.

## **STORAGE AND SHELF-LIFE**

Store only in cool, humidity controlled conditions

Shelf-life 2 years from date of manufacture

Container must be tightly re-sealed to preserve integrity of powder

Life of Solution

24 hours from activation, or

Maximum 20 cycles in Automated Endoscope Reprocessor, or

Until indicated by test-strip,

As per good Infection Control practice solutions must be discarded after 24 hours use

### **EFFICACY**

PeraSafe has independently proven efficacy against viruses (including HIV and Hepatitis B&C), Bacteria (*Ps. Aeruginosa*), Mycobacteria (MIA, TB) Fungi (*Candida albicans*) and Spores (*B. Subtilis*.) These tools show rapid sterilant properties across a wide spectrum of micro-organisms marking PeraSafe ideal for endoscopy.

PeraSafe is suitable for use in Automated Endoscope Reprocessors or immersion baths. Only 10 minutes contact time is needed for sterilisation.

PeraSafe has been independently evaluated by HIRL in the UK, one of only two W.H.O. Appointed laboratories for Infection Control research. HIRL found a reduction in colony forming units of  $> 6 \log$  for *Bacillus subtilis* var niger spores in less than 10 minutes (surface test) and a reduction of  $>5 \log$  (5-8 log ) c.t.u. For *Mycobacterium tuberculosis* in a dirty carrier test with a contact time of 10 minutes. These results prove PeraSafe's rapid efficacy and suitability for endoscope reprocessing.

### **SAFETY**

PeraSafe has exceptional user safety as an aqueous-based fully degradable formulation. Maximum Exposure Limits or Occupational Exposure Standards do not apply to PeraSafe solution. Vapour phase break-down products ( $H_2O_2$  and  $CH_3COOH$ ) are well below their OES limits. No special ventilation systems or monitoring of staff is necessary saving costs and improving working conditions.

### **COMPATIBILITY**

PeraSafe is compatible with flexible and stainless steel rigid endoscopes. PeraSafe should only be used in AER's with stainless steel or inert material valves and pipework. Routine enzymatic pre-cleaning of instruments to remove fixed proteins and other biofilms is unnecessary. Pre-cleaning with non-enzymatic detergent saves cost

### **CERTIFICATION**

Product is registered in accordance with requirements of the Medical Devices Directive, 93/42/EEC as a Medical Device.

PeraSafe is a registered trademark of Antec International. Worldwide patents applied for.

## **CHEMICAL COMPOSITION**

Component

Sodium perborate

Activator

Organic acid

Corrosion inhibitors and stabilisers

**PeraSafe** is a rapid, instrument compatible, user and environmentally friendly chemical sterilant. Supplied as a safe, space-saving powder **PeraSafe** is activated by simply dissolving in tap water. Providing rapid sterilization and re-use of endoscopy instruments, **PeraSafe** gives confidence to users and patients alike. A unique aldehyde-free formulation gives efficacy without harm to instruments, health risks to nursing staff and avoids the need for special fume extraction or waste disposal systems.

# Comparison

Feature	PeraSafe Orthophthalaldehyde	2.0% Peracetic acid	0.55%	0.35%
Contact times				
Sterilisation	10 minutes	N/A**	N/A**	10 minutes
High level disinfection	N/A*	20 minutes	12 minutes	5 minutes
Mycobacterium TB	10 minutes	20 minutes	12 minutes	5 minutes
Sporicidal	10 minutes	10 hours	10 hours	10 minutes
Environmental effects	Safe	Hazard	Potential Hazard	Safe
Special ventilation	Not required	Required	Not required	Required
Sensitising vapour	None	Classified hazardous	No long term data	Irritant
Protective clothing	Minimal	Required	Minimal	Required
Requires activation	Yes	Yes	No	Yes
Device compatibility	Good	Good	Good	Corrosive

\*Achieved within the standard 10 minutes contact time. \*\*Not claimed, Sporicidal contact time is equivalent

## Efficacy data

Centre	Protocol	Result
City Hospital, Birmingham	1 Spore suspension and surface testing 2. M. tuberculosis - surface suspension 3. Endoscope trials	Zero recovery at 1 minute
Healthcare Science	Spore suspension trial - new European protocol	Zero recovery at 1 minute Zero recovery at 10 minute Zero recovery over 1 working day (20 cycles) Zero recovery at 5 minutes
Q Laboratories Ltd, Preston, UK	Bacterial testing - new european protocol (5 minutes contact) Escherichia coli 0157 Staphylococcus aureus (MRSA) Vancomycin-resistant enterococcus Salmonella typhimurium Dt104 Campylobacter jejuni Fungal testing - new European protocol Candida albicans	Zero recovery at 5 minutes Zero recovery at 5 minutes Zero recovery at 5 minutes Zero recovery at 5 minutes Zero recovery at 5 minutes
Viomed (USA)	Inanimate Surface Assay (US EPA test) - HIV Type 1 Adenovirus Type 2	Zero recovery at 5 minutes Zero
Micropathology Ltd	Hepatitis B, HBsAg Assay Hepatitis C, Marker Molecule Assay	Zero recovery at 10 minutes Zero recovery at 10 minutes

## Safety/toxicology data

Test	Product State	Result
Skin irritation	Powder	Non-irritant
Skin irritation	16.2g/L	Non-irritant
Eye irritation	16.2g/L	Irritant
Oral toxicity	Powder	Not harmful

Full copies of independent test data summarised above validating PeraSafe's efficacy and safety claims are available separately from Antec International Limited - Human Health Division.