

67603-4

7/16/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CONFIDENTIAL

Jamie Zajac
Regulatory Specialist
Sherwin Williams Diversified Brands
101 Prospect Avenue
Cleveland, OH 44115

JUL 16 2009

Subject: Spray Disinfectant
EPA Registration No. 67603-4
Application Dated: February 14, 2009
Receipt Date: February 25, 2009

Dear Ms. Zajac:

The following amendment, submitted in connection with registration under section 3 (c) (7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment

- Revise master label to add Sanitizer claim for inanimate, non-food contact surfaces
- Amend the Confidential Statement of Formula (CSF)

Acceptable Data

Efficacy

Data Requirement	Means of Support	Status
<i>Pseudomonas aeruginosa</i> <i>Salmonella enterica</i> <i>Staphylococcus aureus</i> Linen scent	Submitted study, MRID 476971-01	Acceptable, sanitizer hard non-porous surfaces for 10 minutes
<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Salmonella enterica</i> Original scent	Submitted study, MRID 476971-02	Acceptable, sanitizer hard non-porous surfaces or 10 minutes
<i>Staphylococcus aureus</i> <i>Enterococcus aerogenes</i> Linen scent	Submitted study, MRID 476971-03	Acceptable, sanitizer hard non-porous for 5 minutes
<i>Staphylococcus aureus</i> <i>Enterococcus aerogenes</i> Original scent	Submitted study, MRID 476971-04	Acceptable, sanitizer hard non-porous 5 minutes.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Labeling Comments:

1. On page 7 under Disposal of Infectious Materials as per PR 2000-5 Guidance for Mandatory and Advisory Labeling Statements, change the word "should" to "must".
2. Page one delete "(or other appropriate descriptive terms)", all label claims must be approved by the Agency.
3. Page six revise subheadings to read: "Hard Non-Porous Surfaces as a disinfectant" under the headings Microorganisms and Fungi.
4. Page five under the heading Surfaces, revise the subheading to read: "Hard Non-Porous Non-Food Contact Surfaces."
5. Page two revise the Sanitizes claim at the top of page 2 to indicate that the product is for use as a sanitizer on "hard non-porous, non-food contact surfaces."
6. Page two add specific directions for sanitizing as follows:

"To Sanitize: Spray surface until entire area is thoroughly wet. Allow to remain wet for 5 minutes."
7. Revise the HIV directions on page seven to include: "wear masks and eye coverings."

Product Chemistry Comments:

1. All alternate formulations must be identified by either carrying an alphabetic, numeric or alpha-numeric identification. In this submission the alternate formulation was not properly identified and by default it has been designated as Alternate Formulation #1. For your files you must mark your copy accordingly.
2. In the ingredient declaration on the front panel of the label, the "other ingredients" must be marked with an asterisk (*) to tie-in with the "*Contains Sodium Nitrite" declaration.
3. The proposed revised basic CSF and Alternate Formulation #1, both dated 02/14/09, are acceptable. The basic CSF dated February 14, 2009 supersedes all previously accepted ones.

Other Comments:

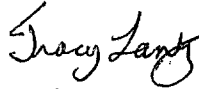
Future labeling amendments may be accomplished by submitting a copy of the electronic label. Refer to the following website for guidance on electronic submissions, including label:
<http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

If you have any questions concerning electronic label submissions, please refer to the above website for a list of contact personnel for more information.

Submit five (5) copies of the final printed label bearing the above revisions. A stamped copy of the accepted labeling is enclosed.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: lantz.tracy@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Tracy Lantz
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosures: (EPA stamped approved label)
Product Chemistry DER: 363099

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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

PREVENTS MOLD & MILDEW

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

FOR COMMERCIAL & INDUSTRIAL USE

INSTITUTIONAL

KILLS 99.9% OF GERMS**

KILLS METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)

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**

Graphic Symbol (Contains No CFC's or other ozone depleting substances)

Federal regulations prohibit CFC
propellant in aerosols.

Keep Out Of Reach Of Children

WARNING

**See Back Panel for additional
Precautionary and First Aid Statements.**

___ oz. ___ g net wt.

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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, Methicillin Resistant Staphylococcus Aureus (MRSA), Mycobacterium bovis (BCG), Salmonella enterica and Trichophyton mentagrophytes (athletes foot fungus) on pre-cleaned, 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), and Enterobacter aerogenes on pre-cleaned, hard, non-porous surfaces with a 5 minute contact time.

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

To Clean: Thoroughly clean all surfaces to be treated by removing heavy soil before application.

To Disinfect: Hold can upright and spray from a distance of 6 to 8 inches until area for treatment is thoroughly moistened. Allow surfaces to remain wet for 10 minutes before wiping.

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.

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STORAGE AND DISPOSAL

Nonrefillable container. Do not reuse or refill this container.

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.

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.

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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 use on polished wood, painted surfaces, leather, rayon fabrics, acrylic plastics or furniture.

Sherwin-Williams
101 Prospect Avenue
Cleveland, OH 44115

Made In U.S.A.

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SURFACES –
Hard Non-porous Surfaces

- Bathtub (Tub) (Tile)
- Chrome
- Diaper Pails
- Door Knob (handle)
- Examination Tables
- Fixtures
- Faucets
- Garbage (cans) (pails) (bins)
- Glass
- Glass-topped furniture
- Glazed ceramic tile
- Glazed porcelain
- Laminate (surfaces)
- Linoleum
- Marble (Cultured)
- Marble (Synthetic)
- Metal+
- Metal Blinds
- Plastic
- Plastic Mattress covers
- Recycling bins
- Remote controls
- Sealed Granite
- Shower (curtain plastic liner)
- Sinks (basin)
- Stainless Steel+
- Telephones
- Tin
- Toilet (seats)(areas)
- (Toilet) (Urinal)(Exteriors)
- Vinyl (tile)
- Wheelchairs
- Windows (windowsills)

+Non-Medical or Fixture

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MICROORGANISMS – must be identified by genus & species. Abbreviations may be included but must appear in (parens)

Hard Non-porous Surfaces

- Staphylococcus aureus (Staph) (ATCC 6538)
- Streptococcus hemolyticus (Strep) (ATCC 21059)
- Pseudomonas aeruginosa (ATCC 15442)
- Mycobacterium bovis (BCG),
- Salmonella enterica (ATCC 10708)
- (Methicillin Resistant) Staphylococcus aureus (Staph) (MRSA) (ATCC 33591)

FUNGI

Hard Non-porous Surfaces

- Trichophyton mentagrophytes ATCC 9533(athletes foot fungus)

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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 be 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.

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

BISSELL[®] Life's Messy. Clean It Up.[®]

SINCE 1876, WE'VE BEEN CREATING SUPERIOR CARPET AND FLOOR CLEANING SOLUTIONS. BUT THESE DAYS, WE'RE MUCH MORE THAN FLOORS. WITH OUR COMPLETE LINE OF KITCHEN, BATH AND HOUSEHOLD CLEANERS, FURNITURE POLISHES, AIR FRESHENERS AND LAUNDRY PRODUCTS AT THE READY, BISSELL HELPS KEEP THE WHOLE HOUSE CLEAN. LIFE'S MESSY. CLEAN IT UP.

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