

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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WASHINGTON, DC 20460

DEC - 6 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Jamie Zajac
Regulatory Affairs Specialist
Sherwin-Williams Consumer Group
601 Canal Road
Cleveland, OH 44113

Subject: Label Amendment
Spray Disinfectant
EPA Registration No. 67603-4
Amendment Application Dated June 5, 2001

Dear Mr. Zajac:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following comments:

- Revise label to add claim against Human Immunodeficiency Virus (HIV)

Labeling Comments:

1. Under the heading "Sprayed on Surfaces", the terms "Staph., Strep. organisms, and "athletes foot fungus" must be deleted. The product is effective against the organisms that cause the disease but not effective against the disease itself. The terms listed above can only be used with clarification as listed under the heading "Spray Disinfectant".
2. The type of furniture must be listed since all furniture is not non-porous.
3. Due to the possibility of electrical shock when used on telephone, some type of precaution must be listed on the label, telling the user to avoid excess spraying of telephone.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

General Comments:

The efficacy data (MRID #454316-01) demonstrated when tested ready to use in the presence of an organic soil load (5% fetal bovine serum) for 10 minutes at room temperature, the subject product was effective against Human Immunodeficiency Virus type 1, Strain HTLV-III_B.

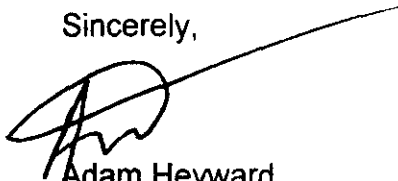
Other Comments:

Enclosed is a stamped copy of the revised label.

Submit 3 copies of your final printed label bearing the label revisions requested above. A copy will be stamped accepted and returned for your records.

Should you have any questions concerning this letter, please contact me at 703 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

SPRAY DISINFECTANT

KILLS HIV
 ELIMINATES ODORS
 DESTROYS ODORS
 TUBERCULOCIDAL
 PSEUDOMONACIDAL
 GERMICIDAL - FUNGICIDAL
 KILLS HOUSEHOLD GERMS
 ANTIBACTERIAL
 PREVENTS BACTERIA, MOLD & MILDEW
 FRESH (or other appropriate descriptive term) SCENT [FRAGRANCE]
 FOR COMMERCIAL & INDUSTRIAL USE
 KILLS 99.9% OF GERMS**

ACTIVE INGREDIENTS

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethyl benzyl ammonium chlorides.....	0.05%
n-Alkyl (68% C12, 32% C14) dimethyl	
ethylbenzyl ammonium chlorides.....	0.05%
Ethyl Alcohol.....	37.00%
INERT INGREDIENTS.....	<u>62.90%</u>
Total.....	100.00%

*Contains Sodium Nitrite

EPA Reg. No.: 67603-4

EPA Est. No.: 10900-OH-1
 33915-MI-1
 257-MD-1

Contains no CFCs or other ozone depleting substances. Federal regulations prohibit CFC propellant in aerosols.

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

DEC - 6 2001

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 67603-4

Keep Out Of Reach Of Children

WARNING

See Back Panel for additional
 precautionary statements.

____ oz. ____ g net wt.

SPRAY DISINFECTANT

Prevents mold, mildew and bacteria on environmental surfaces in your home and in public places. Disinfects and deodorizes surfaces through effective bacterial and fungicidal activity. Kills *Staphylococcus aureus* (Staph), *Streptococcus hemolyticus* (Strep), *Pseudomonas aeruginosa*, *Mycrobacterium bovis* (BCG), *Salmonella choleraesuis* and *Trichophyton mentagrophytes* (athletes foot fungus) on hard, non-porous environmental surfaces.

Meets AOAC Efficacy Standards for hospital aerosol disinfectants.

Sprayed on Surfaces: Deodorizes by disinfecting. Germicidal activity kills most odor-producing organisms. (Disinfects) (Kills) Staph. and Strep. organisms, athletes foot fungus and prevents mold and mildew on hard, non-porous environmental surfaces. Controls unpleasant odors. Pleasantly scented. For use in hospital rooms, sick rooms, doctors' examining rooms, kitchens, nursery and bathrooms.

****Sanitizes:** Kills 99.9% of *Staphylococcus aureus* (Staph), *Streptococcus hemolyticus* and *Salmonella choleraesuis* (Salmonella) on hard, non-porous surfaces.

DIRECTIONS FOR USE

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

SHAKE WELL BEFORE USING

Prior to application, thoroughly clean all surfaces to be treated to remove gross filth or heavy soil.

To Disinfect: Hold can upright and spray from a distance of 6 to 8 inches until area for treatment is thoroughly moistened and allow to dry for 10 minutes before wiping or allow to air dry.

For Control of Mold and Mildew on Hard, Non-Porous Environmental Surfaces: Spray surface until thoroughly moistened. Allow to air dry. Repeat application in 7 days.

For Control of Fungus in areas such as bathrooms, locker rooms, floors, benches, shower stalls or other non-porous environmental surfaces commonly contacted by bare feet: Spray surface until thoroughly moistened. Allow to air dry.

Direct the spray upwards, toward center of room, for 3 to 5 seconds.

For Use On: Walls, floors, bedframes, bedpans, urinals, furniture, fixtures, containers, toilet seats, diaper pails, telephones, trash cans, and sickrooms. Spray telephone and similar bedside equipment not easily subject to normal disinfecting procedures.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store upright in a cool dry place away from heat or open flame.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. This container may be recycled in the few but growing number of communities where (steel) aerosol can recycling is available. Before offering for recycling, empty the can by using the product according to the label. (Do not Puncture!) If recycling is not available, wrap the container and discard in trash.

GENERAL PRECAUTIONS

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.

PRECAUTIONARY STATEMENT HAZARDS TO HUMAN AND DOMESTIC ANIMALS WARNING

Causes substantial, but temporary eye injury. Do not get in eyes or on clothing. Wear safety glasses or face shield. Wash hands before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

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. Call a Poison Control Center or doctor for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not spray on polished wood or furniture.

Sherwin-Williams

Made In U.S.A.

OPTIONAL HIV-1 DIRECTIONS – VERSION A (MUST BE USED WITH HIV-1 BULLET POINT)

KILLS HIV 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 inanimate surfaces or objects with blood or body fluids, and in which the surfaces and objects likely to soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES AND OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

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: Leave surfaces wet for 10 minutes. This contact time will not control other common types of viruses and bacteria.

OPTIONAL HIV-1 DIRECTIONS – VERSION B (MUST BE USED WITH HIV-1 BULLET POINT)

FOR HOSPITALS AND HEALTH CARE FACILITIES: KILLS HIV ON PRE-CLEANED SURFACES AND OBJECTS SOILED WITH BLOOD AND BODY FLUIDS, When Spray Disinfectant is used before and after soiling on surfaces and objects that are likely to become soiled with blood and body fluids, it eliminates the transmission of human immunodeficiency virus Type 1 (HIV-1) which is associated with the AIDS virus.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES AND OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

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: Leave surfaces wet for 10 minutes. This contact time will not control other common types of viruses and bacteria.