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

JUL 13 [redacted]

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Secondary Review of Contractor's (Oak Ridge National Lab) Efficacy Review
EPA Reg. No. 10492-4/Isotex 70 Disinfecting Towelette
Case # 4003 Aliphatic Alcohols Product Reregistration/Eight Month Response
DP Barcode: D235814

FROM: Srinivas Gowda, Microbiologist Srinivas Gowda
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

TO: Karen Jones, Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

THRU: Julie Fairfax, Team Leader, Team 36
Regulatory Branch II
Antimicrobials Division (7510C)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS:

1. The Oak Ridge National Laboratory's efficacy reviews have undergone secondary review by AD, EASSB, EET. The contractor's reviews reflect EPA's Pesticide Assessment Guideline requirements and regulations and the findings/conclusions are scientifically sound. The efficacy data submitted under the MRID numbers 425742-01 (five-minute exposure time for *P. aeruginosa* and six-minute exposure time for *S. choleraesuis* and *S. aureus*) to 425742-04, 415215-02 and 440006-07 to 440006-08 are acceptable.

2. The request for waivers from other efficacy data requirements are granted based on the information provided with the registrant's eight month response for product reregistration and the file record review.

3. The applicant has satisfied the efficacy data requirements for a FIFRA Section 4 reregistration of this product.

4. The use-directions on the product's label dated 05-01-96 are acceptable.

NOTE TO CRM: A Copy of Oak Ridge National Laboratory's Efficacy Evaluation Report dated March 8, 1999 (13 pages) is appended to our memorandum. Our secondary review projects the Findings/Conclusions up in front to assist the CRM in communicating the Agency's decisions to the applicant.

Attachment: Oak Ridge National Laboratory's Efficacy Evaluation Report dated March 8, 1999 (13 pages).

EFFICACY EVALUATION REPORTS

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 98-201

Primary Reviewer: Kathleen H. Mavournin, Ph.D.	Signature:	Kathleen H. Mavournin
	Date:	MAR - 8 1999
Secondary Reviewers: Anthony Q. Armstrong, Ph.D.	Signature:	AQ Armstrong
	Date:	MAR - 8 1999
	Signature:	
	Date:	
Quality Assurance: Bobette D. Nourse, Ph.D.	Signature:	B.D. Nourse
	Date:	MAR - 8 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/4/98

BACTERICIDE CLAIMS			
MRID Number	42574201		
GLP Statement	yes		
Q/A Statement	yes		
Data Package	complete X	confirmatory	
Use Site	food contact	non-food contact X	
Microorganisms(s) Used/ATCC	*Staphylococcus aureus* ATCC 6538 *Salmonella choleraesuis* ATCC 10708 *Pseudomonas aeruginosa* ATCC 15442		
Test Method(s) - Test Dates	Germicidal Use Dilution	4/6/92 - 4/14/92	
Type of carrier used	stainless steel penicylinders		
Number of organisms on carrier	*S. aureus* *S. choleraesuis* *P. aeruginosa*	3.7×10^6 1.1×10^6, 4.6×10^6 (retest) 9.8×10^6	
Hard water?	no		
Organic soil load?	no		
Dilution	neat		
Contact time	5, 6 min		
Temperature	20°C		
Lot #; Date Results 5 min	L-180-1, date not given	*S. aureus* *S. choleraesuis* *P. aeruginosa*	0+/60 1+/60 1+/60
Lot #; Date Results 5 min	L-190-1, date not given	*S. aureus* *S. choleraesuis* *P. aeruginosa*	0+/60 3+/60 1+/60
Lot #; Date Results 5 min	K-020-1, date not given	*S. aureus* *S. choleraesuis* *P. aeruginosa*	0+/60 2+/60 1+/60
Lot #; Date Results 6 min	L-180-1, date not given	*S. choleraesuis*	0+/60

Lot #; Date	Results	6 min	L-022-1, date not given	*S. aureus* *S. choleraesuis*	1+/60 1+/60
Lot #; Date	Results	6 min	K-020-1, date not given	*S. aureus* *S. choleraesuis*	0+/60 0+/60
Phenol resistance			*S. aureus* *S. choleraesuis* *P. aeruginosa*	pass pass pass	
Neutralization test			*S. aureus* *S. choleraesuis* *P. aeruginosa*	pass pass pass	
Protocol Deviations (page #)			all lots are stated to be more than 60 days old but no manufacture dates are given		
Other Deficiencies			copy quality is very poor; exponents are not really discernable but appear to be 6's.		

