



INSTRUCTIONS FOR USE

AMITY OPA

High-Level Disinfectant

AMITY OPA Solution

Active Components: o-Phthalaldehyde

Other Ingredients: Dibasic and mono basic potassium phosphates, benzotriazole, citric acid, N-(hydroxyethyl)-ethylene diaminetriacetate sodium salt (HEDTA), Acid Green 25 dye, purified water.

INSTRUCTIONS FOR USE

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 Australia, EU and UK as Class IIB Medical Device

In Republic of China (Taiwan) as Code J.6885 Liquid chemical Sterilant / HLD Class 2

In Malaysia/Singapore (ASEAN) 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 and against bacterial spores following a 180 minute exposure.

When used in manual disinfection a 5 minute exposure cycle should be used (180 minutes for effectiveness against bacterial spores) .

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

For Endoscopic devices Amity strongly recommends the use of an enzymatic cleaner, e.g. Viruzyme V or Ve, to overcome particular issues relating to biofilm formation that has been reported in these devices.

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 $\geq 20^{\circ}\text{C}$ and is dosed in AER directly at the beginning of the disinfection phase.

Amity OPA may also be used in manual High Level Disinfection applications.

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.

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 prior to high level disinfection using a neutral, free rinsing and preferably low foaming enzymatic detergent cleaner such as Viruzyme, Viruzyme N, Amzyme 3, Viruzyme V or Viruzyme Ve.

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

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.

Ensure that the temperature is set to $\geq 20^{\circ}\text{C}$ for disinfection and that this is achieved for 5 minutes in an AER.

Check OPA solutions for visible signs of presence of precipitates that may be due to use of hard water, if present then discard the OPA solution.

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 Automated Endoscope Reprocessors:

Apply Amity OPA High level disinfectant 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	25 - 55°C	Viruzyme or Viruzyme N or Amzyme 3 or Viruzyme V or Ve	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 INFORMATION

Rinsing.

After cleaning, instruments must be rinsed thoroughly with a large volume of water (preferably RO 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 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 150ml 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. Hepa-filtered 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.)

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. 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, oesophagus 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 or spray mists, 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 transoesophageal 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, oesophagus 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 Technical Data Sheet, Safety Data Sheet and these 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/aprons.
Note: 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 disinfectant active component.
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 $\geq 20^{\circ}\text{C}$ 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 determine the MEC. Follow the Directions For Use provided with the Amity OPA Solution Test Strips.

STORAGE:

Amity OPA solution should be stored in its original container at a temperature between 5°C and 25 °C (41 to 77°F) in a well-ventilated low traffic area.

Once opened the unused portion of the solution may be stored in the original container for up to 75 days until used.

HEALTH & SAFETY:

Amity OPA solutions are classed as eye irritant and appropriate precautions should be taken.

Amity OPA is identified as a sensitizing and may produce an allergic reaction in some individuals after prolonged or repeated contact.

See the Amity OPA Safety Data Sheets for details.



Wash hands thoroughly after handling.

Avoid release to the environment.

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists, Get medical advice/attention.

Dispose of contents/containers to an approved waste disposal plant

Company: Amity Ltd
Address: Libra House, West Street,
Worsbrough Dale,
BARNLEY, S YORKS, S70 5PG
UNITED KINGDOM
Telephone: 01226 770787
Fax: 01226 291936
E-mail: sales@amityinternational.com
Web site: www.amityinternational.com
www.aihc.co.uk

Emergency Information: TEL NUMBER +44 (0) 1226 770787

NOTE: **Text in red** denotes changes from the previous issue, as an aid to the user.



Certificate No. GB06/69741



Certificate No. GB06/69740