CAVICIDE



Technical Bulletin

CaviCide is a multi-purpose disinfectant intended for use in cleaning, decontaminating and disinfecting hard non-porous, inanimate surfaces and non-critical instruments in hospitals, laboratories, and other critical care areas where environmental control of cross contamination between treated surfaces is important.

CaviCide has biocidal effectiveness against the following microorganisms:

Mycobacterium bovis BCG Staphylococcus aureus Pseudomonas aeruginosa Salmonella enterica Trichophyton mentagrophytes Methicillin Resistant Staphylococcus aureus (MRSA) Vancomycin Resistant Enterococcus faecalis (VRE) Staphylococcus aureus with Reduced Susceptibility to Vancomycin (VRSA) Hepatitis B Virus (HBV) Hepatitis C Virus (HEV) Herpes Simplex Virus Type 1 Herpes Simplex Virus Type 2 Human Immunodeficiency Virus (HIV-1) Human Coronavirus (not associated with Severe Acute Respiratory Syndrome or SARS) Influenza A2 Virus

Tuberculocidal Efficacy Studies:

Mycobacterium bovis BCG

"AOAC Tuberculocidal Activity of Disinfectants" Microbiotest, Inc. May 18, 2004. Lab ID # 198-294. Conclusion: When tested as described, CaviCide passed the AOAC Tuberculocidal Activity of Disinfectants Test when M. bovis was exposed to the test material at 20±2C.

"Confirmatory AOAC Tuberculocidal Activity of Disinfectants" Microbiotest, Inc. July 23, 2004. Lab ID # 198-297. Conclusion: CaviCide passed the AOAC Tuberculocidal test when *M. bovis* was exposed to the test material for three minutes at $20\pm2^{\circ}$ C.

Bactericidal Efficacy Studies

Staphylococcus aureus* Pseudomonas aeruginosa* Salmonella enterica* Trichophyton mentagrophytes* Methicillin Resistant Staphylococcus aureus (MRSA) Vancomycin Resistant Enterococcus faecalis (VRE) Staphylococcus aureus with Reduced Susceptibility to Vancomycin

* Note: A 3-minute contact time is required as indicated on the product label.

"CaviCide versus *Staphylococcus aureus* in the AOAC Germicidal Spray Products Test" MicroChem Laboratory. January 9, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 941229-1; 950103-1; 950105-1.

Conclusion: Diluted CaviCide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test 961.02 at 2, 5 and 10 minutes when tested against *S. aureus* at $20\pm1^{\circ}$ C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of CaviCide against *Staphylococcus aureus*" (confirmatory)

ViroMed Laboratories, Inc. May 27, 1993. Amended Report November 2, 1993. Lab ID# 391-SA.

Conclusion: Two lots of CaviCide, used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *S. aureus*. Under the conditions of this study, CaviCide was germicidal against *S. aureus*.

"CaviCide versus *Pseudomonas aeruginosa* in the AOAC Germicidal Spray Products Test" MicroChem Laboratory. January 3, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 941216-1; 941221-1; 941227-1.

Conclusion: Diluted CaviCide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test at 2, 5 and 10 minutes when tested against *P. aeruginosa* at 20±2°C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of CaviCide against *Pseudomonas aeruginosa* (confirmatory)

ViroMed Laboratories, Inc. November 9, 1993. Lab ID# 533-PA.

Conclusion: Two lots of CaviCide used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *P. aeruginosa*. Under the conditions of this study, CaviCide was germicidal against *P. aeruginosa*.

"CaviCide versus Salmonella enterica (choleraesuis) in the AOAC Germicidal Spray Products Test"

MicroChem Laboratory. January 18, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 950111-1; 950116-1.

Conclusion: Diluted CaviCide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test at 2, 5 and 10 minutes when tested against *S. enterica* at 20±1°C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of CaviCide against Salmonella enterica (choleraesuis) (confirmatory)

ViroMed Laboratories, Inc. November 2, 1993. Lab ID# 391-SC.

Conclusion: Two lots of CaviCide, used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *S. enterica*. Under the conditions of this study, CaviCide was germicidal against *S. enterica*.

