8-23-89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 04-07-89 OUT 08-21-89

Reviewed By Emily H. Mitchell 8/23/89 Date 08-21-89

EPA Reg. No. or File Symbol 778-OR

EPA Petition or EUP No. None

Date Division Received 04-25-89

Type Product(s) General Disinfectant

Data Accession No.(s) 410574-10 & 410574-11 411083-01 & 411083-02

Product Mgr. No. PM 32 (Kempter)

Product Name(s) VIRKON-S

Company Name(s) A. H. Robins Company, Inc.

Submission Purpose New submission with efficacy data and proposed label

Chemical & Formulation Powder

Active Ingredient(s):	%
Potassium monopersulfate	22.5%
Sodium Chloride	1.5%

200.0 Introduction

200.1 Uses:

A powder formula effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma.

200.2 Background Information:

The submission received 04-25-89, is a new submission with efficacy data and proposed label provided.

201.0 Data Summary (Accession Nos. 410574-10 & 410574-11 411083-01 & 411083-02)

201.2 Brief Description of Tests:

a. Reports of Bactericidal Tests by Daniel L. Prince, Ph.D. Gibraltar Biological Laboratories, Inc. 122 Fairfield Road, Fairfield, New Jersey 07006

b. Reports of Virucidal Tests by Daniel L. Prince, Ph.D. Gibraltar Biological Laboratories, Inc. 122 Fairfield Road, Fairfield, New Jersey 07006

201.3 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Use Dilution Test, 14 Edition, 1984.

2. Modifications: 5% calf serum and 400 ppm A.O.A.C. hard water ($CaCO_3$)

3. Samples:

Test Bacteria	Lot No:	Date Assayed	Date Completed
P. aeruginosa	08109160 02809160 03809160	1-16-89-1-19-89 1-23-89	1-26-89
S. aureus	08109106 02809160 03809160	1-16-89-1-19-89 1-23-89	1-26-89
S. choleraesuis	01809106 02809160 02809160	1-16-89-1-19-89 1-23-89	1-26-89

E. coli	01809160 02809160	01-27-89	02-16-89
S. pyogenes	01809160 02809160	01-27-89	02-16-89
S. typhi	01809160 02809160	01-27-89	02-16-89
K. pneumoniae	01809160 02809160	01-27-89	02-16-89
S. epidermidis	01809160 02809160	01-27-89	02-16-89
C. pyloridis	01809160 02809160	01-27-89	02-16-89
C. albicans	01809160 02809160	01-27-89	02-16-89

4. Dilution: 1% in 400 ppm
5. Exposure: 10 minutes at 20-25°C
6. Subculture Medium/Neutralizer: Letheen Broth
7. Incubation of Subcultures: 48 hours at 35±1°C
8. Test Bacteria:

Test Bacteria	Identification	Phenol Res.
Pseudomonas aeruginosa	15442 ATCC	Not Listed
Staphylococcus aureus	6538 ATCC	Not Listed
Salmonella choleraesuis	10708 ATCC	Not Listed
Streptococcus pyogenes	GBL #7	Not Listed
Salmonella typhi	GBL #106	Not Listed
Escherichia coli	GBL #642	Not Listed
Klebsiella pneumoniae	GBL #132	Not Listed
Staphylococcus epidermidis	GBL #6	Not Listed
Campylobacter pyloridis	GBL #775	Not Listed
Candida albicans	GBL #648	Not Listed

9. Survival of Inoculum on Control Carriers:

Test Bacteria	Average Colony Forming Units Per Carrier		
P. aeruginosa	1.5×10^6	1.8×10^6	3.7×10^5
S. aureus	7.2×10^4	1.3×10^6	1.6×10^5
S. choleraesuis	1.6×10^5	4.2×10^5	1.6×10^5
S. pyogenes		4.1×10^4	
S. typhi		8.5×10^5	
E. coli		1.7×10^6	
K. pneumoniae		2.9×10^6	
S. epidermidis		9.3×10^4	
C. pyloridis		5.9×10^5	
C. albicans		3.7×10^4	

10. Test Results:

Test Bacteria	Lot No.	No. Carriers Tested	No. of Carriers Demonstrating Growth
Pseudomonas aeruginosa	01809160	60	0
	02809160	60	0
	03809160	60	0
Staphylococcus aureus	01809106	60	0
	02809160	60	0
	03809160	60	0
Salmonella choleraesuis	01809106	60	0
	02809160	60	0
	03809160	60	0
Streptococcus pyogenes	01809160	10	0
	02809160	10	0
Salmonella typhi	01809160	10	0
	02809160	10	0
Escherichia coli	01809160	10	0
	02809160	10	0

Klebsiella pneumoniae	01809160	10	0
	02809160	10	0
Staphylococcus epidermidis	01809160	10	0
	02809160	10	0
Campylobacter pyloridis	01809160	10	0
	02809160	10	0
Candida albicans	01809160	10	0
	02809160	10	0

11. Conclusions: Results show satisfactory performance of the product against all test bacteria when used at a 1% in 400 ppm dilution on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the bacteria tested.

c. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)

2. Modifications: 10% fetal calf serum and hard water

3. Samples:

Batch No.	Preparation Date	Test Date
45616/1D	04-05-89	04-11-89
45616/2D	04-05-89	04-11-89

4. Dilution: 1:100 (400 ppm A.O.A.C. H_2O) (1%)

5. Exposure: 20-25°C for 10 minutes

6. Recovery Medium/Neutralizer/Diluent: Trypticase Soy Broth with 10% calf serum

7. Incubation: 48 hours at 35°C

8. Test Virus Host System:

9-10 day old Chick Embryos

9. Drying Time and Temperature: 35°C for 30-45 minutes.

10. Assay System for Virus Recovery: Hemagglutination

11. Method For Estimating 50 per cent end point: Reed Muench Method

12. Test Virus: Newcastle Disease Virus

13. Test Results:

		ID-50 (-log 10)			
Test Virus	Batch No.	Virus Control	Virus Disin.	Toxicity Control	Virus Inactivation
Newcastle Disease	45616/1D	4.4	1.0	1.0	3.4
	45616/2D	4.4	1.0	1.0	3.4

14. Conclusions: This product showed satisfactory performance against the test virus when used at a 1:100 dilution with 400 ppm A.O.A.C. water (1%) on hard, non-porous surfaces at a contact time of 10 minutes.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 778-OR

Date Division Received 04-25-89

Data Accession No.(s) 411083-01 & 411083-02 410574-10 & 410574-11

Product Manager No. PM 32 (Kempter)

Product Name VIRKON-S

Company Name A. H. Robins Company, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data:

a. The submitted data are acceptable to support effectiveness of the product, as a general disinfectant against all tested bacteria at a 1:100 dilution (1% in 400 ppm hard water) on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the tested bacteria. Refer to 202.2 below.

b. The submitted virucidal data are acceptable to support effectiveness of the product against Newcastle Disease Virus at a 1:100 dilution on hard, non-porous surfaces for a contact time of 10 minutes.

202.2 Additional Data/Information Required to Support Efficacy:

a. The phenol resistance must be provided for all tested bacteria.

203.0 Labeling

a. On BACK PANEL change "Merek's Disease" to read "Marek's Disease".

b. On BACK PANEL change "Sallmonella choleraesuis" to read "Salmonella choleraesuis".