AOA 2/20/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/4/98

TUBERCULOCIDE CLAIMS		
MRID Number	42574202	
GLP Statement	yes	
Q/A Statement	yes	
Data Package	complete	confirmatory X
Use Site	food contact	non-food contact X
Test Method(s) - Test Dates	Rate of kill	3/24/92 - 4/15/92
Microorganisms(s) Used/ATCC	*Mycobacterium bovis* BCG ATCC 35745	
Type of carrier used	test conducted in suspension	
Number of organisms	1.5×10^6 innoculated (see below)	
Hard water?	no	
Organic soil load?	5% newborn calf serum	
Dilution	neat	
Contact time	0.5, 2, 3.5, 5, 10 min	
Temperature	20°C	
Lot #; Date Results	L-180-1, date not given	no organisms recovered at any exposure time
Lot #; Date Results	K-020-1, date not given	no organisms recovered at any exposure time
Phenol resistance	n/a	
Neutralization test	pass	
Protocol Deviations (page #)		
Other Deficiencies	copy quality very poor; innoculum size very difficult to read	

AGA 2/25/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/4/98

FUNGICIDE CLAIMS		
MRID Number	42574203	
GLP Statement	yes	
Q/A Statement	yes	
Data Package	complete	confirmatory X
Use Site	food contact	non-food contact X
Test Method(s) - Test Dates	Germicidal Use Dilution	4/7/92 - 4/17/92
Microorganisms(s) Used/ATCC	*Trichopyton mentagrophytes* ATCC 9533	
Type of carrier used	tested in suspension	
Number of organisms on carrier	not given	
Hard water?	no	
Organic soil load?	no	
Dilution	neat	
Contact time	4 min	
Temperature	20°C	
Lot #; Date Results	L-180-1	0+/10
Lot #; Date Results	K-202-1	0+/10
Phenol resistance	n/a	
Neutralization test	pass	
Protocol Deviations (page #)		
Other Deficiencies		

AQM 2/27/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/4/98

VIRUCIDE CLAIMS			
MRID Number	42574204		
GLP Statement	yes		
Q/A Statement	yes		
Data Package	complete	confirmatory X	
Use Site	food contact	non-food contact X	
Test Method(s)/Date(s)	Germicidal Use dilution	6/26/92 - 7/7/92	
Microorganisms(s) Used/ATCC	Herpes simplex virus type 2 ATCC VR-734 Adenovirus type 2 ATCC VR-864		
Type of carrier used	petri dishes, material not specified		
Hard water?	no		
Organic soil load?	5% serum		
Dilution	neat		
Contact time	1 min		
Temperature	20°C		
Titer Method	Vero cells/CPE (HSV-2); HEK cells/CPE (Ad-2)		
Control Virus Titer (-log)	$TCID_{50} = 6$		
Cytotoxicity Titer (-log)	K-020-1 L-180-1	$TCLD_{50} = 1.5$ $TCLD_{50} = 1.5$	
Reduction of Titer by Treatment	K-020-1 L-180-1	$TCID_{50} \leq 1.5$ $TCID_{50} \leq 1.5$	≥4.5 log decrease ≥4.5 log decrease
Protocol Deviations (page #)			
Other Deficiencies			

KCH 2/23/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/4/98

VIRUCIDE CLAIMS			
MRID Number	41521502		
GLP Statement	yes		
Q/A Statement	yes		
Data Package	complete	confirmatory X	
Use Site	food contact	non-food contact X	
Test Method(s)/Date(s)	Germicidal Use Dilution	3/29/90 - 4/5/90	
Microorganisms(s) Used/ATCC	Human immunodeficiency virus 1, HTLV-III_{RF}		
Type of carrier used	glass petri dishes		
Hard water?	no		
Organic soil load?	no		
Dilution	neat		
Contact time	1 min		
Temperature	23°C		
Titer Method	MT-2 cells/lytic CPE		
Control Virus Titer (-log)	$TCID_{50}$ >7		
Cytotoxicity Titer (-log)	A 199-1 D 139-1	$TCLD_{50} \leq 3.5$ $TCLD_{50} \leq 3.5$	
Reduction of Titer by Treatment	A 199-1 D 139-1	$TCID_{50} \leq 3.5$ $TCID_{50} \leq 3.5$	≥3.5 log decrease ≥3.5 log decrease
Protocol Deviations (page #)			
Other Deficiencies			

