



## **METRICIDE 28**

### **Technical Bulletin**

MetriCide 28 is a 2.5% glutaraldehyde solution which, when activated, attains an alkaline pH of between 7.5 and 8.5, and can be used for the sterilization and high-level disinfection of heat-sensitive medical devices for up to 28 days.

MetriCide 28 is a sterilant when used or reused, according to **Directions for Use**, up to 28 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 28 is a high-level disinfectant when used or reused, according to **Directions for Use**, up to 28 days at 20°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 20 minutes.

MetriCide 28 is intended for use in a tray system with a variety of semi-critical and critical devices – including flexible fiberoptic endoscopes, anesthesia equipment, respiratory therapy equipment, metallic equipment or instruments, rubber objects, plastic objects, and thermometers. It may be reused up to 28 days, 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.

#### Sporicidal Efficacy Studies

*Bacillus subtilis*  
*Clostridium sporogenes*

##### “AOAC Confirmatory Sporocidal Test”

Sponsor: Metrex Research Corporation  
MicroBiotest, Inc. August 30, 2001. Lab ID 198-256.

Conclusion: Metricide 28 passed the AOAC Confirmatory Sporocidal Test when *Bacillus subtilis* and *Clostridium sporogenes* were exposed to the test material for 10 hours at 25±1°C.

##### “AOAC Sporocidal Test”

Sponsor: Metrex Research Corporation  
MicroBiotest, Inc. July 6, 2000. Lab ID 198-221.

Conclusion: When tested as described, Metricide 28 exposed to bacterial spores for 10 hours at 25±1°C, passed the AOAC Sporocidal Test and thus met the FDA established criteria for a chemical sterilant.

##### “AOAC Sporocidal Test”

Sponsor: Metrex Research Corporation  
MicroBiotest, Inc. July 7, 2000. Lab ID 198-227.

Conclusion: When tested as described, Metricide 28 exposed to bacterial spores for 10 hours at 25±1°C, passed the AOAC Sporocidal Test and thus met the FDA established criteria for a chemical sterilant.

“Sporicidal Effectiveness Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. July 13, 1994. Lab ID 198-118, Part B.

Conclusion: When tested as described, MetriCide 28 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*

“AOAC Tuberculocidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. April 15, 1993. Lab Id # 198-110

Conclusion: MetriCide 28 passed the AOAC Tuberculocidal Test when *Mycobacterium bovis* was exposed to the test material for 20 minutes at 20±1°C.

“AOAC Tuberculocidal Test (Confirmatory)”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. April 19, 1993. Lab ID 198-114.

Conclusion: MetriCide 28 passed the AOAC Confirmatory Tuberculocidal Test when *Mycobacterium bovis* was exposed to the test material for 20 minutes at 20±1°C.

Bactericidal Efficacy Studies

*Staphylococcus aureus*

*Pseudomonas aeruginosa*

*Salmonella cholerasuis*

*Trichophyton mentagrophytes*

“AOAC Use-Dilution Test”

Sponsor: Metrex Research Corporation

Biosearch, Inc. January 30, 1983. Analysis No. H558.

Conclusion: MetriCide 28 demonstrated effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella cholerasuis* in the AOAC Use-Dilution Tests within 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 28 was found to kill fungi within the stated label claim.

## Virucidal Efficacy Studies

*Cytomegalovirus*  
*Respiratory Syncytial virus*  
*Rhinovirus*  
*Rotavirus SA-11*  
*Vaccinia virus*  
*Influenza virus A2HK*  
*Adenovirus*  
*Poliovirus 1 and 2*  
*Coxsackievirus B5a*  
*Herpes Simplex virus 1 and 2*  
*HIV-1*

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 11, 1987. Lab ID M10-MX2800-1987-V  
Conclusion: MetriCide 28 demonstrated effectiveness against Cytomegalovirus, Respiratory Syncytial virus, Rhinovirus and Rotavirus SA-11, within 10 minutes at 20°C.

### “Study of Virucidal Efficacy”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. October 11, 1985.  
Conclusion: MetriCide 28 demonstrated effectiveness against Poliovirus Types 1 and 2 within 10 minutes at 23°C.

### “Virus Efficacy Tests”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. January 2, 1986. Lab ID M10-M2800-1986-V  
Conclusion: Metricide 28 was an effective virucidal agent against Vaccinia virus, Influenza A2HK and Poliovirus Type 1 within 10 minutes at 20°C.

### “Study of Virucidal Efficacy”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. December 8, 1985.  
Conclusion: MetriCide 28 demonstrated effectiveness against Coxsackievirus B5a, Herpes Simplex 1 and 2 and Poliovirus 2 within 10 minutes at 23°C.

### “Study of Virucidal Efficacy”

Sponsor: Metrex Research Corporation  
Shaladra Biotest, Inc. January 13, 1986.  
Conclusion: MetriCide 28 demonstrated effectiveness against Adenovirus within the stated label claim.

### “The Effectiveness of Metricide 28 to Inactivate the Acquired Immune Deficiency Virus (AIDS) / HIV –1”

Sponsor: Metricide Research, Inc. (Metrex Research Corporation)  
Bionetics Research, Inc. December 23, 1987. Study No. 22367-57  
Conclusion: MetriCide 28 demonstrated effectiveness against HIV-1, within 10 minutes at 20-25°C.

## Toxicity Studies

The toxicity data was conducted on MetriCide Plus 30. The data is bridged to MetriCide 28. The data was conducted on MetriCide Plus 30 because it contains the highest glutaraldehyde concentration at 3.4%. MetriCide 28 contains 2.5% 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.