

Amity PAA RTU

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

Description & Application:

Amity PAA RTU is a peracetic acid based sporicidal high level disinfectant Ready-to-Use solution for use in manual decontamination and automated procedures. It is an acidic disinfectant for flexible & rigid endoscopes, surgical instruments and medical devices.

Amity PAA RTU is registered as Class IIB Medical Device

(€ UK 1639 CF

Amity PAA RTU is a HLD /cold sterilant fluid effective against spores, mycobacteria, viruses, bacteria, and fungi when used at as supplied at 20 °C within a 5 minute exposure cycle.

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

Primary features attributable to Amity PAA RTU are;

- Powerful peracetic acid based high level disinfectant (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal).
- Ready-to-Use solution.
- PAA concentration: 1,500 4,000 ppm;
- Minimum Effective Concentration (MEC): 1,000 ppm
- Contains anti-corrosion additives;
- Rapid & wide ranging activity including spores.
- Effective at temperatures down to 20°C within a 5 minute exposure.
- Tested to EN 14885 for disinfectant properties.
- Contains no aldehydes and formaldehyde.

Applications

Amity PAA RTU is intended for HLD of critical and semi-critical, heat sensitive flexible endoscopes, surgical instruments and medical devices. Amity PAA RTU use solution has a bath life of up to 14 days, provided the disinfection bath is always covered. The actual bath life depends on how much water is carried over and any residual contaminants on the instruments. Depending on this the Amity PAA RTU





Infection Controlled

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solution should be replaced when the peracetic acid concentration drops below the MEC (Minimum Effective Concentration) value of 1,000 ppm. The solution must also be replaced as soon as it shows signs of contamination (deposits, discolouration, turbidity etc.).

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

Compatibility

Amity PAA RTU is suitable for use on all types of flexible endoscopes, medical devices and instruments.

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
Inconnel	Polyester	
	Polyethylene	
	Polypropylene	
	Polysulphone	
	PVC	
	Polyurethane	
	PTFE	
	PVDF	

The compatibility of Amity PAA RTU 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 RTU provided Amity PAA RTU is used as set out in 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 RTU solutions are classed as biodegradable in accordance with OECD criteria.

Amity PAA RTU solution carries a Warning label being irritant to eyes and skin. Prolonged 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	Transparent, Colourless liquid
Odour	Vinegar type
pH,	2.7 units
Density, g/cm ³ @ 20 °C	1.00
Solubility in water	Completely miscible
Flash Point (Abel closed cup)	Non-flammable

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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 17126	Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area. Test method and requirements (phase 2, step1)
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

The endoscopes and instruments must always be thoroughly cleaned e.g. Viruzyme family or Virudet N and thoroughly rinsed with water prior to disinfection with Amity PAA RTU.

Amity PAA RTU is supplied as a ready-to-use product.

The solution is fully active and can be used immediately.

Amity PAA RTU should always be used in a well ventilated room. Ensure that instruments with recesses and channels are covered without any bubbles.

Following disinfection thoroughly rinse with clean, if possible sterile water.

Test Amity PAA RTU

A safe High Level Disinfection is only guaranteed when the MEC (minimum effective concentration) of the active ingredient, peracetic acid is at least 1,000 ppm.

To ensure that the concentration of peracetic acid is at or above the MEC level, regularly check the Amity PAA RTU solution while it is in use and always after a break in work with the Amity PAA Test Strips.

General Notes:

Do not add other cleaning agents to the Amity PAA RTU solution as they can seriously impair performance of the 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 RTU are discharged.

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CONTACT DETAILS:

For UK and Rest of the World:

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

In the event of any technical queries, please contact: Mr. Ram Singh at the UK/ROW address or by e-mail to:

rsingh@amityinternational.com

Packaging Details:

Amity PAA RTU is available in the following packaging.

- 4 x 5 L container

For North America:

Amity International, PO Box 5254, 1704 Denver Road, ANDERSON, SOUTH CAROLINA, SC29623, USA.

Tel: 864 622 2233 Fax: 864 622 2234

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