"Fungicidal Activity of CaviCide in a Stainless Steel Cylinder Use-Dilution Test and in Suspension"

MicroChem Laboratory. January 24, 1994. Lab ID# 931230-1; 940104-1; 940106-1; 940110-2; 940112-4; 940114-2.

Conclusion: CaviCide killed *Trichophyton mentagrophytes* in suspension within 30 seconds at 20±1°C. CaviCide also killed these fungi on stainless steel surfaces within 1 minute at 20±1°C.

"CaviCide versus Methicillin Resistant *Staphylococcus aureus* (MRSA) in the AOAC Germicidal Spray Products Test"

MicroChem Laboratory. April 19, 1995. Lab ID# 950406-1.

Conclusion: Two lots of CaviCide diluted to the minimum manufacturing concentrations of Isopropanol and Hyamine 1622 passed the AOAC Germicidal Spray Products Test against MRSA in 2 minutes at 20±1°C.

"CaviCide versus Vancomycin Resistant Enterococcus faecalis (VRE) in the AOAC Germicidal Spray Products Test"

MicroChem Laboratory. April 19, 1995. Lab ID# 950406-1.

Conclusion: Two lots of CaviCide diluted to the minimum manufacturing concentrations of Isopropanol and Hyamine 1622 passed the AOAC Germicidal Spray Products Test against VRE in 2 minutes at 20±1°C.

"AOAC Use Dilution Test Supplemental"

Microbiotest, Inc. August 10, 2004. Lab ID # 198-312.

Conclusion: CaviCide passed the AOAC Use Dilution Test when *S. aureus* (with Reduced Susceptibility to Vancomycin) containing 5% organic load was exposed for 2 minutes at 20±2°C.

Virucidal Studies

Hepatitis B Virus (HBV)** Hepatitis C Virus (HCV)** Herpes Simplex Virus Type 1** Herpes Simplex Virus Type 2** Human Immunodeficiency Virus (HIV-1)** Human Coronavirus (not associated with Severe Acute Respiratory Syndrome or SARS)** Influenza A2 Virus**

** Note: A 2-minute contact time is required as indicated on the product label.

"Initial Virucidal Effectiveness test Using Duck Hepatitis B Virus (DHBV)" Microbiotest, Inc. September 27, 2004. Lab ID # 198-301. Conclusion: CaviCide exposed to the challenge virus for two minutes at 20±1 °C, passed the initial virucidal effectiveness test against duck Hepatitis B Virus.

"Confirmatory Virucidal Effectiveness Test Using Duck Hepatitis B Virus" Microbiotest, Inc. October 19, 2004. Lab ID # 198-302. Conclusion: CaviCide exposed to the challenge virus for two minutes at 21 °C passed the confirmatory virucidal effectiveness test against duck Hepatitis B Virus.

"Virucidal Effectiveness Test Using Bovine Viral Diarrhea Virus (BVDV) (Surrogate for human Hepatitis C virus)"

Microbiotest, Inc. September 8, 2004. Lab ID # 198-303.

Conclusion: CaviCide passed the virucidal effectiveness test when bovine viral diarrhea virus was exposed to the test material for 2 minutes at $20\pm2^{\circ}$ C.

"Confirmatory Virucidal effectiveness Test Using Bovine Viral Diarrhea Virus (BVDV) (Surrogate for Human Hepatitis C Virus)"

Microbiotest, Inc. October 13, 2004. Lab ID # 198-304.

Conclusion: CaviCide passed the confirmatory virucidal effectiveness test when bovine diarrhea virus was exposed to the test material for 1 minute at 22°C.

"CaviCide v. Herpes Simplex Virus Type 1" (Spray) Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 278-161-1053. Conclusion: CaviCide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

"CaviCide v. Herpes Simplex Virus Type 1" (Liquid) Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 279-161-1056. Conclusion: CaviCide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

"CaviCide v. Herpes Simplex Virus Type 2" (Spray) Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 275-161-1040. Conclusion: CaviCide inactivated Herpes Simplex Virus Type 2 at 30 seconds.

"CaviCide v. Herpes Simplex Virus Type 2" (Liquid) Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 276-161-1044. Conclusion: CaviCide inactivated Herpes Simplex Virus Type 2 at 30 seconds. "Virucidal Efficacy of CaviCide Against the Human Immunodeficiency Virus (HIV-1)" Southern Research Institute. July 14, 1992. Lab ID# 0051. Conclusion: CaviCide demonstrated virucidal activity against HIV-1 in a CPE assay with MT-2 cells during a 2 minute exposure period.

"Virucidal Effectiveness Test Coronavirus" Microbiotest, Inc. October 15, 2003. Lab ID # 198-287. Conclusion: When tested as described, CaviCide passed the Virucidal Effectiveness Test when Human Coronavirus, containing at least 5% organic load, was exposed to the test agent for 1 minute at 20±2°C.

"Virucidal Effectiveness Test Human Influenza Virus" Microbiotest, Inc. July 30, 2004. Lab ID # 198-308. Conclusion: When tested as described, CaviCide passed the Virucidal Effectiveness Test when Influenza A2 virus containing at least 5% organic load was exposed to the test agent for 30 seconds at 20±2°C.

Toxicity Studies

Oral Toxicity Inhalation Toxicity Dermal Toxicity/Irritation/Sensitization Ocular Irritation

"Acute Oral Toxicity Study of CaviCide in Sprague-Dawley Rats" American Standards Biosciences Corporation. May 23, 1986. Lab ID# 86-367. Conclusion: CaviCide was tested for potential acute oral toxicity in accordance with the procedure outlined in the Pesticide Assessment Guidelines. No signs of toxicity were exhibited at any time during the 14-day observation period of this study. Based on the results obtained in this study, the acute oral toxicity LD₅₀ of CaviCide is greater than 5g/kg of body weight.

"Acute Inhalation Toxicity Limit Test: CaviCide"

Product Safety Labs. May 20, 1996. Lab ID# 4244.

Conclusion: An Acute Inhalation Toxicity Test was conducted with rats to determine the potential for CaviCide to produce toxicity via the inhalation route at an exposure level of 2.0 mg/L. Based on the results of this study, the single exposure Acute Inhalation LC_{50} of the test substance is greater than 2.08 mg/L.

"Acute Dermal Toxicity Study of CaviCide on New Zealand Albino Rabbits" American Standards Biosciences Corporation. June 6, 1986. Lab ID# 86-368. Conclusion: CaviCide was tested to evaluate the potential dermal toxicity on New Zealand Rabbits. The animals did not exhibit any signs of toxicity during the 14-day observation period. Skin reactions did not reveal any erythema, eschar or edema. Based on the results obtained in this study, the LD₅₀ is greater than 2.0 g/kg of body weight. "Primary Dermal Irritation in Rabbits: CaviCide"

American Standards Biosciences Corporation. September 18, 1986. Lab ID# 86-591. Conclusion: CaviCide was tested for potential dermal irritation in accordance with the procedure outlined in the Pesticide Assessment Guidelines. CaviCide exhibited no erythema, no edema and no eschar at 1, 24, 48 and 72 hour intervals during the observation period. Based on the results obtained in this study, CaviCide is not considered an irritant.

"Dermal Sensitization Test: CaviCide"

Product Safety Labs. May 20, 1996. Lab ID# 4243.

Conclusion: A dermal sensitization test was conducted with guinea pigs to determine the potential for CaviCide to produce sensitization after repeated topical applications. Based on the results of this study, CaviCide is not considered to be a contact sensitizer.

"Primary Eye Mucosa Irritation in Rabbits: CaviCide"

American Standards Biosciences Corporation. September 25, 1986. Lab ID# 86-590. Conclusion: New Zealand Albino Rabbits weighing between 2.0-3.0 kg were employed to evaluate the potential irritant effects of CaviCide on the eye mucosa. Based on the criteria outlined in Grades for Ocular Lesions: Pesticide Assessment Guidelines, CaviCide exhibited positive effects that were reversible.

Stability Studies

"CaviCide Product Chemistry and Storage Stability Data"

Metrex Research Corporation. November 3, 2004. Lab ID# M2002.

Conclusion: Three lots of CaviCide were stored at 25±2°C /60% RH. All parameters were found to be within specification during the course of the 24 month study. The data justifies expiration dating of 2 years.