METRICIDE™ OPA PLUS SOLUTION

Technical Bulletin

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, and when used and 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, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20ºC (68ºF), for a reuse period not to exceed 30 days. MetriCide OPA Plus Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (AER) that can be set to a minimum of 25ºC, 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 25ºC (77ºF), 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.

Sporicidal Efficacy Studies

Efficacy demonstrated at 25°C for 32 hours
"AOAC Sporicidal Test"
MicroBiotest, Inc. June 30, 2006. Lab ID # 586-102
Conclusion: MetriCide OPA Plus Solution passed the AOAC Sporicidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the stressed solution at 25-27°C for 32 hours.

"AOAC Sporicidal Test Confirmatory"
MicroBiotest, Inc. February 16, 2007. Lab ID # 586-146
Conclusion: MetriCide OPA Plus Solution passed the AOAC Confirmatory Sporicidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the stressed solution at 25-27°C for 32 hours.

Efficacy demonstrated at 20°C for 32 hours
"AOAC Sporicidal Test"
MicroBiotest, Inc. June 30, 2006. Lab ID # 586-106
Conclusion: MetriCide OPA Plus Solution passed the AOAC Sporicidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the stressed solution at 20-22°C for 32 hours.

"AOAC Sporicidal Test Confirmatory"
MicroBiotest, Inc. February 16, 2007. Lab ID # 586-145
Conclusion: MetriCide OPA Plus Solution passed the AOAC Confirmatory Sporicidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the stressed solution at 20-22°C for 32 hours.

Tuberculocidal Efficacy Studies

Efficacy demonstrated at 25°C for 5 minutes
"Quantitative Tuberculocidal Test"
MicroBiotest, Inc. June 29, 2006. Lab ID # 586-103
Conclusion: MetriCide OPA Plus Solution passed the Quantitative Tuberculocidal when *Mycobacterium bovis* were exposed to the stressed solution at 25-27°C for 5 minutes.

"Automated Simulated Use Test using *Mycobacterium terrae*"
MicroBiotest, Inc. October 31, 2006. Lab ID # 586-133
Conclusion: MetriCide OPA Plus Solution passed the Automated Simulated Use Test using *Mycobacterium terrae* inoculated onto endoscopes when exposed to the stressed solution at 25-27°C for 5 minutes.

Efficacy demonstrated at 20°C for 12 minutes
"Quantitative Tuberculocidal Test"
MicroBiotest, Inc. June 29, 2006. Lab ID # 586-107
Conclusion: MetriCide OPA Plus Solution passed the Quantitative Tuberculocidal when *Mycobacterium bovis* were exposed to the stressed solution at 20-22°C for 12 minutes.

"Manual Simulated Use Test using *Mycobacterium terrae*"
MicroBiotest, Inc. December 29, 2006. Lab ID # 586-141
Conclusion: MetriCide OPA Plus Solution passed the Manual Simulated Use Test using *Mycobacterium terrae* inoculated onto endoscopes when exposed to the stressed solution at 20-22°C for 12 minutes.

Bactericidal/ Fungicidal Efficacy Studies

Efficacy demonstrated at 25°C for 5 minutes

"AOAC Used-Dilution-Test (UDT) Health Care"
MicroBiotest, Inc. June 28, 2006. Lab ID # 586-111
Conclusion: MetriCide OPA Plus Solution passed the AOAC UDT Health Care Test when *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* were exposed to the stressed solution at 25-27°C for 5 minutes.

"AOAC Fungicidal Effectiveness"
MicroBiotest, Inc. June 29, 2006. Lab ID # 586-112
Conclusion: MetriCide OPA Plus Solution passed the AOAC Fungicidal Effectiveness Test when *Trichophyton mentagrophytes* was exposed to the stressed solution at 25-27°C for 5 minutes.

Efficacy demonstrated at 20°C for 12 minutes

"AOAC Used-Dilution-Test (UDT) Health Care"
MicroBiotest, Inc. June 28, 2006. Lab ID # 586-108
Conclusion: MetriCide OPA Plus Solution passed the AOAC UDT Health Care Test when *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* were exposed to the stressed solution at 20-22°C for 12 minutes.

"AOAC Fungicidal Effectiveness"
MicroBiotest, Inc. June 29, 2006. Lab ID # 586-109
Conclusion: MetriCide OPA Plus Solution passed the AOAC Fungicidal Effectiveness Test when *Trichophyton mentagrophytes* was exposed to the stressed solution at 20-22°C for 12 minutes.

Virucidal Efficacy Studies

Efficacy demonstrated at 25°C for 5 minutes

"Virucidal Efficacy Test- Poliovirus 1, Chat Strain"
MicroBiotest, Inc. October 9, 2006. Lab ID # 586-114
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Poliovirus 1, Chat Strain was exposed to the stressed solution at 25-27°C for 5 minutes.

