

PM-31

Reg # 60142-1

198

Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States Environmental Protection Agency Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number 248409

Application for Pesticide - Section I

1. Company/Product Number 60142-1	2. EPA Product Manager Marshall Seindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virahol	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Veridien Corporation 11800 28th Street North St. Petersburg, FL 33716 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) **"NOTIFICATION PER PR NOTICE 88-6"**
 Add an additional plastic non-porous surface, polyvinyl chloride (PVC) material, Naughyde®, a registered name brand PVC of Uniroyal Engineered Products, Inc
 Add additional patent no. See additional pages

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Howard K. Mann	Title Regulatory Affairs	Telephone No. (Include Area Code) 813-572-5500
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Howard K. Mann	3. Title Regulatory Affairs	
4. Typed Name Howard K. Mann	5. Date March 14, 1997	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

298

APR 21 1997

Veridien Corporation
11800 28th Street North
St. Petersburg, FL. 33716

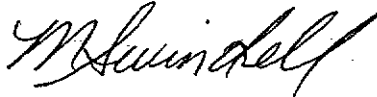
Subject: Virahol
EPA Registration No. 60142-1
Notification Per PR-Notice 95-2
(Formerly PR-Notice 88-6)

Dear Mr. Mann:

This will acknowledge receipt of your notification to add an additional plastic non-porous surface, polyvinyl chloride (PVC) material, Naugahyde which is a registered name brand PVC of Uniroyal Engineered Products, Inc., and to add the additional patent number submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,



Marshall Swindell
Notification Coordinator
Antimicrobial Program Branch
Antimicrobial Division (7505W)

CONCURRENCES

SYMBOL	7505W						
SURNAME	O. J. [unclear]						
DATE	4/21/97						

398
2

TUBERCULOCIDE • VIRUCIDE • BACTERICIDE • FUNGICIDE

VIRAHOL®

HOSPITAL DISINFECTANT / CLEANER & INSTRUMENT PRESOAK*

READY TO USE • DISINFECTS AND DEODORIZES
See Right Panel for Additional Instructions

U.S. PATENT 5,441,723
U.S. PATENT 5,145,663

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

© 1996 VERIDEN CORPORATION

ACTIVE INGREDIENT - Isopropanol ...	70%
INERT INGREDIENTS	30%
TOTAL	100%

NET CONTENTS - 1 U.S. GALLON - (128 Fluid Ounces) - 3.875 Liters

3

868

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING

Causes eye irritation. Do not get in eyes. Harmful if swallowed.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Flammable, keep away from heat & open flame.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an appropriate waste disposal facility.



VERIDIEN CORPORATION
11800 28th St. N.
St. Petersburg, FL 33716
1-800-345-5444

EPA Reg. No. 60142 - 1
EPA Est. No. 60142 - FL - 1

EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

HIV-1 (associated with AIDS) Staphylococcus aureus Poliovirus Type 1	Mycobacterium tuberculosis Salmonella choleraesuis Trichophyton mentagrophytes	Pseudomonas aeruginosa Herpes simplex Type 2
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COMPATIBLE IN CONTACT WITH THESE MATERIALS

Aluminum Epoxy Neoprene * Rigid PVC Teflon * Viton *	Buna N Natural Rubber Nylon Silicone Titanium	Cast Bronze Naugahyde *** Polypropylene Stainless Steel (304,316,440) Tygon **
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* a registered trademark of E.I. duPont de Nemours ** a registered trademark of Norton Co. *** a registered trademark of Unroyal Engineered Products, Inc.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. VIRAHOL® Hospital Disinfectant/Cleaner & Instrument Presoak is designed for effective disinfection, cleaning and deodorizing of hard inanimate surfaces such as walls, sink tops, tables, chairs, telephones and bed frames, and for the decontamination of instruments prior to sterilization.

TO DISINFECT CONTAMINATED SURFACES AND OBJECTS:

For heavily soiled areas, or surfaces of objects soiled with blood or body fluids, a precleaning step is required. Use a clean sponge or lint-free cloth. On precleaned surfaces, apply VIRAHOL® Hospital Disinfectant/Cleaner & Instrument Presoak with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Allow surfaces to remain wet for 10 minutes.

