



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 25, 2001

MEMORANDUM:

Subject: Efficacy Review for EPA Reg. No.: 70791-1 "EcoTru®"
DP Barcode: D275281
Case No: 063507

From: Emily Mitchell, M.S., Team Leader *Emily Mitchell 11/8/01*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward PM34/Portia Jenkins
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: Envirosystems, Inc.
2055 Gateway Place, Suite 220
San Jose, CA 95110-1015

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Parachlorometaxylenol.....	0.20%
<u>Inert Ingredient(s)</u>	99.80%
Total	100.00%

I BACKGROUND:

EnviroSystems has submitted an amendment to add additional organisms to label. The submission was received by the Agency on May 22, 2001. Included in this data package is sixteen studies (MRID Nos. 454130-01 thru 454130-16), letter to the Agency (dated May 18, 2001), and a new proposed label.

II USE DIRECTIONS:

The product, "EcoTru®" is a multi-purpose, broad spectrum, ready to use, highly effective disinfectant and cleaner for use on the surfaces of inanimate objects. It is especially useful in homes, hospitals, restaurants, schools and other medical facilities. When used undiluted, with a contact time of 30 seconds, EcoTru® is an effective cleaner and sanitizer on hard non-porous, non-food contact surfaces. EcoTru® is an effective disinfectant when used undiluted with a contact time of 5 minutes for bactericidal, fungicidal, and tuberculocidal claims. For virucidal and Staph disinfection, the product must stand for a 10 minute contact time.

III AGENCY STANDARDS FOR PROPOSED CLAIMS:

The Agency standards for supplementary label claims for effectiveness of the product against public health organisms is found in DIS-TSS-1 and DIS-TSS-2 which specifies the use of the methods outlined in the Association of Official Analytical Chemists (AOAC) Use-Dilution Method for products. Two samples representing two batches of the product are tested against 10 carriers of the organism for which a label claim is made. The results of the testing must demonstrate killing of the test organism on all carriers. Plate count data must be submitted on each test microorganism. DIS-TSS-7 may be used to test for viruses. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to air dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. The Agency will accept adequate data developed by any virological technique which is recognized technically sound and which simulates to the extent possible in the laboratory the conditions under which the product is intended for use.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES:

Data Summary:

MRID No. 454130-01 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 12, 2001. The product was tested by the A.O.A.C. Use Dilution Method, 15th Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Salmonella typhi* (ATCC 6530) undiluted in the presence of an organic soil load (5% equine serum) at $20 \pm 0.5^\circ\text{C}$ for 5 and 10 minutes. Ten carriers were tested for each batch of product against the

microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Salmonella typhi (ATCC 6530)

1.0×10^2 cfu/carrier

MRID No. 454130-02 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 12, 2001. The product was tested by the A.O.A.C. Use Dilution Method, 15th Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Streptococcus pyogenes* (ATCC 8669) undiluted in the presence of an organic soil load (5% equine serum) at $20 \pm 0.5^\circ$ C for 5 and 10 minutes. Ten carriers were tested for each batch of product against the microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Streptococcus pyogenes (ATCC 8669)

1.0×10^5 cfu/carrier

MRID No. 454130-03 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 12, 2001. The product was tested by the A.O.A.C. Use Dilution Method, 15th Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Escherichia coli* OH157 (ATCC 43888) undiluted in the presence of an organic soil load (5% equine serum) at $20 \pm 0.5^\circ$ C for 2 and 5 minutes. Ten carriers were tested for each batch of product against the microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Escherichia coli OH157 (ATCC 43888)

1.0×10^5 cfu/carrier

MRID No. 454130-04 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 12, 2001. The product was tested by the A.O.A.C. Use Dilution Method, 15th Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Listeria monocytogenes* (ATCC 19111) undiluted in the presence of an organic soil load (5% equine serum) at $20 \pm 0.5^\circ$ C for 5 and 10 minutes. Ten carriers were tested for each batch of product against the microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Listeria monocytogenes (ATCC 19111)

5.5×10^6 cfu/carrier

MRID No. 454130-05 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 12, 2001. The product was tested by the A.O.A.C. Fungicidal Activity of Disinfectants, 15th Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Trichophyton mentagrophytes* (ATCC 9533) undiluted at $27-29^\circ$ C for 2 and 5 minutes. Sixty carriers were tested for each batch of product against the microorganism.

