

60142-1

4/29/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 29 2002

Albina Otte
Veridien Corporation
2875 MCI Drive, Suite B
Pinellas Park, FL 33782

RE: "Virahol Hospital Disinfectant/Cleaner & Instrument Presoak"
EPA Reg. No. 60142-1
Your Submissions Dated 4/5/02 and 4/24/02 (Responding to EPA letter Dated 3/4/02)

The submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which responds to the Agency letter dated 3/4/02 by providing a revised label, generic data matrix and data submitters list for isopropanol, is acceptable with the following comment.

The type size on the final labels must be increased in size. The reviewed label has a typesize that is smaller than 6 point. Use larger more readable typesize.

A stamped copy of the acceptable label is enclosed for your records.

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							

TUBERCULOCIDE • BACTERICIDE • FUNGICIDE • VIRUCIDE

VIRAHOL®

**HOSPITAL DISINFECTANT /
CLEANER &
INSTRUMENT PRESOAK***

**READY
TO USE**

**DISINFECTS
AND
DEODORIZES**

SEE RIGHT PANEL FOR
ADDITIONAL INSTRUCTIONS

ACTIVE INGREDIENT:
ISOPROPANOL..... 70%
OTHER INGREDIENTS.... 30%
TOTAL..... 100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 60142-1
EPA Est. No. 60142-FL-1 (A)
EPA Est. No. 9359-NY-2 (B)
EPA Est. No. 051580-NY-001 (C)

U.S. Patent # 5,145,663
U.S. Patent # 5,441,723

NET CONTENTS:
1 U.S. Gallon
(128 fl oz or 3.785 L)

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

The letter in () following the Est. No.
corresponds to the letter suffix of the lot code
and identifies which Est. produced this lot.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 29 2002

Under the Federal Insecticide
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

60142-1

"SIDE PANEL"

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS & DOMESTIC ANIMALS

Caution. Causes moderate eye irritation. Harmful if inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for further treatment and advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment and advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment and advice.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat, sparks and open flame.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE 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: Wastes resulting from use of this product must be disposed of on site or at an appropriate waste disposal facility.



Veridien Corporation
2875 MCI Drive, Suite B
Pinellas Park, FL 33782-6105
1-800-345-5444

LOT #	UPC code
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EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

TUBERCULOCIDAL: Mycobacterium tuberculosis

BACTERICIDAL: Pseudomonas aeruginosa, ATCC#15442; Salmonella choleresuis, ATCC#10708; Staphylococcus aureus, ATCC#6538; Streptococcus pyogenes, ATCC#49399, #19615; Escherichia coli, Strain 0157, ATCC#43895; Vancomycin-resistant Enterococcus faecalis (VRE), ATCC#51299; Methicillin-resistant Staphylococcus aureus (MRSA), ATCC#33593

FUNGICIDAL: Trichophyton mentagrophytes, ATCC#9533

VIROCIDAL: Cytomegalovirus (CMV), ATCC#VR538; Respiratory syncytial virus (RSV), ATCC#VR26; Rotavirus (SA-11; Group A), Influenza type A2 (Hong Kong), ATCC#VR544, Adenovirus type 2, ATCC#VRB46; Herpes simplex type 2, ATCC#VR539 HIV-1 (AIDS Virus) - 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 and objects likely to be soiled with blood or body fluids can be associated with the potential for the transmission of Human Immunodeficiency Virus (HIV-1) (AIDS virus).

COMPATIBLE IN CONTACT WITH THESE MATERIALS:

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

* a registered trademark of E. I. DuPont de Nemours
** a registered trademark of Norton Co.
*** a registered trademark of Dupont Dow-Elastomers

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION: This product is designed to provide effective cleaning, deodorizing and disinfection for hospitals, clinics, laboratories, nursing homes, ambulances, industrial clean rooms, schools, transportation terminals, office buildings, manufacturing facilities, hotels or lodging establishments, veterinary offices, retail businesses and athletic and/or recreational facilities, spa or health clubs, amusement parks, restaurants, and food service establishments where housekeeping is of prime importance in controlling the hazard of cross contamination. When used as directed this product is designed for effective disinfecting and cleaning of hard, nonporous, inanimate surfaces such as walls, sink tops, stainless steel surfaces, metal surfaces, bathrooms, shower stalls, bathtubs, toilet seats, tables, chairs and telephones. This product may be used in kitchen preparation areas on counters, sinks, tables, chairs, thermometers and appliances. For surfaces which may come into contact with food a potable water rinse is required. This product also deodorizes those areas that are hard to keep fresh smelling, such as garage storage areas, empty garbage bins and containers, basements, restrooms and other areas which are prone to odors caused by micro-organisms.

GENERAL PRECAUTIONS AND RESTRICTIONS: When using strong cleaners and disinfecting agents, it is always advisable to first test in an inconspicuous area. 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.

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 this product. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waster disposal. **Contact Time:** Apply this product 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. A ten-minute contact time is required for all other organisms listed on this label.

APPLICATION INSTRUCTIONS: 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 this product with a mop, cloth, sponge, or mechanical sprayer so as to thoroughly wet precleaned surfaces. **DO NOT DILUTE.** Surfaces must remain wet for a full ten minutes. Re-apply if needed to keep surfaces visibly wet for a full ten minutes. Applications to direct or indirect food contact surfaces requires a thorough potable water rinse.

***INSTRUMENT PRESOAK - TO DECONTAMINATE INSTRUMENTS PRIOR TO STERILIZATION:** Completely immerse instruments for 10 minutes prior to preparation for sterilization.

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

* bed frames

ACCEPTED
with COMMENTS
in EPA Letter Dated

APR 29 2002

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Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

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