

67603-4

06/23/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 23, 2005

Jamie Zajac
Regulatory Affairs Specialist
The Sherwin-Williams Company
101 Prospect Avenue, N.W.
Cleveland, OH 44115-1075

Subject: Spray Disinfectant
EPA Registration Number 67603-4
Application Date: May 31, 2005
EPA Received Date: June 8, 2005

Dear Ms. Zajac:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Revised labeling

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

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

CONCURRENCES

| | | | | | | | |
|------|---------|--|--|--|--|--|--|
| MBOL | 7510 | | | | | | |
| NAME | Adam | | | | | | |
| TE | 67603-4 | | | | | | |

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| | | |
|--|---|---------------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 | Registration | OPP Identifier Number 245241 |
| | Amendment | |
| | <input checked="" type="checkbox"/> Other | |

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number 67603-4 | 2. EPA Product Manager Adam Heyward | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Spray Disinfectant | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) The Sherwin-Williams Company 101 Prospect Avenue, N.W. Cleveland, OH 44115-1075 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ | |

Section - II

☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.
☒ Notification - Explain below. ☐ Other - Explain below.

Notification of adding the word "Institutional" to the bullet point section. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III**1. Material This Product Will Be Packaged In:**

| | | | |
|---|---|--|--|
| Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging Wgt. Container | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging Wgt. Container | 2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) |
| *Certification must be submitted | | | |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(s) Retail Container | | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other | | | |

Section - IV**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

| | | |
|---------------------|--|---|
| Name Jamie Zajac | Title Regulatory Affairs Specialist | Telephone No. (Include Area Code) (216) 515-8892 |
|---------------------|--|---|

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punished by fine or imprisonment or both under applicable law.

| | | |
|------------------------------------|---|--|
| 2. Signature <i>Jamie Zajac</i> | 4. Title Regulatory Affairs Specialist | 6. Date Application Received (Stamped) |
| 4. Typed Name Jamie Zajac | 5/31/05 | |

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SPRAY DISINFECTANT

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES

ELIMINATES ODORS

DESTROYS ODORS

TUBERCULOCIDAL

PSEUDOMONACIDAL

GERMICIDAL - FUNGICIDAL

KILLS HOUSEHOLD GERMS

ANTIBACTERIAL

PREVENTS MOLD & MILDEW

FRESH (or other appropriate descriptive term) SCENT [FRAGRANCE]

FOR COMMERCIAL & INDUSTRIAL USE

INSTITUTIONAL

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%

OTHER INGREDIENTS..... 62.90%

Total..... 100.00%

*Contains Sodium Nitrite

EPA Reg. No.: 67603-4

EPA Est. No.: 10900-OH-1 or 33915-MI-1

*Refer to bottom of container for
production facility



Federal regulations prohibit CFC
propellant in aerosols.

Keep Out Of Reach Of Children

WARNING

See Back Panel for additional
precautionary statements.

___ oz. ___ g net wt.

SPRAY DISINFECTANT

Prevents mold and mildew 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*, *Mycobacterium 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. 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.

For Use On: Walls, floors, bedframes, bedpans, urinals, fixtures, containers, toilet seats, diaper pails, telephones, trash cans, and sickrooms. Due to the possibility of electric shock when used on telephones, avoid excess spraying of telephone.

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.

Container Disposal: 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.

Contains no CFCs which deplete the ozone layer. Federal regulations prohibit CFC propellants in aerosols.

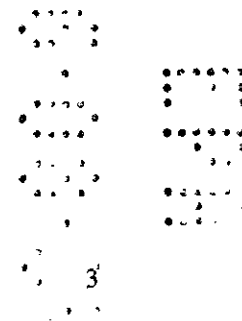
GENERAL PRECAUTIONS

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

NOTICE: This product contains a chemical known to the State of California to cause cancer.

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.



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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.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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.

HIV-1 DIRECTIONS – (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).

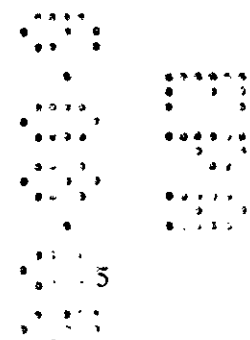
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES AND OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

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.

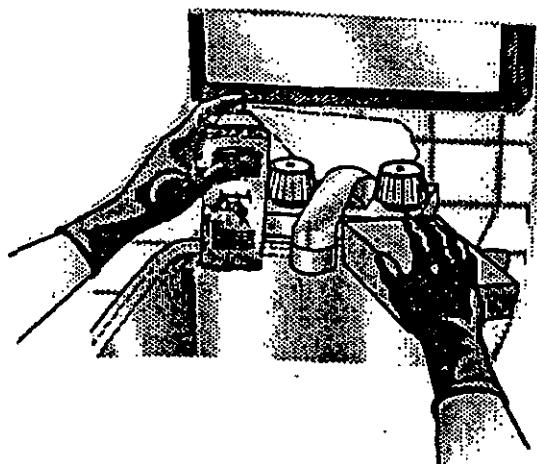
CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

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 GRAPHICS & SYMBOLS TO BE USED ON FRONT OR BACK PANEL OF LABELING:



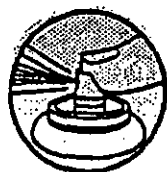
1. Hold can upright.



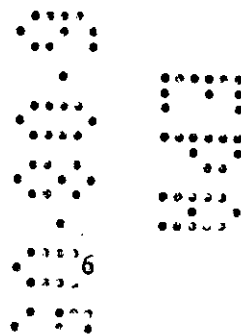
2. Spray from a distance of 6 to 8 inches until area for treatment is thoroughly moistened.



3. Allow to dry for 10 minutes before wiping or allow to air dry.



made in U.S.A.





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THE SHERWIN-WILLIAMS COMPANY
Environmental, Health & Regulatory Services
101 Prospect Avenue NW
Cleveland, Ohio 44115-1075
Facsimile: (216) 566-2730

May 31, 2005

Mr. Adam Heyward, PM34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. EPA
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Spray Disinfectant, EPA Reg. #67603-4
Notification to add "Institutional" to bullet point section

Dear Mr. Heyward:

Enclosed please find our application for notification to add the word "Institutional" to the bullet point section of our Spray Disinfectant EPA Reg. #67603-4 as well as one label copy with the highlighted additional word.

If you have any questions or need additional information please do not hesitate to contact me at (216) 515-8802.

Sincerely,

A handwritten signature in cursive script that reads 'Jamie Zapac'.

Jamie Zapac
Regulatory Affairs Specialist