MRID No. 454130-06 - The submitted study was conducted by Shelli Baxter, Nelson Laboratories, Inc., 6280 South Redwood Road, Salt Lake City, UT 84123, report dated April 16, 2001. The product was tested by the A.O.A.C. Fungicidal Activity of Disinfectants, 15th

Edition, 1990. The lots (68035-1045 and 68739-1045) were tested against *Candida albicans* (ATCC 10231) undiluted at 27-29°C for 5 and 10 minutes. Ten carriers were tested for each batch of product against the microorganism.

MRID No. 454130-07 - The submitted study was conducted by Donna Suchmann, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 15, 2001. The product was tested by the A.O.A.C. Use Dilution Method. The lots (1110-1 and 68739-1110) were tested against *Campylobacter jejuni* (ATCC 29248) undiluted in the presence of an organic soil load (5% horse serum) at 20 ± 2°C for 10 minutes. Ten carriers were tested for each batch of product against the microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Campylobacter jejuni (ATCC 29248) 8.3 x 10⁵ cfu/carrier

MRID No. 454130-08 - The submitted study was conducted by Donna Suchmann, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 15, 2001. The product was tested by the A.O.A.C. Use Dilution Method. The lots (1110-1 and 68739-1110) were tested against *Legionella pneumophila* (ATCC 33153) undiluted in the presence of an organic soil load (5% horse serum) at 20 ± 2°C for 10 minutes. Ten carriers were tested for each batch of product against the microorganism. The quantitation of test organisms recovered from the dried carriers was derived using a standard plate count, the reported numbers:

Legionella pneumophila (ATCC 33153) 1.0 x 10⁶ cfu/carrier

MRID No. 454130-09 - The submitted study was conducted by Nicole Braddock, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated December 19, 2000. The product was tested by the Quantitative Tuberculocidal Test. The lots (68739-307 and 308-1) were tested against *Mycobacterium bovis* (ATCC 35743, TMC 1028) undiluted in the presence of an organic soil load (5% bovine serum) at 21 ± 2°C for 2, 3, 5 and 6 minutes.

MRID No. 454130-10 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 14, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Human Immunodeficiency Virus Type 1 (HIV-1), received from Zepto Metrix Corporation, undiluted in the presence of an organic soil load (5% fetal bovine serum) at 21 ± 2°C (22C) for 5 minutes.

MRID No. 454130-11 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 14, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Rhinovirus 39, ATCC VR-340, undiluted in the presence of an organic soil load (5% fetal bovine serum) at 21 ± 2°C (21C) for 10 minutes.

MRID No. 454130-12 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 14, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Influenza A2, ATCC VR-100,

undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ (21C) for 10 minutes.

MRID No. 454130-13 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 14, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Bovine Viral Diarrhea Virus, undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ (21C) for 5 and 10 minutes.

MRID No. 454130-14 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 14, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Duck Hepatitis B Virus (DHBV), undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ for 5 minutes.

MRID No. 454130-15 - The submitted study was conducted by Keaira Brown, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated May 2, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Duck Hepatitis B Virus (DHBV), (Received from Hepadna Virus Testing, Inc.), undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ for 5 minutes.

MRID No. 454130-16 - The submitted study was conducted by Nicole Braddock, MicroBio Test, Inc., 105B Carpenter Drive, Sterling, VA 20164, report dated January 30, 2001. The product was tested by EPA Guidelines DIS/TSS-7, November 1981 and ASTM test method designated E 1053-97. The lots (68739-307 and 308-1) were tested against Herpes simplex virus Type 1, ATCC VR-260, Herpes simplex virus Type 2, ATCC VR-734, undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ for 5 minutes.

V RESULTS:

MRID No. 454130-01

Organism <i>Salmonella typhi</i>	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68035-1045	5	10	0	10
	10	10	0	10
Lot #68739-1045	5	10	0	10
	10	10	0	10

MRID No. 454130-02

Organism <i>Streptococcus pyogenes</i>	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68035-1045	5	10	0	10
	10	10	0	10
Lot #68739-1045	5	10	0	10
	10	10	0	10

MRID No. 454130-03

Organism <i>Escherichia coli</i> OH157	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68035-1045	2	10	1	9
	5	10	0	10
Lot #68739-1045	2	10	1	9
	5	10	0	10

MRID No. 454130-04

Organism <i>Listeria monocytogenes</i>	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68035-1045	5	10	0	10
	10	10	0	10
Lot #68739-1045	5	10	0	10
	10	10	0	10

MRID No. 454130-05

Organism <i>Trichophyton mentagrophytes</i>	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68739-1045	2	60	11	49
	5	60	1	59
Lot #68035-1045	2	60	0	60
	5	60	1	59

MRID No. 454130-06

Organism <i>Candida albicans</i>	Time Point (Mins.)	No. of Carriers Tested	No. Showing Growth	No. Showing No Growth
Lot #68739-1045	5	10	0	10
	10	10	0	10
Lot #68035-1045	5	10	0	10
	10	10	0	10

MRID No. 454130-07

<i>Campylobacter jejuni</i>	
Lot 1110-1	Lot 68739-1110
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0

MRID No. 454130-08

<i>Legionella pneumophila</i>	
Lot 1110-1	Lot 68739-1110
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0
0	0

MRID No. 454130-09

Mycobacterium bovis

Contact Time	Replicate	Lot Number	Average Recovery	Average CFU/mL
2 minutes	A	68739-307	2.3×10^1	2.1×10^1
	B		2.8×10^1	
	C		1.6×10^1	
	D		1.5×10^1	
2 minutes	A	308-1	3.5×10^2	2.7×10^2
	B		2.5×10^2	
	C		2.2×10^2	
	D		2.4×10^2	

Contact Time	Replicate	Lot Number	Average Recovery	Average CFU/mL
3 minutes	A	68739-307	6.0×10^0	4.3×10^0
	B		8.0×10^0	
	C		2.0×10^0	
	D		1.0×10^0	
3 minutes	A	308-1	2.9×10^1	2.4×10^1
	B		2.8×10^1	
	C		1.9×10^1	
	D		2.1×10^1	

Contact Time	Replicate	Lot Number	Average Recovery	Average CFU/mL
5 minutes	A	68739-307	$<1.0 \times 10^0$	$<1.0 \times 10^0$
	B		$<1.0 \times 10^0$	
	C		$<1.0 \times 10^0$	
	D		$<1.0 \times 10^0$	
5 minutes	A	308-1	$<1.0 \times 10^0$	$<1.0 \times 10^0$
	B		$<1.0 \times 10^0$	
	C		$<1.0 \times 10^0$	
	D		$<1.0 \times 10^0$	

Contact Time	Replicate	Lot Number	Average Recovery	Average CFU/mL
6 minutes	A	68739-307	$<1.0 \times 10^0$	$<1.0 \times 10^0$
	B		$<1.0 \times 10^0$	
	C		$<1.0 \times 10^0$	
	D		$<1.0 \times 10^0$	
6 minutes	A	308-1	$<1.0 \times 10^0$	$<1.0 \times 10^0$
	B		$<1.0 \times 10^0$	
	C		$<1.0 \times 10^0$	
	D		$<1.0 \times 10^0$	

MRID No. 454130-10

HIV-1

Dilution	Lot No. 68739-307	Lot No. 308-1
10^{-1}	PNS	PNS
10^{-2}	----	----
10^{-3}	----	----
10^{-4}	----	----
10^{-5}	----	----
10^{-6}	----	----
10^{-7}	----	----
CCID ₅₀ /mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$

MRID No. 454130-11

Rhinovirus 39

Dilution	Lot No. 68739-307	Lot No. 308-1
10^{-1}	PNS	PNS
10^{-2}	----	----
10^{-3}	----	----
10^{-4}	----	----
10^{-5}	----	----
10^{-6}	----	----
10^{-7}	----	----
CCID ₅₀ /mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$

MRID No. 454130-12

Influenza A2

Dilution	Lot No. 68739-307	Lot No. 308-1
10^{-1}	PNS	PNS
10^{-2}	----	----
10^{-3}	----	----
10^{-4}	----	----
10^{-5}	----	----
10^{-6}	----	----
10^{-7}	----	----
ELD/EID ₅₀ /mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$

MRID No. 454130-13

Bovine Viral Diarrhea Virus

Dilution	Lot No. 68739-307	Lot No. 308-1	Lot No. 68739-307	Lot No. 308-1
	5 minutes	10 minutes	5 minutes	10 minutes
10^{-1}	PNS	PNS	PNS	PNS
10^{-2}	----	----	----	----
10^{-3}	----	----	----	----
10^{-4}	----	----	----	----
10^{-5}	----	----	----	----
10^{-6}	----	----	----	----
10^{-7}	----	----	----	----
CCID ₅₀ /mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	$\leq 10^{1.50}$	$\leq 10^{1.50}$

MRID No. 454130-14

Duck Hepatitis B Virus

Dilution log ₁₀	Lot No. 68739-307	Lot No. 68739-307	Lot No. 301-1	Lot No. 308-1
	Carrier #1	Carrier #2	Carrier #1	Carrier #2
10 ⁻¹	PNS	PNS	PNS	PNS
10 ⁻²	----	----	----	----
10 ⁻³	----	----	----	----
10 ⁻⁴	----	----	----	----
10 ⁻⁵	----	----	----	----
10 ⁻⁶	----	----	----	----
Log ₁₀ MPN/mL	0	0	0	0
Mean of duplicates (log ₁₀ MPN/mL)	0	0	0	0

MRID No. 454130-15

Duck Hepatitis B Virus

Dilution log ₁₀	Lot No. 68739-307	Lot No. 68739-307
	Carrier #1	Carrier #2
10 ⁻¹	PNS	PNS
10 ⁻²	----	----
10 ⁻³	----	----
10 ⁻⁴	----	----
10 ⁻⁵	----	----
10 ⁻⁶	----	----
Log ₁₀ MPN/mL	0	0
Mean of duplicates (log ₁₀ MPN/mL)	0	0

Dilution	Lot No. 68739-307	Lot No. 308-1	Lot No. 68739-307	Lot No. 308-1
	Herpes Simplex I	Herpes Simplex I	Herpes Simplex II	Herpes Simplex II
10^{-1}	PNS	PNS	PNS	PNS
10^{-2}	----	----	----	----
10^{-3}	----	----	----	----
10^{-4}	----	----	----	----
10^{-5}	----	----	----	----
10^{-6}	----	----	----	----
10^{-7}	----	----	----	----
PFUD ₅₀ /mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	$\leq 10^{1.50}$	$\leq 10^{1.50}$

VI CONCLUSIONS:

The efficacy data submitted supports the product's effectiveness against *Salmonella typhi* (ATCC 6530), *Streptococcus pyogenes* (ATCC 8669), *Escherichia coli* OH157 (ATCC 43888), *Listeria monocytogenes* (ATCC 19111), *Trichophyton mentagrophytes* (ATCC 9533), and *Candida albicans* (ATCC 10231) undiluted in the presence of an organic soil load (5% equine serum) at $20 \pm 0.5^{\circ}\text{C}$ for 5 minutes.

The efficacy data submitted supports the product's effectiveness against *Campylobacter jejuni* (ATCC 29248), *Legionella pneumophila* (ATCC 33153), undiluted in the presence of an organic soil load (5% horse serum) at $20 \pm 2^{\circ}\text{C}$ for 10 minutes.

The efficacy data submitted supports the product's effectiveness against Human Immunodeficiency Virus Type 1 (HIV-1), received from Zepto Metrix Corporation, Bovine Viral Diarrhea Virus, Duck Hepatitis B Virus (DHBV), Herpes simplex virus Type 1 (ATCC VR-260), and Herpes simplex virus Type 2 (ATCC VR-734) undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ (22C) for 5 minutes.

The efficacy data submitted supports the product's effectiveness against Rhinovirus 39 (ATCC VR-340) and Influenza A2 (ATCC VR-100) undiluted in the presence of an organic soil load (5% fetal bovine serum) at $21 \pm 2^{\circ}\text{C}$ (22C) for 10 minutes.

The efficacy data submitted supports the product's effectiveness against *Mycobacterium bovis* (ATCC 35743, TMC 1028) undiluted in the presence of an organic soil load (5% bovine serum) at $21 \pm 2^{\circ}\text{C}$ for 5 minutes.

VII LABELING COMMENTS:

1. On front label, remove the claim for Hepatitis C. Proposed test protocol was not submitted for this claim.
2. All organisms listed on the label should have complete nomenclature including ATCC numbers.
3. The spelling for "*Pseudomonas aerugionosa*" should be revised to reflect the correct spelling "*Pseudomonas aeruginosa*."
4. The efficacy data submitted for the organisms *Campylobacter jejuni* (ATCC 29248) and *Legionella pneumophila* (ATCC 33153) is acceptable for a 10 minute contact time. Therefore, the label must be revised to reflect the 10 minute claim.
5. The disinfection label claims for *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* must have a contact time of 10 minutes. The label must be revised for a 10 minute disinfection claim for all 3 organism listed above.
6. Revise page 3 under "Directions For Use" to say 5 minute contact for fungicidal and tuberculocidal and a 10 minute contact time for bactericidal claims.

