

# **METRICIDE PLUS 30**

## **Technical Bulletin**

MetriCide Plus 30 is a 3.4% glutaraldehyde solution which, when activated, attains an alkaline pH of between 7.5 and 8.5, and can be used and reused for the sterilization and high-level disinfection of various medical devices for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in the **Directions for Use** in the package insert. **DO NOT** rely solely on days in use.

MetriCide Plus 30 is a sterilant when used or reused, according to **Directions for Use**, up to 28 days at a temperature of 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 Plus 30 is a high-level disinfectant when used or reused, according to **Directions for Use**, up to 28 days at a temperature of 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 90 minutes.

MetriCide Plus 30 is intended for use in a tray system with a variety of semi-critical and critical devices – including anesthesia equipment, respiratory therapy equipment, metallic equipment or instruments, rubber objects, plastic objects, and thermometers.

### Sporicidal Efficacy Studies

*Bacillus subtilis*

*Clostridium sporogenes*

#### “AOAC Sporocidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. July 31, 2001. Lab ID Number 198-222.

Conclusion: When tested as described, Metricide Plus 30, 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, 2001. Lab ID Number 198-228.

Conclusion: When tested as described, Metricide Plus 30, 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.

#### “Sporocidal Effectiveness Test”

Sponsor: Metrex Research Corporation

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

Conclusion: When tested as described under the conditions portrayed, the test material, MetriCide Plus 30, passes the AOAC Sporocidal Effectiveness Test.

“AOAC Sporocidal Testing of MetriCide Plus 30”

Sponsor: Metrex Research Corporation

Presque Isle Cultures. April 13, 1994. Study Number Metrex 94-2.

Conclusion: The results demonstrate that all *Clostridium sporogenes* and *Bacillus subtilis* carriers exposed to MetriCide Plus 30 were sterilized.

Tuberculocidal Efficacy Studies

*Mycobacterium bovis*

“Quantitative Tuberculocidal Test”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. April 19, 1996. Lab ID Number 198-135

Conclusion: MetriCide Plus 30 meets the requirements of a tuberculocide when exposed to the challenge *Mycobacterium*. MetriCide Plus 30 supports a 90-minute tuberculocidal label claim.

“Quantitative Tuberculocidal Test (Suspension Test)”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. August 2, 2000. Lab ID Number 198-225

Conclusion: When tested as described by the Quantitative Tuberculocidal, Suspension Test, at 25±2 °C, MetriCide Plus 30 supports a 90-minute tuberculocidal label claim.

“Quantitative Tuberculocidal Effectiveness”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. November 1, 1995. Lab ID Number 198-124

Conclusion: When tested as described, MetriCide Plus 30 supports a 90-minute label claim for tuberculocidal effectiveness at 25 °C.

Bactericidal Efficacy Studies

The bactericidal data was conducted on MetriCide 28. This data is bridged to the MetriCide Plus 30 product. The data was conducted on MetriCide 28 because it has a lower glutaraldehyde concentration, at 2.5%. MetriCide Plus 30 is a 3.4% glutaraldehyde product; therefore, the product would be even more efficacious.

*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

Shaladra 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

The virucidal data was conducted on MetriCide 28. This data is bridged to the MetriCide Plus 30 product. The data was conducted on MetriCide 28 because it has a lower glutaraldehyde concentration, at 2.5%. MetriCide Plus 30 is a 3.4% glutaraldehyde product; therefore, the product would be even more efficacious.

*Cytomegalovirus*

*Respiratory Syncytial virus*

*Rhinovirus*

*Rotavirus SA-11*

*Vaccinia virus*

*Influenza A2HK*

*Adenovirus*

*Poliovirus 1 and 2*

*Coxsackievirus B5a*

*Herpes Simplex 1 and 2*

*HIV-1*

“Virus Efficacy Tests”

Sponsor: Metrex Research Corporation

Integrity Bioservices, Inc. September 15, 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.

“Virus Efficacy Tests”

Sponsor: Metrex Research Corporation

Integrity Bioservices, Inc. January 2, 1986. Lab Project ID M10-M2800-1986-V

Conclusion: Metricide 28 was an effective virucidal agent 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 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-N2800-1986-V

Conclusion: Metricide 28 was an effective virucidal agent against Poliovirus 1 within 10 minutes at 20°C.

“Study of Virucidal Efficacy”

Sponsor: Metrex Research Corporation  
Integrity Bioservices, Inc. November 1, 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

*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.

“Primal 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.