

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 29 2002

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

RE: "Virahol Hospital Surface Disinfectant Towelette"
EPA Reg. No. 60142-3
Your Submissions Dated 4/5/02 and 4/24/02 (Responding to EPA letter Dated 3/4/02)

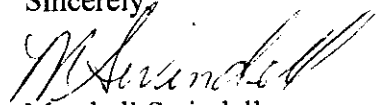
The submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which responds to the Agency letter dated 3/4/02 by providing a revised label, generic data matrix and data submitters list for isopropanol, is acceptable 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 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#33591;
Vancomycin-resistant Enterococcus faecium (VRE),
ATCC#51559; Streptococcus pyogenes, ATCC#19615;
Pseudomonas aeruginosa, ATCC#15442; Staphylococcus aureus,
ATCC#6538; Salmonella choleraesuis, ATCC#10708; Escherichia
coli, ATCC#11229.

FUNGICIDAL: Trichophyton mentagrophytes, ATCC#9533;
VIRUCIDAL: Herpes simplex type 1, ATCC#VR260; HIV-1 (AIDS Virus) Inactivates
HIV-1 on pre-cleaned 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 transmission of Human Immunodeficiency
Virus (HIV-1) (AIDS virus).

DIRECTIONS FOR USE: It 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, industrial clean rooms, nursing homes, ambulances, veterinary offices, hotels,
restaurants, schools, professional salons and health spas. This product is designed for effective cleaning,
disinfecting and deodorizing of hard non-porous, inanimate surfaces such as walls, sink tops, stainless steel
surfaces, equipment, tables, chairs, telephones, toilet seats and bed frames. When using strong cleaners and
disinfecting agents, it is always advisable to first test in an inconspicuous area. 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 may also be used to deodorize areas which generally
are hard to keep fresh smelling, such as garage storage areas, empty garbage bins and cans, restrooms and other areas
which are prone to odors caused by micro-organisms. 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.

APPLICATION INSTRUCTIONS: Pull out towelette from dispenser and wipe surface to be disinfected with towelette. Make certain to wet
surface thoroughly. Surface must remain visibly wet for a full 10 minutes. Use additional towelettes if needed to assure a 10 minute
wet contact time. For surfaces which may come into contact with food, a potable water rinse is required. Dispose of towelette in regular trash.

**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. **Contact Time:** Surface must remain visibly wet for a full 10 minutes. Use additional towelettes if needed to assure a
10 minute wet contact time. **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.
No warranty, either expressed or implied, is given to use contrary to instructions given herein.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
APR 29 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the product to be
registered under FIFRA Reg. No.

60142-3

2/2

"SIDE PANEL"

"FRONT PANEL"

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**

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 and disposal

PESTICIDE STORAGE: Store in a cool, dry place, at room temperature.

CONTAINER DISPOSAL: Do not reuse container. Discard empty container in trash.

PESTICIDE DISPOSAL: Discard used towelettes and empty container in regular trash.

VIRAHOL[®]

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**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.

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

**UPC
code**

Lot #

EPA Reg. No. 60142-3
EPA Est. No. 60142-FL-1 (A)
EPA Est. No. 073573-ISR-001 (B)

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, this product is registered under the authority of the Environmental Protection Agency.

60142-3