

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 27 2004

Howard Bochner
Veridien Corporation
2875 MCI Drive, Suite B
Pinellas Park, FL 33782

RE: "Virahol Hospital Disinfectant/Cleaner & Instrument Presoak"
EPA Reg. No. 60142-1
Your Re-Submission Dated 12/23/03

The re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which provides a revised label which responds to the EPA letters dated 10/8/03 and 12/5/03, and which adds label claims against Hepatitis A, B, and C, is acceptable with the comments listed below and providing three copies of a final printed label are submitted within 90 days from the date of this letter which make the following changes:

Page 3/7

Change the broad, unqualified claim, "Effective against a broad range of pathogens" to the following, "Effective against a broad range of pathogens listed on this label".

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Delete the following use sites, "stainless steel surfaces (including Stainless Steel 304, 316, 440), appliances". These have been blacked-out on the enclosed stamped label. As per prior EPA letters, stainless steel surfaces and appliances are not considered to be specific use sites. Actual types of items made from stainless steel and actual types of appliances are considered to be possible use sites (eg., refrigerator doors, autoclave doors, etc.), and can be added by amendment later.

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1. For clarity, in the special instructions for heavily soiled areas, add a period after "concern" in "...mentagrophytes is a concern". Then, unbold the statement "A precleaning step is required".
2. In this same section, change "On precleaned surfaces, apply this product with a mop, cloth, sponge, or mechanical sprayer so that precleaned surfaces are visibly wet", to the following, "On precleaned surfaces, apply this product with a mop, cloth, sponge, or mechanical sprayer so that precleaned surfaces remain visibly wet for a full ten minutes. Applications to direct or indirect food contact surfaces require a thorough potable water rinse."

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Isopropanol TGAI Data Matrix

Submit a revised matrix with the final printed labels which satisfies the following:

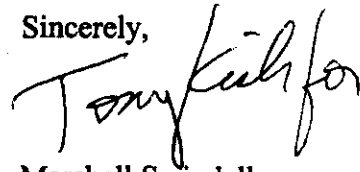
The acute primary skin, acute sensitization, and avian oral studies are missing and must be added.

Hepatitis A, B, and C Virus Efficacy Data

The submitted studies for Hepatitis A (MRID 459102-01); Hepatitis B (MRID 46013801 and 46013802), and Hepatitis C (MRID's 45910202/-03), are now considered acceptable.

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								

**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
FRONT PANEL**

• TUBERCULOCIDE • BACTERICIDE • FUNGICIDE • VIRUCIDE

READY TO USE /DISINFECTS AND DEODORIZES,

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

NET CONTENTS:
1 Gallon
(128 FL. OZ.)
3.78 L

KEEP OUT OF REACH OF CHILDREN
CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

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)

US. Patent # 5,145,663
US. Patent # 5,441,723

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:

FEB 27 2004

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

60142-1

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**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
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. Wear protective eyewear (goggles)

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 or food through storage or disposal.

PESTICIDE STORAGE: Store in a cool dry place away from open flame.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incinerate, 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

ACCEPTED
with COMMENTS
in EPA Label dated:
FEB 27 2004

Lot #	UPC Code
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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68142-1

**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
SIDE PANEL**

EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS LISTED ON THIS LABEL ✓

VIRUCIDAL: Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV-1) (AIDS virus) - Inactivates HIV-1, Hepatitis B Virus, and Hepatitis C Virus on precleaned environmental surfaces/objects previously soiled with blood or body fluids. Cytomegalovirus (CMV), ATCC-VR538; Respiratory syncytial virus (RSV), ATCC#VR26; Rotavirus (SA-11; Group A), Influenza type A-2 (Hong Kong), ATCC#VR544, Adenovirus type 2, ATCC#VR846; Herpes simplex type 2, ATCC#VR539;

TUBERCULOCIDAL: Mycobacterium tuberculosis (TB)

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

FUNGICIDAL: Trichophyton mentagrophytes, ATCC#9533

COMPATIBLE IN CONTACT WITH THESE MATERIALS: Aluminum, Buna N, Cast Bronze, Nylon, Polypropylene, Rigid PVC, Titanium, Stainless Steel (304,316,440), Teflon*, Tygon**, Viton***

- * a registered trademark of E.I. DuPont de Nemours and Company.
- ** a registered trademark of Norton Company.
- *** a registered trademark of DuPont -Dow Elastomer.

