

PM

33

60142-1

11/10/99

page 18 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 10 1999

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

**RE: Virahol Hospital Disinfectant/Cleaner & Instrument Presoak
EPA Reg. No. 60142-1
Your Notification Dated 10/15/99**

The Notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to declare an pesticide producing establishment number for Horizons Pharmaceuticals, is acceptable.

Note that you are not required to notify this EPA Antimicrobial Division office of future additions or deletions of establishment numbers. Your local Regional EPA offices take care of these requests. However, if you use multiple establishment numbers, your label must make it very clear which establishment number is the actual production site for a product lot.

Additionally, you do not have to send us the Kosher re-certification letter. You should request Kosher re-certification as required, and keep the certificate letters in your files in case we request them.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
 265615

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 Hospital Disinfectant/Cleaner & Instrument Presoak	PM# 33	
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.) PR Notice 98-10

Amendment of label to include additional establishment number;
 Submission of current Kosher certification

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 5, 10 & 55 gal; 1.2, 2, 3, 4, 6, 8, 16, 32 & 64 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" 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 Albina L. Otte	Title Deputy Director of Special Affairs	Telephone No. (Include Area Code) 1-800-345-3444
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 <i>Andrew T. Libby, Jr.</i>	3. Title Executive Vice President & Chief Operating Officer	
4. Typed Name Andrew T. Libby, Jr.	5. Date October 15, 1999	

TUBERGULOCIDE • 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



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

NET CONTENTS - 1 U.S. GALLON - (128 Fluid Ounces) - 3.785 Liters

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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[®]

Manufactured for
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 (A)

EPA Est. No. 72666 - FL - 001 (B)

The letters (A) following the Est. No. correspond to the letter
suffix of the list code and identify which Est. preceded this list.

EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

HIV-1 (associated with AIDS)
Staphylococcus aureus

Mycobacterium tuberculosis
Salmonella choleraesuis
Trichophyton mentagrophytes

Pseudomonas aeruginosa
Herpes simplex type 2

COMPATIBLE IN CONTACT WITH THESE MATERIALS

Aluminum
Epoxy
Neoprene *
Rigid PVC
Teflon **
Viton ****

Buna N
Natural Rubber
Nylon
Silicone
Titanium

Cast Bronze
Nugabylite ***
Polypropylene
Stainless Steel (304,316,440)
Tygon **

*** a registered trademark of duPont de Nemours

* 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. When using strong cleaners and disinfecting agents, it is always advisable to first test in an inconspicuous area.

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.

*INSTRUMENT PRESOAK - TO DECONTAMINATE INSTRUMENTS PRIOR TO STERILIZATION:

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.

Inactivates HIV 1 on precleaned environmental surfaces and 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 or 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.

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