



Amity PAA 15

A Peracetic Acid based Sporicidal High Level Disinfection (HLD) Fluid (Cold Sterilant) for Medical Devices & Instruments Technical Information

Description & Application:

Amity PAA 15 is a powerful peracetic acid based sporicidal high level disinfectant concentrate for use in Automated Endoscope Reprocessors (AERs) and manual decontamination systems. It is an acidic disinfection concentrate for flexible endoscopes and medical devices.

Amity PAA 15 is registered as Class IIB Medical Device

Amity PAA 15 is a sporicidal HLD fluid effective against bacteria, mycobacteria, viruses, spores and fungi when used at a concentration of 1% at 25 °C within a 10 minute exposure cycle.

Devices and endoscope parts should be cleaned prior to disinfection with Amity PAA 15 using suitable cleaners such as Viruzyme family or Virudet N.

Primary features attributable to Amity PAA 15 are;

- Powerful peracetic acid based high level disinfectant (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal);
- Recommended dilution 1% in water;
- Single component & does not require activator compounds;
- Contains anti-corrosion additives;
- Rapid & wide ranging activity including spores;
- Effective at temperatures down to 25°C within a 10 minute exposure.
- Tested to EN 14885 for disinfectant properties.
- Tested to EN 15883-4.
- Contains no aldehydes and formaldehyde.

Applications

Amity PAA 15 is intended for HLD of critical and semi-critical, heat sensitive flexible endoscopes and medical medical devices in AERs. Amity PAA 15 is intended for single use at 25°C and is dosed in AER directly at the beginning of the disinfection phase. The Chloride content in the water for disinfection must be less than 50mg/litre.



Certificate No. GB06/69741



Certificate No. GB06/69740

CE
1639

Certificate No.
GB19/964425

**Infection
Controlled**

Please read and follow the instructions for use and precautionary statements contained on the label and SDS.

Compatibility

Amity PAA 15 is suitable for use on all types of flexible endoscopes, medical devices and instruments. It is recommended that the water used in the automated reprocessor equipment does not have a chloride content in excess of 50mg/L

List of compatible materials:

Metals	Plastics	Elastomers
301 Stainless Steel	Acetal	Aflas
304 Stainless Steel	Nylon	EPDM
316 Stainless Steel	PETG	Santoprene
Hastelloy	Polycarbonate	Silicone Rubber
Inconel	Polyester	
	Polyethylene	
	Polypropylene	
	Polysulphone	
	PVC	
	Polyurethane	
	PTFE	
	PVDF	

The compatibility of Amity PAA 15 has been carried out by conducting intensive exposure tests with the use solution. The endoscope surfaces must be visually examined after each cycle to check for any material changes.

No damage to endoscopes is to be anticipated when using Amity PAA 15 provided Amity PAA 15 is used as directions for use. As with all Peracetic Acid products some cosmetic effects may be noticed, such as bleaching of the colour from black adhesives and anodised surfaces.

- These Aluminium parts can be replaced with plastic or plastic covers.
- Chromium-plated or Nickel plated brass surfaces (e.g. light sources) with mechanical damage (e.g. scratches) must be protected with a resistant protective cover during reprocessing;

Health and Safety

Amity PAA 15 solutions are classed as biodegradable in accordance with OECD criteria.

The neat product is identified as Dangerous, being Oxidising, Harmful and Corrosive. Contact with skin and eyes should be avoided. Avoid breathing or ingesting mist, vapour or liquid droplets.

See relevant Safety Data Sheets for details.

Typical Properties

Appearance	Clear colourless liquid
Odour	Pungent odour
pH,	< 1.5 units (Neat solution) 2.7 units (1% solution)
Density, g/cm ³ @ 20 °C	1.10 (neat)
Solubility in water	Completely miscible
Flash Point (Abel closed cup)	Flammable vapours may occur above SADT

SADT = Self-Accelerating Decomposition Temperature

Shelf Life: Concentrate – Not less than 24 months in unopened original containers when stored between 5 °C and 25 °C out of direct sunlight.

Testing Compliance

EN 13704	Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas
EN 13727	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics
EN 13624	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area
EN 14347	Chemical disinfectants and antiseptics - Basic sporicidal activity
EN 14348	Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants
EN 14476	Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine
EN 14561	Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area
EN 14562	Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area
EN 14563	Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area

Directions for Use

Amity PAA 15 is supplied as a concentrated product that requires dilution prior to use.

Application:

For Cleaning of Endoscopy instruments and equipment in Automated Endoscope Reprocessors:

Apply Amity PAA 15, diluted at 1% at 25°C for 10 minutes then thoroughly rinsed with water.

A recommended cleaning cycle is set out below:

Phase	Time	Temp.	Solution	dosage
Wash	5 min	25 - 55°C	Viruzyme V	5ml/L or 0.5%
Rinse	3 min	-	-	-
Disinfection	10 min	25°C	Amity PAA 15	10 ml/L or 1%
Rinse	3 min	25°C	-	-
Rinse	3 min	25°C	-	-
Dry				

Drying time and temp according to the machine manufacturer

General Notes:

Do not add other cleaning agents to the Amity PAA 15 solution as they can seriously impair performance of the cleaner/disinfectant.

Containers and basins used to contain the cleaning process must be resistant to acids as must be the sinks and pipes, through which the working solutions of Amity PAA 15 are discharged.

After cleaning, instruments must be rinsed thoroughly with water (preferably DI water) and then dried.

CONTACT DETAILS:

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For any further information, please contact your distributor or Amity.

In the event of any technical queries, please contact:
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Packaging Details:

Amity PAA 15 is available in the following packaging.

- 5 L container (min order is 4 x 5L)