Fact Sheet

Safe use of *ortho*-phthalaldehyde (OPA)

OPA solutions are instrument-grade high level disinfectants commonly used in SA Health facilities to reprocess semi-critical reusable medical devices (RMDs) in accordance with manufacturer's instructions. Commonly used products include Cidex® and Opal®.

The active ingredient is *ortho*-phthalaldehyde at a concentration between 0.55% and 0.57%, which has a wide spectrum of antimicrobial activity and when used correctly, inactivates all microorganisms with the exception of large numbers of bacterial endospores.

This document outlines details for the safe use of OPA. For complete information on the spectrum of antimicrobial activity, materials compatibility and directions for use, see individual manufacturer's instructions for use (IFU) and safety data sheet (SDS).

Recommendations for Use

OPA solutions may be used in manual or automated systems. Where manual disinfection is undertaken the containers must be made from a compatible material and of sufficient dimensions to fully immerse the intended RMDs. OPA solutions may also be used in an automated endoscope reprocessor (AER) which has been validated to deliver OPA at the temperature and exposure time required by the IFU.

When a RMD is reprocessed in OPA solution the device must first be cleaned according to the RMD manufacturer's IFU. Additional information may be found in the facility's validated cleaning protocol for the RMD and AS/NZS4187:2014 *Reprocessing of reusable medical devices in health service organizations*.

OPA solutions may be safely re-used for a limited time period specified in the IFU and provided the solution is above the Minimum Effective Concentration (MEC) prior to each occasion of use. OPA manufacturers provide chemical indicator strips with their own IFU, which must be followed to ensure a valid MEC test is conducted at each instance of disinfection.

Device compatibility

If questions arise regarding the compatibility of a RMD with OPA solution, contact the RMD manufacturer.

Product suitability

OPA solution is not suitable for use on critical RMDs i.e. those which enter sterile tissue. In such a case, sterilisation of the RMD is required.

OPA solution should not be utilised to process any urological instrument used to treat patients with a history of bladder cancer. In rare instances, OPA solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

OPA solution should not be utilised to process instrumentation for patients with known sensitivity to OPA solution or any of its components.

Hazard Management

It is important that a SDS for OPA solution is available at the point of use and is easily accessible as it provides directions for safe use of the chemical product, including directions for the management of spills, storage and handling of the chemical.

Rinsing RMDs following disinfection with OPA

ALWAYS follow the manufacturer's IFU for rinsing RMDs after disinfection with OPA, as solution may remain on the device. Failure to follow rinsing instructions exactly may result in chemical burns, irritation and/or staining of the skin and mucosa of patients.

Water used to rinse RMDs after manual disinfection must meet quality requirements set out in *AS/NZS4187:2014*. As these requirements generally exceed the quality of normal tap water, it is necessary to consult with infection control and/or facility management professionals to implement water treatment and a testing schedule in any area in which OPA is used.

Precautions

It is essential that precautions appropriate to the risk and mechanism of infection are followed when reprocessing RMDs. (Refer to the *NHMRC Australian Guidelines for the Prevention and Control of Infection and Healthcare* for additional guidance on the application of Standard and Transmission-based Precautions).

Personal Protective Equipment is required to prevent OPA from contacting the skin and eyes. A full-face visor should be worn throughout the disinfection process. Note: Contact lenses may pose a special hazard and may absorb or concentrate irritants. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation

Gloves must be of appropriate length and should be made from a compatible material.

Selection of gloves should be based on consideration of the task requirements

- frequency and duration of contact,
- chemical resistance of glove material, knowledge of breakthrough times l,
- glove thickness
- dexterity

OPA solution must be used in a well-ventilated area in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use under local exhaust hood, or under ductless fume hood or portable ventilation device. These should contain filter media that absorbs OPA from the air.

Sprays, mists and aerosols must not be generated during use of OPA.

It is important that containers used in manual processes are filled and emptied in a manner which does not put the worker at risk. Automated dispensing systems which can be programmed to dispense the required amount of OPA are available commercially.

User Training

The user should be adequately trained in the decontamination and disinfection of RMDs and the handling of liquid chemical disinfectants.

Disinfectant/Container Disposal Information

Disinfectant Disposal

All OPA solutions must be neutralised to inactivate the disinfectant before disposal to sewer. Solutions containing OPA can be neutralised using glycine powder or an approved neutralising agent. The final concentration of treated solutions must not exceed 200 mg/L active OPA.

OPA solution **DOES NOT** need to be neutralised if it is used in an automated endoscope reprocessor as a **SINGLE USE** disinfectant, providing the final concentration of OPA in the discharge does not exceed 200mg/L.

Container Disposal

Do not reuse empty container. Dispose of the container in accordance with facility policy and the Environmental Protection Authority's regulations and guidelines.

References

1. Infection Control in Endoscopy. 3rd edition 2010 (reprinted 2011). Gastroenterological Society of Australia (GESA). Victoria. https://www.gesa.org.au/resources/infection-control-in-endoscopy/
2. SA Water. Glutaraldehyde and *Ortho*-Phthaladehyde (OPA) Disinfectant Disposal to Sewer. Trade Waste Guideline. 2017. https://www.sawater.com.au/__data/assets/file/0015/11409/Glutaraldehyde-and-OPA-disposal.pdf
3. Standards Australia. AS/NZA 4187:2014 *Reprocessing of reusable medical devices in health service organizations.*
4. National Health and Medical Research Council (2019) *Australian Guidelines for the Prevention and Control of Infection in Healthcare* https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019

For more information

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