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 various medical devices for up to 28 days. It is manufactured by Metrex Research Corporation, 28210 Wick Road, Romulus, MI 48174.

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 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 28 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. 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 Sporicidal Test"
Sponsor: Metrex Research Corporation
MicroBiotest, Inc. August 30, 2001. Lab ID 198-256.
Conclusion: Metricide 28 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. 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 Sporicidal Test and thus met the FDA established criteria for a chemical sterilant.

"AOAC Sporicidal 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 Sporicidal 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

"Quantitative Tuberculocidal Test"
Sponsor: Metrex Research Corporation
MicroBiotest, Inc. September 6, 2001. Lab ID 198-255.
Conclusion: When tested as described, MetriCide 28 passed the Quantitative Tuberculocidal Test when *Mycobacterium bovis* was exposed to the test material for 90 minutes at 25±1 °C.

"Quantitative Tuberculocidal Test (Screening Test)"
Sponsor: Metrex Research Corporation
MicroBiotest, Inc. May 24, 2000. Lab ID 198-202.
Conclusion: When tested as described by the Quantitative Tuberculocidal Screening Test at 25±1 °C, MetriCide 28, supports a 90-minute tuberculocidal label claim.

"Quantitative Tuberculocidal Test (Suspension Test)"
Sponsor: Metrex Research Corporation
MicroBiotest, Inc. June 28, 2000. Lab ID 198-224.
Conclusion: When tested as described by the Quantitative Tuberculocidal Suspension Test at 25±2 °C, MetriCide 28, supports a 90-minute tuberculocidal label claim.

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
Shaldra 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 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
Shaldra 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_{50} 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.