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**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
SIDE PANEL (Continued)**

DIRECTIONS FOR USE

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

GENERAL INFORMATION: When used as directed this product is designed for effective cleaning, disinfecting and deodorizing of hard, nonporous, inanimate surfaces including countertops, walls, floors, bathrooms (toilet seats, sinks, shower stalls, bathtubs), bedframes, stretchers, thermometers, ~~_____~~, ~~_____~~, ~~_____~~, ~~_____~~, tables, chairs, computer keyboards, 2 way radios, telephones, and other similar surfaces, in hospital, industrial, institutional, and commercial settings where housekeeping is of prime importance in controlling the hazard of cross contamination between hard, non-porous surfaces. These settings may include hospitals, clinics, medical and dental offices, laboratories, nursing homes, ambulances, industrial clean rooms, schools, transportation terminals, office buildings, manufacturing facilities, hotels and lodging establishments, veterinary offices, retail businesses, athletic and recreational facilities, spa and health clubs, amusement parks, restrooms, garage storage areas, empty garbage bins, basements, restaurants, food service establishments, and kitchen preparation areas. For surfaces which may come into contact with food, a potable water rinse is required.

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.

INSTRUMENT PRESOAK - TO DECONTAMINATE INSTRUMENTS PRIOR TO STERILIZATION: Completely immerse instruments for 10 minutes prior to preparation for sterilization. This product may be used to preclean or decontaminate critical or semi-critical medical devices (including scalpels, implants, thermometers, endoscopes, knobs/levers, dental instruments, etc) prior to sterilization or high-level disinfection.

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**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
SIDE PANEL (Continued)**

APPLICATION INSTRUCTIONS:

TO DISINFECT CONTAMINATED HARD NON-POROUS SURFACES AND OBJECTS:

FOR GENERAL CLEANING AND DISINFECTING: Apply this product with a mop, cloth, sponge, or mechanical sprayer so as to thoroughly wet surfaces. **DO NOT DILUTE.** Surfaces must remain visibly 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 require a thorough potable water rinse.

SPECIAL INSTRUCTIONS FOR HEAVILY SOILED AREAS, SURFACES OF OBJECTS SOILED WITH BLOOD OR BODY FLUIDS, AND WHERE CONTAMINATION WITH TRYCHOPHYTON MENTAGROPHYTES IS A CONCERN, A PRECLEANING STEP IS REQUIRED. On pre-cleaned surfaces, apply this product with a mop, cloth, sponge, or mechanical sprayer so that pre-

cleaned surfaces ~~are~~ ^{REMAIN} visibly wet ^{FOR A FULL TEN MINUTES.} Applications to ~~direct or indirect food~~ ^{CONTACT SURFACES REQUIRE A THOROUGH POTABLE WATER RINSE.}

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS, OR HEPATITIS C VIRUS 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. **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. **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.

SPECIFIC INFORMATION FOR HIV-1, HEPATITIS B VIRUS, AND HEPATITIS C VIRUS DISINFECTION: This product is effective 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 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) and/or Hepatitis B Virus, and Hepatitis C Virus.

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

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**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
SIDE PANEL (Continued)**

Note: [Bracketed information is optional text]

DISINFECTANT CLAIMS

- [For general disinfection: One step cleaner/disinfectant]
[For general disinfection: Cleans and disinfects in one step]
- [Effective against Hepatitis A Virus (HAV)]
- [Kills Hepatitis A Virus (HAV)]
- [Effective against Hepatitis B Virus (HBV)]
- [Kills Hepatitis B Virus (HBV)]
- [Effective against Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on precleaned environmental surfaces/objects previously soiled with blood or body fluids].
- [Kills Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on precleaned environmental surfaces/objects previously soiled with blood or body fluids].
- Effective against TB (Mycobacterium tuberculosis), HIV (Human Immunodeficiency Virus), MRSA (Methicillin Resistant Staphylococcus aureus), VRE (Vancomycin Resistant Enterococcus faecium)
- [Kills [more than] 99.9% [bacterial] germs and viruses* (*Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Cytomegalovirus (CMV), ATCC-VR538; Respiratory syncytial virus (RSV), ATCC#VR26; Rotavirus (SA-11; Group A), Influenza type A-2 (Hong Kong), ATCC#VR544, Adenovirus type 2, ATCC#VR846; Herpes simplex type 2, ATCC#VR539)]
- [Virucidal], [Bacteriocidal], [Germicidal], [Tuberculocidal], [Fungicidal]
- [Kills bacteria and viruses [important to First Responders] such as Hepatitis A (Hepatitis A Virus), Hepatitis B (Hepatitis B Virus), Hepatitis C (Hepatitis C Virus), HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus)), TB (Mycobacterium tuberculosis), MRSA (Staphylococcus aureus), and VRE(Enterococcus faecium).]

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**VIRAHOL® HOSPITAL DISINFECTANT/CLEANER & INSTRUMENT
PRESOAK
SIDE PANEL (Continued)**

MARKETING CLAIMS AND SURFACE SAFETY CLAIMS

- Ready To Use
- Full strength
- Non-staining
- Non-corrosive
- Contains no abrasives
- Will not harm most surfaces
- Compatible with most surfaces
- Non-damaging to most surfaces
- Incidental contact does not compromise integrity of turnout gear**
- Leaves pleasant citrus scent
- Deodorizes and leaves a pleasant citrus scent

** turnout gear is protective gear used by first responders (including firefighters, paramedics and police)

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