

ENVIROCIDE

Technical Bulletin

Envirocide 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.

Envirocide has biocidal effectiveness against the following microorganisms:

Mycobacterium bovis BCG
Staphylococcus aureus
Pseudomonas aeruginosa
Salmonella choleraesuis
Trichophyton mentagrophytes
Methicillin Resistant Staphylococcus aureus (MRSA)
Vancomycin Resistant Enterococcus faecalis (VRE)
Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)
Herpes Simplex Virus Type 1
Herpes Simplex Virus Type 2
Human Immunodeficiency Virus (HIV-1)

Tuberculocidal Efficacy Studies:

Mycobacterium bovis BCG

“AOAC Tuberculocidal Activity of Disinfectants Confirmatory In Vitro Test”
MicroBiotest, Inc. February 29, 2000. Lab ID # 386-113.

Conclusion: Envirocide passes the AOAC Tuberculocidal Test when *M. bovis* is exposed to the test material for five minutes at 20±2C.

“AOAC Tuberculocidal Activity of Disinfectants Confirmatory In Vitro Test”
MicroBiotest, Inc. August 15, 2000. Lab ID # 198-214.

Conclusion: Envirocide exposed to *Mycobacterium bovis* for five minutes at 20±2C passed the AOAC Tuberculocidal Test.

“AOAC Confirmative Tuberculocidal Activity of Envirocide”
MicroChem Laboratory. July 19, 1994. Lab ID# 940412-2.

Conclusion: Envirocide killed 100% of the *Mycobacterium bovis BCG* labeled cylinders within 5 minutes at 20°C. Envirocide can pass the AOAC Confirmative Tuberculocidal Test within 5, 10, 20, 30 and 45 minutes at 20°C.

Bactericidal Efficacy Studies:

*Staphylococcus aureus**

*Pseudomonas aeruginosa**

*Salmonella choleraesuis**

*Trichophyton mentagrophytes**

Methicillin Resistant Staphylococcus aureus (MRSA)*

Vancomycin Resistant Enterococcus faecalis (VRE)*

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

“Envirocide 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 Envirocide (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±1°C.

“AOAC Use-Dilution Test: Evaluation of the Efficacy of Envirocide against *Staphylococcus aureus*” (confirmatory)

ViroMed Laboratories, Inc. May 27, 1993. Amended Report November 2, 1993.

Lab ID# 391-SA.

Conclusion: Two lots of Envirocide, 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, Envirocide was germicidal against *S. aureus*.

“Envirocide 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 Envirocide (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 Envirocide against *Pseudomonas aeruginosa*” (confirmatory)

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

Conclusion: Two lots of Envirocide, 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, Envirocide was germicidal against *P. aeruginosa*.

“Envirocide versus *Salmonella 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 Envirocide (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. choleraesuis* at 20±1°C.

“AOAC Use-Dilution Test: Evaluation of the Efficacy of Envirocide against *Salmonella choleraesuis*” (confirmatory)

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

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

“AOAC Use-Dilution Test: Envirocide versus *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis*”

Shaladra Biotest, Inc. August 22, 1986.

Conclusion: Three lots of Envirocide showed no growth of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* when tested for 10 minutes at 20°C.

“Bactericidal Activity of Envirocide in a Stainless Steel Cylinder Test and in Suspension”

MicroChem Laboratory. January 18, 1994. Amended Report November 10, 1994.

Lab ID# 931203-1; 931206-3; 931208-1; 931213-2; 931217-1; 931222-1; 931228-3; 931229-1; 940105-1; 940113-3.

Conclusion: In these studies, tests were designed to determine how quickly bacteria were killed on stainless steel surfaces, and in suspension by Envirocide at 20±1°C. Several procedures were used to eliminate any questions that Envirocide might inhibit rather than kill the bacteria. Envirocide was found to kill *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* in suspension within 15 seconds at 20±1°C. Envirocide also killed these bacteria on stainless steel surfaces within 10 minutes at 20±1°C.

“Quantitative Analysis of the Kill or Removal of Bacteria in Heavy Organic Soil from Surfaces by Envirocide” (custom-designed test)

MicroChem Laboratory. April 18, 1995. Lab ID# 950327-1; 950329-1; 950331-1; 950412-1.

Conclusion: The study was designed to measure the extent to which Envirocide could kill *S. aureus*, *P. aeruginosa* and *S. choleraesuis* dried in concentrations up to 20% calf serum on glass slide surfaces. A 10 minute exposure to Envirocide at 20±2°C. killed more than or equal to 10⁴ bacteria dried in 5%, 10% or 20% calf serum on glass cover slips. No surviving bacteria were found in the Envirocide drained from the glass slips. These data indicate that the health hazard to personnel from bacteria, and by comparison to other microbes, on contaminated medical instruments could be reduced by decontaminating the instruments with Envirocide prior to further process.

“Fungicidal Activity of Envirocide 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: Envirocide killed *Trichophyton mentagrophytes* in suspension within 30 seconds at 20±1°C. Envirocide also killed these fungi on stainless steel surfaces within 1 minute at 20±1°C.

“Envirocide 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 Envirocide 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.

“Envirocide 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 Envirocide 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.

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)**

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

“Confirmatory Virucidal Effectiveness Test Using Duck *Hepatitis B Virus*”

MicroBiotest, Inc. March 13, 2001. Lab ID # 198-245.

Conclusion: Envirocide, exposed to the challenge virus for three minutes at 20±1 °C, was confirmed to be an effective virucidal agent against duck *Hepatitis B Virus*.

“Virucidal Effectiveness Test Using Duck *Hepatitis B Virus*”

MicroBiotest, Inc. August 9, 2000. Lab ID # 198-145.

Conclusion: Envirocide proved to be an effective virucide against duck *Hepatitis B Virus* with a contact time of 3 minutes.

“Virucidal Effectiveness Test Using Bovine viral diarrhea virus (BVDV)-Surrogate for human *Hepatitis C Virus*”

MicroBioTest, Inc. April 14, 2003. Laboratory ID# 198-282.

When tested as described, Envirocide passed the Virucidal Effectiveness Test when BVDV, containing at least 5% organic load, was exposed to the test material for 3 minutes at 20±2C.

”Confirmatory Virucidal Effectiveness Test Using Bovine viral diarrhea virus (BVDV)-Surrogate for human *Hepatitis C Virus*”

MicroBioTest, Inc. April 17, 2003. Laboratory ID# 198-283.

When tested as described, Envirocide passed the Confirmatory Virucidal Effectiveness Test when BVDV, containing at least 5% organic load, was exposed to the test agent for 3 minutes at 20±2C.

“Envirocide v. *Herpes Simplex Virus Type 1*” (Spray)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 278-161-1053.

Conclusion: Envirocide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

“Envirocide v. *Herpes Simplex Virus Type 1*” (Liquid)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 279-161-1056.

Conclusion: Envirocide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

“Envirocide v. *Herpes Simplex Virus Type 2*” (Spray)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 275-161-1040.

Conclusion: Envirocide inactivated Herpes Simplex Virus Type 2 at 30 seconds.

“Envirocide v. *Herpes Simplex Virus Type 2*” (Liquid)
Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 276-161-1044.
Conclusion: Envirocide inactivated Herpes Simplex Virus Type 2 at 30 seconds.

“Virucidal Efficacy of Envirocide Against the *Human Immunodeficiency Virus (HIV-1)*”
Southern Research Institute. July 14, 1992. Lab ID# 0051.
Conclusion: Envirocide demonstrated virucidal activity against HIV-1 in a CPE assay with MT-2 cells during a 2 minute exposure period.

Toxicity Studies

Oral Toxicity

Inhalation Toxicity

Dermal Toxicity/Irritation/Sensitization

Ocular Irritation

“Acute Oral Toxicity Study of Envirocide in Sprague-Dawley Rats”
American Standards Biosciences Corporation. May 23, 1986. Lab ID# 86-367.
Conclusion: Envirocide 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 Envirocide is greater than 5g/kg of body weight.

“Acute Inhalation Toxicity Limit Test: Envirocide”
Product Safety Labs. May 20, 1996. Lab ID# 4244.
Conclusion: An Acute Inhalation Toxicity Test was conducted with rats to determine the potential for Envirocide 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 LC₅₀ of the test substance is greater than 2.08 mg/L.

“Acute Dermal Toxicity Study of Envirocide on New Zealand Albino Rabbits”
American Standards Biosciences Corporation. June 6, 1986. Lab ID# 86-368.
Conclusion: Envirocide 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: Envirocide”
American Standards Biosciences Corporation. September 18, 1986. Lab ID# 86-591.
Conclusion: Envirocide was tested for potential dermal irritation in accordance with the procedure outlined in the Pesticide Assessment Guidelines. Envirocide 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, Envirocide is not considered an irritant.

“Dermal Sensitization Test: Envirocide”
Product Safety Labs. May 20, 1996. Lab ID# 4243.
Conclusion: A dermal sensitization test was conducted with guinea pigs to determine the potential for Envirocide to produce sensitization after repeated topical applications. Based on the results of this study, Envirocide is not considered to be a contact sensitizer.

“Primary Eye Mucosa Irritation in Rabbits: Envirocide”

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 Envirocide on the eye mucosa. Based on the criteria outlined in Grades for Ocular Lesions: Pesticide Assessment Guidelines, Envirocide exhibited positive effects that were reversible.

Stability Studies

“Physical and Chemical Characteristics of Envirocide: Storage Stability and Corrosion Characteristics - 1 Year at Room Temperature”

Case Consulting Laboratories. February 11, 1997. Lab ID# 63-17 and 63-20.

Physical Assessment After 1 Year at Room Temperature: No physical changes were noted for the test substance.

Corrosion Characteristics After 1 Year at Room Temperature: No changes noted in the high density polyethylene packaging material.

“Envirocide Product Chemistry and Storage Stability Data”

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

Conclusion: Three lots of Envirocide were stored at $25\pm 2^{\circ}\text{C}$ /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.