

44446-20

10/28/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Quest Chemical Corporation
12255 FM 529
Houston, TX 77041

OCT 28 2008

Attention: Mitch Whitney
Vice President for Quest Chemical Corporation

Subject: Staf Hospital Spray
EPA Reg. No. 44446-20
Amendment Letter Dated June 4, 2008

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 provided the following label revisions are incorporated:

- On page 1, the proposed label states "Kills MRSA" This claim is misleading and needs to be qualified to read "Kills MRSA on treated surfaces".
- On page 3, under the "General Information" section, the the American Type Culture Collection (ATCC) has changed the nomenclature of *Salmonella choleraesuis* to *Salmonella enterica*. Therefore, your label needs to reflect this change.
- On page 4, under the "Mildewstat" section, a statement must be submitted to address protection of inhalation exposure from a user applying the product in an automobile air conditioning system. Appropriate instructions should read, "After applying product into the air conditioning system, get out of the car immediately. Do not return for 4 – 10 minutes so air in the compartment can be properly ventilated".
- On page 4, move the language in the "HAZARDS TO HUMANS & DOMESTIC ANIMALS" section that states: "Flammable! Contents under..." to its on separate section titled "PHYSICAL OR CHEMICAL HAZARDS" . Per 40 CFR 156.78, this section addresses flammability, explosive potential and precautions.
- Your company needs to follow the ATTC number policy by listing ATTC numbers for all organisms appearing on the product label. You can choose to list ATTC numbers for the tested organisms in on of the following locations:

- The Data Matrix
 - The Master Label (as optional text) with the listing of the organism claimed.
- The company's name and address needs to be added to the label per the guidelines set forth in the 40 Code of Federal Regulations (CFR).
 - All references to "other" or "etc" must be removed from the label. These terms are ambiguous and are not specific to the area that should be treated.

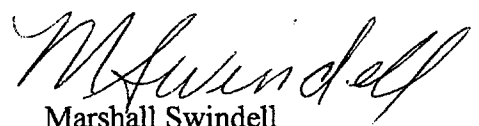
Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
 Product Manager (33)
 Regulatory Management Branch 1
 Antimicrobials Division (7510C)

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STAF
Hospital Spray
Disinfectant

Bactericidal – Staphylocidal
Pseudomonocidal
Eliminates Odors – Fungicidal
Virucidal Against HIV-1 (AIDS Virus)*

Air Sanitizer

[Kills MRSA] - on treated surfaces

ACCEPTED
with COMMENTS
in EPA Letter Data
OCT 28 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
44446-20

ACTIVE INGREDIENTS:

- n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
- dimethyl benzyl ammonium chloride 0.10%
- n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl
- ammonium chloride 0.10%
- Triethylene glycol 6.00%

OTHER INGREDIENTS 93.80%

TOTAL 100.00%

EPA Reg. No. 44446-20

EPA Est. No. 44446-TX-1

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See Additional Precautionary Statements on Back Panel

NET WT. 16.5 OZ. (468 g)

DIRECTIONS FOR USE

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

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 the 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.

SURFACE DISINFECTION & DEODORIZATION: (1) First remove soil deposits from surface to be treated. (2) Hold can six inches from surface & spray until completely wet, allow the surface to remain wet for 10 minutes.

AIR DEODORIZER, AIR FRESHENER & AIR SANITIZER: Shake well before each use. To temporarily reduce airborne odor-causing bacteria and eliminate odors, close all doors, windows, and air vents. Hold can upright, press button and spray towards the center of an average size room (12'x12'x9') for 10 seconds. For maximum effectiveness, relative humidity should be between 45% and 70%. Resume normal room ventilation after spray has settled. Repeat as necessary.

AUTOMATIC DISPENSER: Remove protective cap from top of can and insert can into dispenser in accordance with instructions on machine. **IMPORTANT:**

When used with the dispenser, one unit should be installed for each 6,000 square foot area to be treated. It is usually advisable to mount the dispenser 7-8 feet from the floor and at a point where wind flow will carry the particles throughout the room. The dispenser automatically actuates the special metered valve every 15 minutes, treating the air against odors. One unit lasts approximately 30 days.

MILDEWSTAT: To control mold and mildew on hard non-porous surfaces (such as floors, walls, table tops) spray the surface to be treated, making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

For use in automobile air conditioning systems, with engine running and air conditioner on maximum speed and cooling, spray the product into the air intake vent. Hold can eight to twelve inches above the vent while spraying four to six seconds. Make sure the spray tip is pointed directly at the intake vent before spraying. The recirculating system will pick up the product and the entire system will be deodorized in seconds. Shut off engine and air conditioner after applying the product.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

Cleaning procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time: Effective against HIV-1 (AIDS virus) on hard non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) providing 1800 ppm of active quaternary water for a contact time of 10 minutes at room

temperature (20-25°C). Use a ten (10) minute contact time for disinfection against all other bacteria and fungi claimed (listed on labeling).

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.

STORAGE AND DISPOSAL

Do not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partially full:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

GENERAL INFORMATION

This product has been designed specifically for Homes, Hospitals, Nursing Homes, Institutions, Offices, Schools, Motels & Hotels as a disinfectant, deodorant & air refresher. It is recommended for disinfection of telephones, springs, door knobs, linen carts, wheelchairs, light switches, garbage pails & other clean hard non-porous inanimate surfaces. It will also remove foul musty odors from automobile air conditioning systems caused by mildew and other odor producing organisms. Powerful deodorizers keep the automobile interiors smelling fresh and clean. [This product has been formulated to quickly and effectively remove foul musty odors from automobile air conditioning systems. It will freshen foul-smelling systems by killing odor producing organisms.] In addition, this product deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins & cans, restrooms, shower stalls & other areas which are prone to odors caused by micro-organisms). This product may also be applied directly to ash trays, food spills, in automobiles to eliminate odors from these sources. When used as directed, this product demonstrates effective disinfection against Staphylococcus aureus, Staphylococcus aureus-MRSA, Salmonella choleraesuis, Pseudomonas aeruginosa & Trichophyton mentagrophytes. This product is fungicidal against Pathogenic fungi (Athletes Foot Fungus), when used as directed on hard surfaces found in the bathroom, shower stalls & locker rooms or other clean hard non-porous surfaces commonly contacted by the bare feet.

***Kills HIV-1 (AIDS virus)** on precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/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).

MOLD & MILDEWSTAT: This product controls mold, mildew & the odors they cause on hard non-porous inanimate surfaces when used as directed.

1-800-CLEANUP
with COMMENTS
to EPA Letter Dated

OCT 28 2008

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

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RECEIVED
with COMMENTS
to EPA Letter Dated

OCT 28 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

CAUTION: Keep out of reach of children. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum using tobacco, or using the toilet. Harmful if swallowed. **Flammable!** Contents under pressure. Do not use near fire, sparks or flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

FIRST AID

*Move into
separator
Physicals
Chemical
Hazards
Section*

If Inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

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 eye.
- Call a poison control center or doctor for treatment advice.

If swallowed:

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

Have the product container or 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

INGREDIENTS (CAS#): Isopropyl Alcohol (67-63-0), Propane-Isobutane (68476-85-7), Water (7732-18-5), Triethylene Glycol (112-27-6), Quaternary Compound (N/A).

HMIS RATING: HEALTH-1, FLAMMABILITY-2, REACTIVITY-1, PERSONAL-A.

ITEM 329

[Alternate text]

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