



METRICIDE™ OPA PLUS TECHNICAL BULLETIN

Product Description

MetriCide OPA Plus is a 0.60% ortho-phthalaldehyde solution that can be used for reprocessing heat sensitive semi-critical medical devices for which sterilization is not suitable. It can be reused for a period of up to 14 days in an automatic endoscope reprocessor or 30 days when manual reprocessing according to the labeled **Directions for Use**. MetriCide OPA Plus Solution may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by the MetriCide OPA Plus Solution Test Strips. It can be reused in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed 30 days. Alternatively, it may also be used or reused in a legally marketed automatic endoscope reprocessor (AER) that can be set to a minimum of 25°C, at or above its Minimum Recommended Concentration (MRC), as determined by MetriCide OPA Plus Solution Test Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.

Semi-critical medical devices reprocessed in MetriCide OPA Plus Solution must first be cleaned according to a validated cleaning protocol or standard, such as the ASTM F 1518 "US Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Note: If your AER cannot be set to a minimum of 25°C, please follow the time and temperature stated in the labeled **Directions for Use**, Manual Processing.

Minimum Recommended Concentration (MRC): 0.3%. Use MetriCide OPA Plus Solution Test Strips prior to every use of MetriCide OPA Plus Solution.

MetriCide OPA Plus Solution is intended for use in a tray system or AER with a variety of heat sensitive medical devices for which sterilization is not suitable: including lensed instruments, anesthesia equipment, respiratory therapy equipment, rubber objects, plastic objects, sharp instruments, thermometers and flexible fiber endoscopes.

Active Ingredient

0.60% ortho-phthalaldehyde 0.60%

Efficacy

Sporicidal Efficacy Studies

Contact Time Tested **32 hours**
Test Method AOAC Sporocidal Test Confirmatory
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the AOAC Confirmatory Sporocidal Test

Contact Time Tested **32 hours**
Test Method AOAC Sporocidal Test Confirmatory
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the AOAC Confirmatory Sporocidal Test

Tuberculocidal Efficacy Studies

Contact Time Tested **5 minutes**
Test Method Quantitative Tuberculocidal Test
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Quantitative Tuberculocidal Test

Contact Time Tested **5 minutes**
Test Method Automated Simulated Use Test using Mycobacterium terrae
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Automated Simulated Use Test

Contact Time Tested **12 minutes**
Test Method Quantitative Tuberculocidal Test
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the Quantitative Tuberculocidal Test

Contact Time Tested **12 minutes**
Test Method Manual Simulated Use Test using Mycobacterium terrae
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the Manual Simulated Use Test

Bactericidal/ Fungicidal Efficacy Studies

Contact Time Tested **5 minutes**
Test Method AOAC Used-Dilution-Test (UDT) Health Care
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the AOAC UDT Health Care Test

Contact Time Tested **5 minutes**
Test Method AOAC Fungicidal Effectiveness
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the AOAC Fungicidal Effectiveness Test

Contact Time Tested **12 minutes**
Test Method AOAC Used-Dilution-Test (UDT) Health Care
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the AOAC UDT Health Care Test

Contact Time Tested **12 minutes**
Test Method AOAC Fungicidal Effectiveness
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the AOAC Fungicidal Effectiveness Test

Virucidal Efficacy Studies

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Poliovirus 1, Chat Strain
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Herpes Simplex Virus Type 1
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Hepatitis A Virus
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Human Immunodeficiency Virus, Type-1 (HIV-1)
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Rhinovirus Type 42
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Avian Influenza Virus
Temperature 25°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Influenza A Virus (Hong Kong)
Temperature 25°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **5 minutes**
Test Method Virucidal Efficacy Test- Duck Hepatitis B Virus
Temperature 25°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Poliovirus 1, Chat Strain
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Herpes Simplex Virus Type 1
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Human Immunodeficiency Virus, Type-1 (HIV-1)
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Rhinovirus Type 42
Temperature 20°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Avian Influenza Virus
Temperature 20°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Influenza A Virus (Hong Kong)
Temperature 20°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Contact Time Tested **12 minutes**
Test Method Virucidal Efficacy Test- Duck Hepatitis B Virus
Temperature 20°C
Conclusion MetriCide OPA Plus Solution passed the Virucidal Efficacy Test

Clinical In-Use Studies

Contact Time Tested **5 minutes**
Test Method Clinical In-Use
Temperature 25-27°C
Conclusion MetriCide OPA Plus Solution demonstrated high-level disinfection in reprocessing reusable endoscopes using automated processing procedures in a clinical setting at 25-27°C for 5 minutes. 19 endoscopes were included in this study. Each endoscope was evaluated for microorganisms at 3 to 5 sites per endoscope. No surviving microorganisms (human flora) were recovered.

Contact Time Tested **12 minutes**
Test Method Clinical In-Use
Temperature 20-22°C
Conclusion MetriCide OPA Plus Solution demonstrated high-level disinfection in reprocessing reusable endoscopes using manual processing procedures in a clinical setting at 20-22°C for 12 minutes. 19 endoscopes were included in this study. Each endoscope was evaluated for microorganisms at 3 to 5 sites per endoscope. No surviving microorganisms (human flora) were recovered.

Toxicity Studies

Study	Test Results
ISO Maximization Sensitization	Under the conditions of the study, tests for irritation and delayed-type hypersensitivity with the solution showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
ISO Skin Irritation	Under conditions of the study, the test article was evaluated for primary skin irritation. The primary irritation index for test article was categorized as moderate.
FHSA Oral Toxicity	Under conditions of this study the test article was evaluated for oral toxicity in accordance guidelines of the Federal Hazardous Substance Act (FHSA) Regulations. The test article would be considered toxic, at 5g/kg by the oral route in the rat.
FHSA Dermal Toxicity	Under conditions of this study the test article was evaluated for dermal toxicity in accordance with Federal Hazardous Substance Act (FHSA) Regulations. The test article would not be considered toxic by the dermal route in a rabbit at 2g/kg. A single dose of 2g/kg produced no mortality or significant evidence of toxicity.

Endoscope Compatibility

Test Method

Compatibility Testing Flexible Fiber Endoscopes

Conclusion

MetriCide OPA Plus Solution when tested on Pentax Colonoscope (Model No. EC-3801L) and Olympus Colonoscope (Model No. CF-100L) showed no discernible differences between the evaluation prior to the test and the evaluation post test. These conclusions were based on observed data.

Carcinogen: According to the SDS, none of the components is listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA