

# **METRICIDE**

## **Technical Bulletin**

MetriCide is a 2.6% glutaraldehyde solution which, when activated, attains a pH of between 6.5 and 8.5, and can be used for the sterilization and high-level disinfection of heat-sensitive medical devices for up to 14 days.

MetriCide is a sterilant when used or reused, according to the **Directions for Use**, up to 14 days at 25 °C, assuming the Minimum Effective Concentration (MEC) of glutaraldehyde, as measured by a chemical indicator; remains within acceptable parameters and other conditions of use are met, with an immersion time of at least 10 hours.

MetriCide is a high-level disinfectant when used or reused, according to the **Directions for Use**, up to 14 days at 25 °C, assuming the Minimum Effective Concentration (MEC) of glutaraldehyde, as measured by a chemical indicator; remains within acceptable parameters and other conditions of use are met, with an immersion time of at least 45 minutes.

MetriCide is intended for use in a tray system with a variety of semi-critical and critical devices – including lensed instruments, anesthesia equipment, respiratory therapy equipment, rubber objects, plastic objects, sharp instruments, thermometers, and flexible fiberoptic endoscopes.

### Sporicidal Efficacy Studies

*Bacillus subtilis*

*Clostridium sporogenes*

“AOAC Confirmatory Sporicidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. August 30, 2001. Lab ID # 198-254

Conclusion: Metricide passed the AOAC Confirmatory Sporicidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the test material for 10 hours at 25±1 °C.

“AOAC Sporicidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. June 30, 2000. Lab ID # 198-220

Conclusion: When tested as described, Metricide, exposed to bacterial spores for 10 hours at 25±1 °C, passed the AOAC Sporicidal Test and thus meets the FDA established criteria for a chemical sterilant.

“AOAC Sporicidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. May 18, 2000. Lab ID # 198-207

Conclusion: When tested as described, Metricide, exposed to bacterial spores for 10 hours at 25±1 °C, passed the AOAC Sporicidal Test and thus meets the FDA established criteria for a chemical sterilant.

“Sporicidal Effectiveness Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. April 22, 1994. Lab ID #198-117

Conclusion: Metricide passed the AOAC Sporicidal Effectiveness Test against *Bacillus subtilis* and *Clostridium sporogenes* carried on silk suture loops and porcelain penicylinders in 10 hours at 25 °C.

## Tuberculocidal Efficacy Studies

### *Mycobacterium bovis*

#### “Quantitative Tuberculocidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. August 30, 2001. Lab Id # 198-253

Conclusion: MetriCide passed the Quantitative Tuberculocidal Test when *Mycobacterium bovis* was exposed to the test material for 45 minutes at 25±1 °C.

#### “Quantitative Tuberculocidal Test (Suspension Test)”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. July 5, 2000. Lab Id # 198-223

Conclusion: When tested as described by the Quantitative Tuberculocidal or Suspension Test at 25±2 °C, Metricide supports a 45-minute tuberculocidal label claim.

#### “Quantitative Tuberculocidal Test (Suspension Test)”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. May 14, 2000. Lab Id # 198-199

Conclusion: When tested as described by the Quantitative Tuberculocidal or Suspension Test at 25±2 °C, Metricide supports a 45-minute tuberculocidal label claim.

## Bactericidal Efficacy Studies

### *Staphylococcus aureus*

### *Pseudomonas aeruginosa*

### *Salmonella cholerasuis*

### *Trichophyton mentagrophytes*

#### “AOAC Use Dilution Test”

Sponsor: Metrex Research Corporation

Shaldr Biotest, Inc. October 10, 1985.

Conclusion: AOAC Use-Dilution Tests with *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella cholerasuis* demonstrated that MetriCide would kill all of these vegetative bacteria in 10 minutes at 20 °C.

#### “AOAC Fungicidal Test”

Sponsor: Metrex Research Corporation

Shaldr Biotest, Inc. October 10, 1985.

Conclusion: When tested under the AOAC Fungicidal Test protocol, MetriCide was found to kill *Trichophyton mentagrophytes* in 10 minutes at 20 °C.

## Simulated In-Use Studies

### *Pseudomonas aeruginosa*

#### “Simulated In-Use Test of the Chemistry and Antimicrobial Activity of Disinfectants”

Sponsor: Metrex Research Corporation

Norman Miner, Consultant. August 4, 1992. Lab ID Numbers: 33092-2; 41592-2; 42292-1; 71692-1; 81192-1

Conclusion: Stressed MetriCide from simulated in-use tests killed  $5 \times 10^7$  *Pseudomonas aeruginosa* within 10 minutes at 20 °C.

## Virucidal Efficacy Studies

*Influenza virus A2HK*  
*Cytomegalovirus*  
*Respiratory Syncytial virus*  
*Rhinovirus*  
*Rotavirus SA-11*  
*Herpes Simplex virus 1 and 2*  
*Poliovirus 1 and 2*  
*Adenovirus*  
*Vaccinia virus*  
*HIV-1*

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 11, 1987. Lab Project ID: M10-MX1400-1987-V  
Conclusion: Stressed MetriCide demonstrated effectiveness against Cytomegalovirus, Respiratory Syncytial virus, Rhinovirus and Rotavirus SA-11 within 10 minutes at 20 °C.

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 1, 1985.  
Conclusion: MetriCide demonstrated effectiveness against Poliovirus – 1 and Adenovirus within 10 minutes at 20 °C.

### “Virucidal Efficacy of Metricide”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 12, 1985.  
Conclusion: MetriCide demonstrated effectiveness against Poliovirus – 2 and Herpes Simplex Virus – 1 and 2 within 10 minutes at 23 °C.

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. March 28, 1986.  
Conclusion: MetriCide demonstrated effectiveness against Vaccinia virus, within 10 minutes at 20 °C.

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 16, 1985. Lab Project ID: M10-MS1400-1985-V  
Conclusion: MetriCide demonstrated effectiveness against Poliovirus – 1, within 10 minutes at 20 °C.

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. October 11, 1985.  
Conclusion: MetriCide demonstrated effectiveness against Poliovirus – 1 and 2, within 10 minutes at 23 °C.

### “The Effectiveness of Metricide stressed 14 days to inactivate the Acquired Immune Deficiency Virus (AIDS) / HIV-I”

Sponsor: Metrex Research Corporation  
Shaladra Biotest. December 23, 1987. Study No. 22367-58  
Conclusion: MetriCide demonstrated effectiveness against HIV-I, within 10 minutes at 20 °C.

“Virucidal Efficacy Test”

Sponsor: Metrex Research Corporation  
Shaldra Biotest. May 24, 1985.

Conclusion: Metricide demonstrated effectiveness against Influenza virus within 10 minutes at 20 °C.

Toxicity Studies

The toxicity data was conducted on MetriCide Plus 30. The data is bridged to MetriCide. The data was conducted on MetriCide Plus 30 because it contains the highest glutaraldehyde concentration at 3.4%. MetriCide contains 2.6% glutaraldehyde; therefore, the toxicity of the product is lessened.

*Oral Toxicity*

*Dermal Irritation/Sensitization/Toxicity*

*Ocular Irritation*

“Acute Oral Toxicity Study”

Sponsor: Metrex Research Corporation

American Standards Biosciences Corporation. September 14, 1987. Study No. 87-315.

Conclusion: Under the conditions of the test, the oral LD<sub>50</sub> was calculated to be greater than 3.4g/kg.

“Primary Dermal Irritation”

Sponsor: Metrex Research Corporation

American Standards Biosciences Corporation. July 30, 1987. Study No. 87-316.

Conclusion: Under the conditions of the test, immediate irritation was observed, but subsided within 72 hours.

“Guinea Pig Maximization Study”

Sponsor: Metrex Research Corporation

American Standards Biosciences Corporation. September 14, 1987. Study No. 87-319.

Conclusion: Under the conditions of the test, the product is considered nonallergenic (a nonsensitizer).

“Acute Dermal Toxicity”

Sponsor: Metrex Research Corporation

American Standards Biosciences Corporation. August 5, 1987. Study No. 87-318.

Conclusion: Under the conditions of the test, the acute dermal toxicity is greater than 2.0g/kg of body weight.

“Effect on the Eye Mucosa of New Zealand Albino Rabbits”

Sponsor: Metrex Research Corporation

American Standards Biosciences Corporation. August 3, 1987. Study No. 87-317.

Conclusion: The test material exhibited a positive effect on the eye mucosa.