

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 1 3 2009

Ms. Kim Inman ABC Compounding Co, Inc. PO Box 16247 Atlanta, GA 30321

SUBJECT: Mint 7

EPA Reg. No.: 3862-75

Amendment Date: December 23, 2008 EPA Receipt Date: January 13, 2009

Dear Ms. Inman,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Proposed Amendment

• Update "Storage and Disposal" statements per 2007-4

Conditions

Revise the label as follows:

- 1. Update the species name for Salmonella choleraesuis to read "Salmonella enterica."
- 2. Move the "Directions for Use" heading and "It is a violation to use this product in a manner inconsistent with its labeling" to appear above the "Cleaning and Deodorizing" directions.
- 3. Qualify the surface, tile, as hard nonporous by stating "glazed" tile.
- 4. Revise the "Disinfecting" directions by adding the statement, "Prepare a fresh solution daily or when use solution becomes visibly diluted or soiled."
- 5. Revise the "Storage and Disposal" statements as follows:
 - a) Move the statement, "Open dumping is prohibited" to appear under the Container

Disposal statement.

- b) Add a subheading to appear after the "Container Disposal" that reads "If container is damaged," and place the appropriate statements from the "Pesticide Storage" statements in this section.
- c) The proposed "Container Disposal" statements are not applicable to antimicrobial products. The rinsate cannot be placed into the application equipment, mix tank, or stored for later use because the use dilution rate is critical in mitigating microorganisms cited on your label.

Therefore, revise the "Container Disposal" statements by deleting the statement, "Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal." It must be replaced with the following statement:

Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.

- 6. Revise the "Precautionary Statements" to be in agreement with the Label Manual by stating the "Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or clothing. Wear protective eyewear (goggles or safety glasses), protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco. Remove contaminated clothing and wash before reuse."
- 7. Revise the first statement under the "Environmental Hazards" section to read "This product is toxic to "This product is toxic to fish, aquatic invertebrates, oysters, and shrimp."

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)



Manufactured by:

ABC Compounding Co., Inc. P.O. Box 16247 Atlanta, GA 30321-0247 Toll Free 800-795-9222

EPA REG. NO. 3862-75 EPA EST. NO. 3862-GA-1

ACTIVE INGREDIENT:

Alkyl (C14, 58%; C16, 28%; C₁₂, 14%) dimethyl benzyl ammonium chloride...... 2.0%

INERT INGREDIENTS......98.0%

TOTAL INGREDIENTS.....100.0%



DISINFECTANT, CLEANER, DEODORANT

THIS DISINFECTANT is effective against a wide variety of gram-positive and gram-negative bacteria. Kills: Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.
When applied as directed to precleaned hard, non-porous surfaces, this disinfectant also kills the following organisms at 5 ounces per gallon: Candida albicans, Escherichia coli, Streptococcus pyogenes, Enterobacter aerogenes, Shigella sonnei.

Limpiador y desodorante Desinfectante

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detaile. Of you do not understand this label, find someone to explain it to you in detail.)

KEEP OUT OF REACH OF CHILDREN

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

Net Contents:

Batch No.:

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PSEUDOMONACIDAL STAPHYLOCIDAL FUNGICIDAL

This product effectively eliminates odors at their source. This product is effective against all of the following organisms on inanimate environmental surfaces: Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella mentagrophytes (Athlete's Foot Fungus), Candida albicans, Virucidal against *HIV-1 (AIDS Virus) Dilution: 1:32-4 ounces per gal. Disinfectant 1:32-4 ounces per gallon. 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 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

USES: Floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, garbage cans, showers, athletic equipment, conductive flooring, and lavatory fixtures in institutions, schools, and hospitals. APPLICATION: For disinfecting, remove filth and heavy soil deposits. Preclean all surfaces prior to disinfection, then thoroughly wet surfaces. Use 4 ounces of concentrate per gallon of water for a minimum contact time of 10 minutes. This product is extremely versatile and can be applied with a mop, sponge, or cloth as well as soaking. Rinsing is not necessary on floor surfaces unless floors are to be waxed or polished. Fresh solution are often if the solution becomes diluted or soiled. TO CLEAN AND DISINFECT TOILET BOWLS Flush toilet. Remove gross filth. Add 3 fluid oz. directly to water in toilet bowl. Brush to cover all interior surfaces of the bowl including under the rim. Allow disinfectant solution to remain at least 10 minutes. Flush toilet. To clean badly stained bowl, repeat above treatment using 4 to 5 fluid ounces. For use in urinals, add 3 fluid oz, to 3/4 gallon of water. Apply by brush to all urinal surfaces. Allow disinfectant solution to remain at least 10 minutes. Flush

*Kills HIV-1 (AIDS virus) on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care 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 OF SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex gloves, gowns, masks, eye coverings as 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) when used at a 1:32 dilution (providing 500 ppm of active quaternary). Leave surface wet for 5 minutes. Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses plaimed (listed on label). Disposal Of Infectious Materials: Blood and other body fluids autoclaved and disposed of according to federal, state, local regulations for infectious waste disposal. 649241SA_0812

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: This product must be kept under locked storage sufficient to make it inaccessible to children and persons unfamiliar with its proper use. Open dumping is prohibited. Do not reuse empty container. PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office to revisitations.

CONTAINER DISPOSAL - (For containers greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows. Expenditure or refill this container. Clean container promptly after emptying. Fill the container 1/4 full with water. Replace and lighten closures. To container on its side and roll it back and both, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several

compiler revolution, for 30 seconds, stand the container on its end and up it deck and brin several times. Turn the container over onto, its other and and to it back and brin several times. Then offer-for-recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burned, stay out of smoke.

(For containers equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows:

Fill the container 1/4 full with water and recep. Shake for 10 seconds

begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS Hazardous to Humans and Domestic Animals DANGER

Comosive: Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, (goggles, leas shield, or safety glasses), protective clothing and rubber gloves. Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. FIRST AID

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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 swallowed	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. On 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 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 prod	duct container or label with you when calling a poison control center or doctor, or going for

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

ENVIRONMENTAL HAZARDS (For containers 5 gallons or greater): Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System(NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.