TO DECONTAMINATE INSTRUMENTS PRIOR TO STERILIZATION (Instrument Presoak*):

Completely immerse instruments for 10 minutes prior to preparation for sterilization. This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Kills HIV-1 on precleaned environmental surfaces & objects previously soiled with blood or body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces, objects with blood or body fluids, and in which the surfaces & objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON HARD INANIMATE SURFACES AND / OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

Personal Protection: When handling items soiled with blood or body fluids use disposable latex gloves, gown, mask and / or eye coverings.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of Virahol® Hospital Disinfectant/Cleaner & Instrument Presoak.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

Contact Time: Apply Virahol® Hospital Disinfectant/Cleaner & Instrument Presoak with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Allow surfaces to remain wet for one minute to ensure total inactivation of HIV virus. This contact time will not control other common types of viruses and bacteria. For example, a ten minute contact time is required to control Mycobacterium tuberculosis at 20°C.

No warranty, either expressed or implied, is given to usage contrary to the instructions given herein.

4



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number
249007

Application for Pesticide - Section I

1. Company/Product Number 60142-1	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virahol®	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Veridien Corporation 11800 28th Street North St. Petersburg, FL 33716 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) **"NOTIFICATION PER PR NOTICE 88-6"**
 Virahol to be marketed under additional brand name of "VIRAHOL DISINFECTANT/CLEANER FOR VETERINARY USE" and adding additional surface substrate to "Directions for Use" and for an additional pest that does not pose a threat to public health
 See page 2

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container.		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Howard K. Mann	Title Regulatory Affairs	Telephone No. (Include Area Code) 813-572-5500
2. Signature <i>Howard K. Mann</i>		3. Title Regulatory Affairs
4. Typed Name Howard K. Mann		5. Date 3/27/97
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

698

APR 21 1997
1997

Veridien Corporation
11800 28th Street North
St. Petersburg, FL. 33716

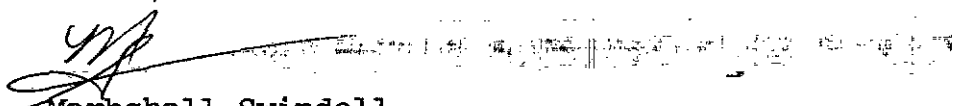
Subject: Virahol
EPA Registration No. 60142-1
Notification Per PR-Notice 95-2
(Formerly PR-Notice 88-6)

Dear Mr. Mann:

This will acknowledge receipt of your notification for Virahol to be marketed under an additional brand name "Virahol Disinfectant/Cleaner for Veterinary Use", to add an additional surface substrate to the "Directions for Use", and an additional pest submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,



Marshall Swindell
Notification Coordinator
Antimicrobial Program Branch
Antimicrobial Division (7505W)

CONCURRENCES

SYMBOL	7505W						
SURNAME	P. Hasty						
DATE	3/2/97						

TUBERCULOCIDE • VIRUCIDE • BACTERICIDE • FUNGICIDE

VIRAHOL®

DISINFECTANT / CLEANER FOR VETERINARY USE

READY TO USE • INSTRUMENT PRESOAK • DISINFECTS AND DEODORIZES
See Right Panel for Additional Instructions

U.S. PATENT 5,441,723
U.S. PATENT 5,145,663

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

© 1996 VERIDEN CORPORATION

ACTIVE INGREDIENT - Isopropanol ... 70%
INERT INGREDIENTS 30%

TOTAL 100%

NET CONTENTS - 1 U.S. GALLON - (128 Fluid Ounces) - 3.875 Liters

798

798

868

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING

Causes eye irritation. Do not get in eyes. Harmful if swallowed.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Flammable, keep away from heat & open flame.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an appropriate waste disposal facility.



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EPA Reg. No. 60142 - 1
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EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

Canine Parvovirus	Poliovirus Type 1	Trichophyton mentagrophytes
HIV-1 (associated with AIDS)	Mycobacterium tuberculosis	Pseudomonas aeruginosa
Staphylococcus aureus	Salmonella choleraesuis	Herpes simplex Type 2

COMPATIBLE IN CONTACT WITH THESE MATERIALS

Aluminum	Buna N	Cast Bronze
Epoxy	Natural Rubber	Naugahyde ***
Neoprene *	Nylon	Polypropylene
Rigid PVC	Silicone	Stainless Steel (304,316,440)
Teflon *	Titanium	Tygon **
Viton *		

* a registered trademark of E.I. duPont de Nemours ** a registered trademark of Norton Co. *** a registered trademark of Uniroyl Engineered Products, Inc.

DIRECTIONS FOR USE

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Kills HIV-1 on precleaned environmental surfaces & objects previously soiled with blood or body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces, objects with blood or body fluids, and in which the surfaces & objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus (HIV-1) (associated with AIDS).

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