

MAY 20 2003

Sheldon Fenton
Veridien Corporation
2875 MCI Drive, Suite B
Pinellas Park, FL 33782-6105

**Subject: Virahol Hospital Surface Disinfectant Towelette
EPA Reg. No. 60142-3
Your Amendment Dated 2/27/03**

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised label which adds the following required statement, "For heavily soiled areas, or surfaces of objects soiled with blood or body fluids, a precleaning step is required", and makes no other changes, is acceptable with the following comments.

With your next scheduled label amendment for this product, you must make the following changes:

1. Delete the duplicate back panel "Signal Word", child statement, and entire ingredient statement. The submitted revised label consists of two separate pages, each of which duplicates these statements. Pesticide products are only allowed to list these statements once.
2. Separate the non-HIV related cleaning instructions from the directions for use. As per DISS/TSS-15, "Cleaning instructions must be clearly separated from the directions for use..."

A copy of the label stamped "Accepted with comments" is attached 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 SURFACE DISINFECTANT TOWELETTE

**FOR DISINFECTING, CLEANING AND
DEODORIZING HARD, NON-POROUS
ENVIRONMENTAL SURFACES
NON-STAINING**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

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

*Does not include the weight of towelette.

EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

TUBERCULOCIDAL: Mycobacterium bovis (BCG)
BACTERICIDAL: Staphylococcus aureus (MRSA), ATCC#3359
 vancomycin-resistant Enterococcus faecium (VRE), ATCC#51155
 Streptococcus pyogenes, ATCC#19615; Pseudomonas aeruginosa
 ATCC#15442; Staphylococcus aureus, ATCC#6538; Salmonel-
 la enteritidis, ATCC#10708; Escherichia coli, ATCC#11229.

FUNGICIDAL: Trichophyton mentagrophytes, ATCC#9533;

VIRUCIDAL: Herpes simplex type 1, ATCC#VR260; HIV-1 (AIDS Virus) (inactivated) on pre-cleaned environmental surfaces and objects previously soiled with blood or body fluids in health-care settings or other settings in which there is an expected likelihood of soiling of non-pore 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 transmission of Human Immunodeficiency Virus (HIV) (AIDS Virus).

DIRECTIONS FOR USE: This is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR DISINFECTING, CLEANING AND DEODORIZING HARD, NON-POROUS SURFACES:

GENERAL INFORMATION: An effective disinfectant and deodorant towelette for hospitals, clinics, medical and dental offices, laboratories, food and meat stores, nursing homes, ambulances, veterinary offices, hotels, restaurants, schools, dress shops, salons and hair salons. This product is designed for effective cleaning, disinfecting and deodorizing of hard non-porous, non-pore surfaces such as walls, sink tops, stainless steel surfaces, equipment, tables, chairs, countertops, mirrors and bed frames. When using strong cleaners or disinfecting agents, it is always advisable to first clean or neutralize the area. This product may be used in kitchen environments provided it is never used on food, food preparation areas and dishes. For disinfecting and deodorizing of hard non-porous, non-pore surfaces, use the following directions. Do not use on porous or absorbent surfaces such as paper, fabric, carpet, wood, or other materials. Do not use on electrical equipment or sensitive electronic equipment. Do not use on painted surfaces. Do not use on leather or vinyl. Do not use on surfaces that are to be painted. Do not use on surfaces that are to be polished. Do not use on surfaces that are to be waxed. Do not use on surfaces that are to be oiled. Do not use on surfaces that are to be greased. Do not use on surfaces that are to be lubricated. Do not use on surfaces that are to be treated with any other substance. Do not use on surfaces that are to be treated with any other substance. Do not use on surfaces that are to be treated with any other substance. Do not use on surfaces that are to be treated with any other substance.

APPLICATION INSTRUCTIONS:

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

Personal Protection: Wear gloves and eye protection when cleaning blood or body fluids.
Cleaning Procedures: Clean the surface with a solution of 1:10 bleach and water. Rinse with clean water.
Contact Time: 10 minutes.
Disposal of Infectious Materials: Dispose of all materials in a leak-proof container and discard in an approved container.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

MAY 20 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
60142-3

2
2
3

TUBERCULOCIDE • BACTERICIDE • FUNGICIDE • VIRUCIDE

NET CONTENTS:
160 Towelettes 5.5" X 7.9"

PRECAUTIONARY STATEMENTS

**HAZARD TO HUMANS & DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN**

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

Keep the product container or label with you when taking 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. Do a thorough hair wash immediately after use.

If inhaled: Move person to fresh air and rest. Breathing apparatus and artificial respiration, if needed, should be given in fresh air. Call a poison control center or doctor for further treatment and advice.

PHYSICAL OR CHEMICAL HAZARDS: Highly flammable. May be fatal if inhaled.

STORAGE AND DISPOSAL: Store in original container. Do not use if container is damaged.

PESTICIDE STORAGE: Store in original container. Do not use if container is damaged.

CONTAINER DISPOSAL: Recycle if possible. Do not use if container is damaged.

PESTICIDE DISPOSAL: Do not use if container is damaged.

OTHER PRECAUTIONS: Do not use if container is damaged.

**VIRAHOL®
HOSPITAL SURFACE
DISINFECTANT TOWELETTE**

**FOR DISINFECTING, CLEANING AND
DEODORIZING HARD, NON-POROUS
ENVIRONMENTAL SURFACES
NON-STAINING**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

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

*Does not include the weight of towelette.

UPC
code

Lot #



**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

MAY 20 2003

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

60142-3

383

Veridien Corporation • 2875 MCI Drive • Suite B • Pinellas Park, FL 33782-6105 • Tel: (727) 576-1600 • Fax: (727) 576-6111