"Virucidal Efficacy Test- Herpes Simplex Virus Type 1"
MicroBiotest, Inc. May 30, 2006. Lab ID # 586-116
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Herpes Simplex Virus Type 1 was exposed to the stressed solution at 25-27°C for 5 minutes.

“Virucidal Efficacy Test- Hepatitis A Virus”
MicroBiotest, Inc. November 8, 2006. Lab ID # 586-118
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Hepatitis A Virus was exposed to the stressed solution at 25-27°C for 5 minutes.

“Virucidal Efficacy Test- Human Immunodeficiency Virus, Type-1 (HIV-1)”
MicroBiotest, Inc. May 30, 2006. Lab ID # 586-121
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Human Immunodeficiency Virus, Type-1 (HIV-1) was exposed to the stressed solution at 25-27°C for 5 minutes.

“Virucidal Efficacy Test- Rhinovirus Type 42”
MicroBiotest, Inc. May 30, 2006. Lab ID # 586-122
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Rhinovirus Type 42 was exposed to the stressed solution at 25-27°C for 5 minutes.

“Virucidal Efficacy Test- Avian Influenza Virus”
MicroBiotest, Inc. May 16, 2006. Lab ID # 586-124
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Avian Influenza Virus was exposed to the stressed solution at 25°C for 5 minutes.

“Virucidal Efficacy Test- Influenza A Virus (Hong Kong)”
MicroBiotest, Inc. May 16, 2006. Lab ID # 586-126
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Influenza A Virus (Hong Kong) was exposed to the stressed solution at 25°C for 5 minutes.

“Virucidal Efficacy Test- Duck Hepatitis B Virus”
MicroBiotest, Inc. November 8, 2006. Lab ID # 586-128
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Duck Hepatitis B Virus was exposed to the stressed solution at 25°C for 5 minutes.

Efficacy demonstrated at 20°C for 12 minutes
“Virucidal Efficacy Test- Poliovirus 1, Chat Strain”
MicroBiotest, Inc. May 26, 2006. Lab ID # 586-115
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Poliovirus 1, Chat Strain was exposed to the stressed solution at 20-22°C for 12 minutes.

“Virucidal Efficacy Test- Herpes Simplex Virus Type 1”
MicroBiotest, Inc. May 26, 2006. Lab ID # 586-117
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Herpes Simplex Virus Type 1 was exposed to the stressed solution at 20-22°C for 12 minutes.

“Virucidal Efficacy Test- Human Immunodeficiency Virus, Type-1 (HIV-1)”
MicroBiotest, Inc. May 26, 2006. Lab ID # 586-120
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Human Immunodeficiency Virus, Type-1 (HIV-1) was exposed to the stressed solution at 20-22°C for 12 minutes.

“Virucidal Efficacy Test- Rhinovirus Type 42”
MicroBiotest, Inc. November 6, 2006. Lab ID # 586-123
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Rhinovirus Type 42 was exposed to the stressed solution at 20°C for 12 minutes.

“Virucidal Efficacy Test- Avian Influenza Virus”
MicroBiotest, Inc. May 17, 2006. Lab ID # 586-125
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Avian Influenza Virus was exposed to the stressed solution at 20°C for 12 minutes.

“Virucidal Efficacy Test- Influenza A Virus (Hong Kong)”
MicroBiotest, Inc. May 17, 2006. Lab ID # 586-127
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Influenza A Virus (Hong Kong) was exposed to the stressed solution at 20°C for 12 minutes.

“Virucidal Efficacy Test- Duck Hepatitis B Virus”
MicroBiotest, Inc. December 29, 2006. Lab ID # 586-129
Conclusion: MetriCide OPA Plus Solution passed the Virucidal Efficacy Test when Duck Hepatitis B Virus was exposed to the stressed solution at 20°C for 12 minutes.

Clinical In-Use Studies

Efficacy demonstrated at 25°C for 5 minutes

“Clinical In-Use”
MicroBiotest, Inc. February 16, 2007 Lab ID # 586-137
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.

Efficacy demonstrated at 20°C for 12 minutes

“Clinical In-Use”
MicroBiotest, Inc. December 28, 2006 Lab ID # 586-138
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

"ISO Maximization Sensitization"
NAMSA, November, 2006. Lab Test No. T1261_306
Conclusion: 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"
NAMSA, November, 2006. Lab Test No. T1262_809
Conclusion: 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"
NAMSA, December, 2006. Lab Test No. TA004-900
Conclusion: 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"
NAMSA, December, 2006. Lab Test No. 06T_57870_04
Conclusion: 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

"Compatibility Testing Flexible Fiber Endoscopes"
MicroBiotest, Inc. February 16, 2007. Lab ID # 586-140
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 posttest. These conclusions were based on observed data