

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 <sup>WEC
8/21/89</sup> 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

<u>Active Ingredient(s):</u>	<u>%</u>
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 (CaCO₃)
3. Samples:

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

E. <u>coli</u>	01809160 02809160	01-27-89	02-16-89
S. <u>pyogenes</u>	01809160 02809160	01-27-89	02-16-89
S. <u>typhi</u>	01809160 02809160	01-27-89	02-16-89
K. <u>pneumoniae</u>	01809160 02809160	01-27-89	02-16-89
S. <u>epidermidis</u>	01809160 02809160	01-27-89	02-16-89
C. <u>pyloridis</u>	01809160 02809160	01-27-89	02-16-89
C. <u>albicans</u>	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: Lethen Broth
7. Incubation of Subcultures: 48 hours at 35±1°C
8. Test Bacteria:

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

9. Survival of Inoculum on Control Carriers:

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

10. Test Results:

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

<u>Klebsiella</u>	01809160	10	0
<u>pneumoniae</u>	02809160	10	0
<u>Staphylococcus</u>	01809160	10	0
<u>epidermidis</u>	02809160	10	0
<u>Campylobacter</u>	01809160	10	0
<u>pyloridis</u>	02809160	10	0
<u>Candida</u>	01809160	10	0
<u>albicans</u>	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:

<u>Batch No.</u>	<u>Preparation Date</u>	<u>Test Date</u>
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. H₂O) (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)

<u>Test Virus</u>	<u>Batch No.</u>	<u>Virus Control</u>	<u>Virus Disin.</u>	<u>Toxicity Control</u>	<u>Virus Inactivation</u>
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".