



Amity OPA

A o-Phthalaldehyde based Sporicidal High-Level Disinfection (HLD) Fluid (Cold Sterilant) for Medical Devices & Instruments

Technical Information

Description & Application:

Amity OPA is a powerful o-phthalaldehyde based sporicidal high-level disinfectant for use in Automated Endoscope Reprocessors (AERs) and manual decontamination systems. It is a disinfectant for flexible endoscopes and medical devices and does not require activation prior to use.

Amity OPA is classified as:

- In UK/EU as Class IIb Medical Device
- In Republic of China (Taiwan) as Code J.6885 Liquid chemical Sterilant / HLD Class 2
- In Malaysia/Singapore as Class C

Amity OPA is a sporicidal HLD fluid effective against bacteria, mycobacteria, viruses, and fungi when used as supplied at 20 °C within a 5-minute exposure cycle.

When used in manual disinfection a 5-minute exposure cycle should be used.

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

Primary features attributable to Amity OPA are;

- Powerful high-level disinfectant (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal).
- Single component & does not require activator compounds.
- Contains anti-corrosion additives.
- Rapid & wide-ranging activity including spores.
- Effective at temperatures down to 20°C within a 5-minute exposure.

Applications

Amity OPA is intended for HLD of critical and semi-critical, heat sensitive flexible endoscopes and medical devices in AERs.

Amity OPA is intended for single use at 20°C and is dosed in AER directly at the beginning of the disinfection phase.



**Infection
Controlled**

The Chloride content in the water for disinfection must be less than 50mg/litre.

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

Compatibility

Amity OPA 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 OPA 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 OPA provided that it is used as set out in the directions for use.

Health and Safety

Amity OPA solutions are classed as eye irritant and appropriate precautions should be taken. The product is identified as a sensitizing and may produce an allergic reaction in some individuals after prolonged or repeated contact.

See relevant Safety Data Sheets for details.

Typical Properties

Appearance	Clear colourless liquid
Odour	Odourless
pH,	7 units (Neat solution)
Density, g/cm ³ @ 20 °C	1.00 (neat)
Solubility in water	Completely miscible
Flash Point (Abel closed cup)	None

Shelf Life: **Concentrate** – Not less than 24 months in unopened original containers when stored between 5 °C and 25 °C out of direct sunlight.
Opened containers should be used up within 75 days.

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 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 OPA is supplied as a Ready-to-Use (RTU) solution that does not require any pre-activation or mixing.

Endoscopes and devices must be cleaned using a neutral, free rinsing and preferably low foaming enzymatic or detergent cleaner such as Viruzyme N or Virudet N.

The following guidance is provided however these shall not over-ride any instructions provided the device or probe manufacturer.

Users should also consult Appendix A to this data sheet for additional important guidance for the safe use of Amity OPA product

Application:

For Manual Disinfection applications

Thoroughly pre-clean the device with the selected cleaner ensuring all channels and entrapment areas are treated.

Apply Amity OPA disinfectant at a minimum of 20°C for 5 minutes again ensuring all channels and crevices are completely treated.

Finally the device shall be thoroughly rinsed with water and dried.

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

Apply Amity OPA at 20°C for 5 minutes then thoroughly rinsed with water.

A recommended cleaning cycle is set out below:

Phase	Time	Temp.	Solution	dosage
Wash	5 min	45 - 55°C	Viruzyme N	5ml/L or 0.5%
Rinse	3 min	-	-	-
Disinfection	5 min	20°C	Amity OPA	neat
Rinse	3 min	20°C	-	-
Rinse	3 min	20°C	-	-
Dry				

Drying time and temp according to the machine manufacturer

General Notes:

Where the Amity OPA is reused, ensure that the OPA solution achieves greater than a MEC (Minimum Effective Concentration) of 0.3% as determined using Amity OPA test strips.

Check the MEC value prior to each use cycle.

The maximum reuse period shall not be allowed to exceed 14 days in any case.

Amity OPA has demonstrated effective disinfection in the presence of organic and microbiological soils during reuse provided the MEC is above 0.3%.

Do not add other cleaning agents to the Amity OPA solution as they can seriously impair performance of the disinfectant.

Note: Amity OPA stains protein and so rigorous rinsing must be employed to remove Amity OPA traces from endoscope surfaces.

Rinsing.

After cleaning, instruments must be rinsed thoroughly with a large volume of water (preferably DI water or sterile water). The sterile water rinse may be reserved for the final rinse cycle if acceptable to the local Infection Control Authority).

Sterile water is recommended for devices that are used in known high risk patients and for devices (e.g. bronchoscopes) where the risk of contamination from potable water supplies (e.g. micro-organisms) may pose a risk.

Where a potable water or DI supply is used for rinsing then it is recommended that the supply be fitted with an in-line bacterial retentive 0.2 µm filter or a UV sterilisation unit. (Ensure maintenance/replacement procedures recommended by the filter/UV unit manufacturer are followed to ensure correct functioning.

Keep the device immersed for at least 1 minute (or for minimum time advised by the device manufacturer) and then flush out the device with fresh rinse water. Discard all rinse water and residues, do not reuse rinse water.

Manually flush all lumens with at least 100ml of rinse water unless otherwise advised by the device manufacturer.

Repeat the procedure a further two times. (In automated endoscope reprocessors the rinse cycle shall be in accordance with the equipment manufacturer recommendation).

Finally ensure the device is dried prior to returning to re-use. Warm air or a 70% solution of Propan-2-ol may be employed to effect speed up of drying process.

Disposal of used OPA solution.

Dispose of used OPA solutions in accordance with local Regulations.

Glycine may be used to neutralise the OPA active component prior to disposal if required.

A minimum of 25 g of glycine is required to 4.5 litres of Amity OPA solution (allow a reaction time of 60 minutes to effect neutralisation prior to discard to foul water sewer system.)

CONTACT DETAILS:

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

Packaging Details:

Amity OPA is available in the following packaging.

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

ANNEX A
SAFE USAGE OF AMITY OPA SOLUTIONS
SUPPLIMENTARY INFORMATION

USE

Amity OPA Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices, for which sterilization is not suitable, and when used according to the Directions for Use.

Contraindications

1. Amity OPA solutions should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer.
It has been reported that there have been instances where OPA Solutions have been associated with anaphylaxis-like reactions in patients undergoing repeated cystoscopies.
2. Amity OPA should not be utilized to process instrumentation for patients with known sensitivity to OPA.
3. Amity OPA should not be used to sterilize heat sensitive medical devices.
When sterilization by a process that can be biologically monitored is not feasible, then high level disinfection of rigid endoscopes is recommended by the relevant National Authority for Infection Control (e.g. in the US the Centres for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC)).

Warnings

All applicable warnings associated with the use of the Amity OPA are provided in the Technical Data Sheets and Instructions-for-Use.

1. Amity OPA may elicit an allergic reaction. Possible allergic reactions have been reported in rare instances. In the majority of these instances health care workers were not using the product in a well-ventilated room or not wearing proper personal protective equipment. (See PRECAUTIONS).
2. Avoid contact with eyes, skin, or clothing. (See PRECAUTIONS – for important information on how to protect eyes, skin and clothing.) Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary staining. Repeated contact with skin may cause skin sensitization. In case of eye contact, immediately flush eyes with large quantities of water for at least 15 minutes. Seek medical attention. In case of skin contact, immediately wash with water. Refer to the SDS for additional information.
Do not form sprays, mists or aerosols of this product as it may induce respiratory irritation and sensitization.
3. Avoid contamination of food. Ingestion may cause irritation or chemical burns of the mouth, throat, esophagus and stomach. If swallowed, DO NOT INDUCE VOMITING. Drink large quantities of water and call a physician immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.
4. Avoid exposure to *ortho*-phthalaldehyde vapours, as they may be irritating to the respiratory tract and eyes. May cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and tightness, difficulty with breathing, wheezing, tightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, dry mouth or headache. May aggravate a pre-existing asthma or bronchitis condition. In case of adverse reactions from inhalation of vapour, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention.
5. The use of Amity OPA Solution with semi-critical devices must be part of a validated rinsing procedure as provided by the device manufacturer. See DIRECTIONS FOR USE Rinsing Instructions – for important information in rinsing.
6. ALWAYS follow the Directions For Use Rinsing Instructions (Part B) and the SPECIAL INSTRUCTIONS for transesophageal echocardiography (TEE) probes in Part C EXACTLY or residues of Amity OPA Solution may remain on the device.
Failure to follow rinsing instructions exactly has resulted in reports of chemical burns, irritation, and staining of the mouth, throat, esophagus and stomach.
7. This product is not to be sold, distributed, or used for any other purpose.

Precautions

All general precautions associated with the use of the Amity OPA products are provided in the Instructions-for-Use.

Follow Blood-borne Pathogens Universal Precautions when handling and cleaning soiled devices.

1. When disinfecting devices, use gloves of appropriate type and length, eye protection and fluid-resistant gowns.

When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g., after 12 minutes of exposure.

For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves, or butyl rubber gloves may be used.

Note: Contact with Amity OPA Solution may stain exposed skin or clothing.

2. Use Amity OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb *ortho*-phthalaldehyde from the air.
3. Contaminated reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection, since residual contamination with soil or lubricants will decrease the effectiveness of the germicide.
4. The user **MUST** adhere to the Directions for Use, as modification to the Directions for Use may affect the safety and effectiveness of the germicide.
5. Do not use Amity OPA Solution on critical medical devices that are intended for use in a sterile area of the body (e.g. cataract surgical instruments).
6. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using Amity OPA Solution.
7. The use of Amity OPA Solution in automated endoscope reprocessors must be part of a validated reprocessing procedure. The contact conditions must be 20°C for 5 minutes. (See note following the Indications for Use section).
8. Use Amity OPA Solution Test Strips to detect *ortho*-phthalaldehyde concentration before each cycle to detect the MEC. Follow the Directions For Use provided with the Amity OPA Solution Test Strips.

Potential Adverse Effects

None specified.