



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 heat-sensitive 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 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 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, 2000. 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, 2000. 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 Sporidical 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

“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.

*This data was bridged to support the MetriCide Plus 30 high-level disinfection claim since the products are comparable in formulation, but MetriCide Plus 30 contains a higher glutaraldehyde concentration. Therefore, the product would be even more efficacious.

“AOAC Tuberculocidal Test (Confirmatory)”

Sponsor: Metrex Research Corporation

MicroBiotest, Inc. April 16, 1993. Lab ID 198-111.

Conclusion: MetriCide Plus 30 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

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

Shaldrá 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. 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

Shaldrá 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 LD₅₀ 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.