

44446-23

10/15/2008

1025

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 15 2008

Ms. Mitch Whitney
Vice-President
Quest Chemical Corporation
12255FM 529
Northwoods Industrial Park West
Houston, TX 77041

Dear: Ms. Whitney:

Subject: **Germ Away Foaming Germicidal Cleaner**
PA Registration No. 44446-23
Letter Date June 4, 2008
EPA Received Date June 13, 2008

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comment.

Proposed Amendment:

- ° Add a claim for MRSA

Labeling Comments:

- The submitted data (MRID 474486-01) support the use of the product, Germ Away Foaming Germicidal Cleaner, as a hard surface hospital/medical use disinfectant with bactericidal activity against Methicillin Resistant *Staphylococcus aureus* (MRSA) at full strength in the presence of light organic soil at room temperature with a contact time of 10 minutes. Killing was demonstrated on all ten carriers per lot. Controls, including resistance testing, were acceptable for a valid test.
- The proposed label claims that the product, Germ Away Foaming Germicidal Cleaner, is an effective one-step disinfectant against **Methicillin Resistant *Staphylococcus aureus* (MRSA)** in the presence of moderate organic soil (5% serum) at full strength with a contact time of 10 minutes on hard, nonporous surfaces. These claims are acceptable as they are supported by the submitted data.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

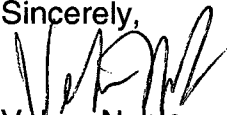
3. Page 1 of the proposed label states "**Kills MRSA.**" This is misleading and **must be qualified** to read "Kills MRSA on treated surfaces."
4. The ATCC has changed the nomenclature of ***Salmonella choleraesuis*** to ***Salmonella enterica***. You need to reflect this change on page 3 of the label.
5. You must follow the ATCC number policy by **listing ATCC numbers for all organisms** appearing on the product label (See ATCC Letter, soon to be posted online). You must choose to list ATCC numbers for the tested organisms in one of the following locations:
 - On the data matrix,
 - On the master label (as optional text) with the listing of the organisms claimed, or
 - As the final page of the master label (as optional text).

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Verma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: copy of Efficacy Review approved Dated 9/8/08 and Label

2045

GERM AWAY
Foaming
Germicidal Cleaner
Cleans as it Disinfects
Porcelain, Formica, Tile, Vinyl, Stainless Steel, Finished Woodwork and Other
Hard, Non-Porous Surfaces

COPY

Virucidal Against HIV-1
(AIDS Virus)*, Herpes Simplex Virus
Type 1 & 2, and Canine Parvovirus

~~MRSA~~ on treated surfaces

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 chlorides 0.10%

OTHER INGREDIENTS:

99.80%

TOTAL

100.00%

ACCEPTED
 with **COMMENTS**
 in EPA Letter Dated:

OCT 15 2008

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 4446-23

EPA Reg. No. 44446-23

EPA Est. No. 44446-TX-1

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See Additional Precautionary Statements on Back Panel

NET WT. 18 OZ. (510 g)

QUEST CHEMICAL CORPORATION

12255 FM 529 • HOUSTON, TEXAS 77041

SPRAYS RIGHT SIDE UP/UPSIDE DOWN

This product has been designed specifically for Homes, Nursing Homes, Hospitals, Institutions, Offices, Schools, Motels and Hotels. When used as directed, this product is formulated to disinfect inanimate hard surfaces (such as walls, sink tops, tables, chairs, telephones, bathrooms, shower stalls, bathtubs, hampers, cabinets and bed springs). In addition, this product deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins and cans, restrooms, shower stalls and other areas which are prone to odors caused by microorganisms). When used as directed, this product demonstrates effective disinfection against Staphylococcus aureus, Staphylococcus Aureus-MRSA, Salmonella choleraesuis, Pseudomonas aeruginosa, Canine Parvovirus, Herpes simplex type 1, Herpes simplex type 2 and Legionella pneumophila, thus meeting requirements for hospital use. Efficacy tests have demonstrated that the product is an effective one-step cleaner disinfectant in the presence of organic soil (5% blood serum). This product is fungicidal against Pathogenic fungi (T. mentagrophytes), when used as directed on hard surfaces found in the bathroom, shower stall, and locker room, or other clean, hard, non-porous surfaces commonly contacted by bare feet. This product is a versatile disinfectant and virucide for veterinarian and animal care applications when used as directed below. This product can be used in Veterinary clinics, animal life science laboratories, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, tack shops and other animal care facilities.

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

STORAGE AND DISPOSAL

4095

Do not puncture or incinerate! If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

DIRECTIONS FOR USE

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

DISINFECTION, DEODORIZATION AND CLEANING: 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. Surfaces which come into contact with food must be rinsed with potable water after disinfection. Do not use this product to disinfect or clean dishes, glassware or eating utensils. To disinfect hard non-porous surfaces (such as bathroom tiles, walls, fixtures, shower stalls, sinks, bathtubs, hampers, tables, chairs, HVAC catchpans and air conditioning evaporator coils), proceed as indicated below: (1) Shake can before using. (2) Hold six to eight inches from surface to be treated. (3) Spray area until it is covered with a white foam. Allow foam to penetrate and remain wet for 10 minutes. No scrubbing necessary. (4) Wipe off with a clean cloth, mop or sponge. This product will not leave grit or soap scum. For heavily soiled areas, remove gross soil before treatment.

For animal quarters and kennels, veterinary clinics, animal life science laboratories, pet shops, kennels, breeding and grooming establishments, tack shops: Remove all animals, poultry, and their feed/food from premises. Remove all litter, droppings and manure from all surfaces to be treated. Apply Germ Away as directed above. Germ Away will disinfect and clean the following surfaces: Equipment, utensils, instruments, cages, kennels, stables, stalls and catteries. After disinfection, ventilate buildings, coops and other closed spaces. Do not house poultry, or other animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water (racks, troughs, automatic feeders, fountains, waterers and other similar equipment) must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

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

***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).

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.

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

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

PHYSICAL OR CHEMICAL HAZARD

Contents under pressure. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator.

FIRST AID

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.

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 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 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

INGREDIENTS (CAS#): Water (7732-18-5), 2-Butoxy Ethanol (111-76-2), Propane/n-Butane (68476-86-8), Isopropyl Alcohol (67-63-0), EDTA (60-00-4).

HMIS Ratings: Health – 1, Flammability – 0, Reactivity – 1, Personal – A.

**For MSDS or additional product information:
www.questchemicalcorp.com**

ITEM 217 Made in USA

Alternate Text