AGA 2/25/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/7/98

BACTERICIDE CLAIMS		
MRID Number	44000607	
GLP Statement	yes	
Q/A Statement	yes	
Data Package	complete	confirmatory X
Use Site	food contact	non-food contact X
Microorganisms(s) Used/ATCC	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Salmonella choleraesuis* ATCC 10708	
Test Method(s) - Test Dates	Rate of Kill	date not given
Type of carrier used	in suspension	
Number of organisms	*S. aureus* *P. aeruginosa* *S. choleraesuis*	5×10^7 6×10^8 4×10^8
Hard water?	no	
Organic soil load?	no	
Dilution	n/a	
Contact time	0.5, 1, 2, 5, 10 min	
Temperature	20°C	
Lot #; Date Results	lot # & date not given	*S. aureus* no organisms recovered at any time *P. aeruginosa* no organisms recovered at any time *S. choleraesuis*
Phenol resistance	*S. aureus* *P. aeruginosa.* *S. choleraesuis*	fail
Neutralization test	*S. aureus* *P. aeruginosa.* *S. choleraesuis*	pass

AM 2/25/99

Protocol Deviations (page #)	no indication that the requisite 4 replications of this test were conducted, p.11; the experiment was done to determine that the bacteria were actually killed by the germicide and not just wiped from the slide, so probably wasn't intended to stand alone as a valid test.
Other Deficiencies	

BACTERICIDE CLAIMS	
MRID Number	44000607
GLP Statement	yes
Q/A Statement	yes
Data Package	complete X confirmatory
Use Site	food contact non-food contact X
Microorganisms(s) Used/ATCC	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Salmonella choleraesuis* ATCC 10708
Test Method(s) - Test Dates	Hard Surface Wipe date not given
Type of carrier used	glass slides, 75 x 25 mm
Number of organisms on carrier	*S. aureus* $\geq 10^5$ *P. aeruginosa* $\geq 10^6$ *S. choleraesuis* $\geq 10^3$, $> 10^4$
Hard water?	no
Organic soil load?	no
Dilution	n/a
Contact time	1 min
Temperature	22±2°C
Lot #; Date Results	H075-B, date not given *S. aureus* 0+/60 *P. aeruginosa* 0+/60 *S. choleraesuis* 0+/60
Lot #; Date Results	H235-A, date not given *S. aureus* 0+/60 *P. aeruginosa* 0+/60 *S. choleraesuis* 1+/60
Lot #; Date Results	H014-A, date not given *S. aureus* 0+/60 *P. aeruginosa* 1+/60 *S. choleraesuis* 0+/60

Phenol resistance	*S. aureus* *P. aeruginosa* *S. choleraesuis*	fail fail fail
Neutralization test	*S. aureus* *P. aeruginosa* *S. choleraesuis*	pass pass pass
Protocol Deviations (page #)		
Other Deficiencies		

AA 2/25/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/7/98

FUNGICIDE CLAIMS		
MRID Number	44000608	
GLP Statement	yes	
Q/A Statement	yes	
Data Package	complete	confirmatory X
Use Site	food contact	non-food contact X
Test Method(s) - Test Dates	Hard Surface Wipe	date not given
Microorganisms(s) Used/ATCC	Trichophyton mentagrophytes ATCC 9533	
Type of carrier used	glass slides, 75 x 25 mm	
Number of organisms on carrier	$\geq 2 \times 10^4$	
Hard water?	no	
Organic soil load?	no	
Dilution	n/a	
Contact time	1 min	
Temperature	22±2°C	
Lot #; Date Results	H-075-B, date not given repeat test	1+/10 0+/10
Lot #; Date Results	H-235-A, date not given	0+/10
Phenol resistance	n/a	
Neutralization test	pass	
Protocol Deviations (page #)		
Other Deficiencies		

AOA 2/25/99

DP Barcode: D235814 Reviewer: Kathleen H. Mavournin, Ph.D. Date: 12/7/98

FUNGICIDE CLAIMS	
MRID Number	44000608
GLP Statement	yes
Q/A Statement	yes
Data Package	complete confirmatory X
Use Site	food contact non-food contact X
Test Method(s) - Test Dates	Rate of Kill date not given
Microorganisms(s) Used/ATCC	Trichophyton mentagrophytes ATCC 9533
Type of carrier used	in suspension
Number of organisms	$\geq 1 \times 10^8$
Hard water?	no
Organic soil load?	no
Dilution	n/a
Contact time	0.5, 1, 2, 5, 10 min
Temperature	20°C
Lot #; Date Results	lot # & date not given no organisms recovered at any time
Phenol resistance	n/a
Neutralization test	pass
Protocol Deviations (page #)	
Other Deficiencies	no indication that the requisite 4 replications of this test were conducted, pp.10-11; the experiment was done to determine that the fungi were actually killed by the germicide and not just wiped from the slide, so probably wasn't intended to stand alone as a valid test.

ADM 2/20/99