

3862-86

11/23/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 23 2009

Ms. Kim Inman
Regulatory Chemist
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321

Subject: **Rough & Ready**
EPA Registration Number 3862-86
Notification Application Dated October 28, 2009
EPA Received Date November 3, 2009

Dear Ms. Inman:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

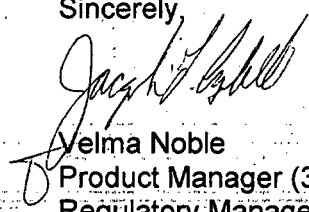
General Comment:

Based on a review of the material submitted; the following comment apply:

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

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

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
CONCURRENCES Division (7510P)

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 3862-86	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rough & Ready	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321 <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. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

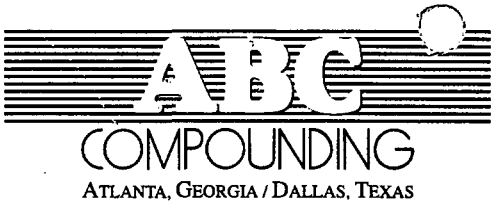
Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 "Notification of addition of the following text: "Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)." per PR Notice 95-2."
 "This notification is consistent with the provisions of PR Notice 95-2 and 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 18U.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 95-2 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55,35,20,5,1 gallon & quart		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" 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 Kim Inman	Title Regulatory Chemist	Telephone No. (Include Area Code) 770-968-9222
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 punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Chemist	
4. Typed Name Kim Inman	5. Date 10-28-09	



ATLANTA, GEORGIA
 P.O. Box 16247
 Atlanta, GA 30321 0247
 Phone: 770.968.9222
 Toll Free: 800.795.9222
 Fax: 770.968.7281

DALLAS, TEXAS
 Phone: 972.988.9200
 Fax: 972.641.8170

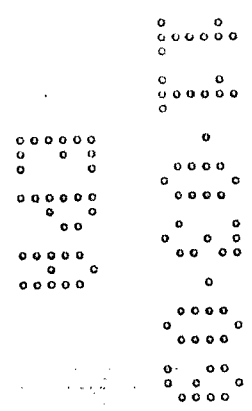
Velma Noble, Product Manager 31
 Regulatory Management Branch I
 Antimicrobials Division (7510C)
 U.S. Environmental Protection Agency
 Ariel Rios Building
 1200 Pennsylvania Ave., NW
 Washington, D.C. 20460

November 2, 2009

Ms. Noble,

Enclosed is the 8570-1 form for PR Notice 95-2 for 3862-86. Please send your decision via e-mail to kim.inman@abccompounding.com.
 Thank you,

Kim Inman
 Regulatory Chemist
 ABC Compounding Co., Inc.
 PO Box 16247
 Atlanta, GA 30321
 phone 678-833-2107
 fax 770-960-1059
kim.inman@abccompounding.com



NOTIFICATION
Date Reviewed: 11/23/15
Reviewed By: [Signature]



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

EPA Establishment No. 3862-GA-1
EPA Registration No. 3862-86

ACTIVE INGREDIENTS
n-Alkyl (C14 60%, C16 30%, C12 5%,
C18 5%) dimethyl benzyl ammonium
chlorides:.....0.09%
n-Alkyl (C12 50%, C14 30%, C16 17%,
C18 3%) dimethyl ethylbenzyl
ammonium chlorides:.....0.09%
INERT INGREDIENTS:.....99.82%
TOTAL:.....100.00%

Rough & Ready
**Ready To Use Germicide
Cleaner - Disinfectant - Deodorant**
Desodorante y desinfectante germicida

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

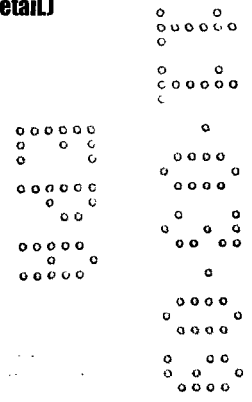
KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

Net Contents:

Batch No.:



Not only helps control the hazard of cross-contamination from treated surfaces on hard nonporous, environmental surfaces but also kills many microorganisms that cause odors. Recommended for disinfecting hard nonporous inanimate surfaces. For use in schools, colleges and office buildings. Kills *Streptococcus pyogenes*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Trichophyton mentagrophytes* (Athlete's Foot Fungus). Virucidal against Influenza Type A/Michigan, Herpes Simplex Type 2, and *HIV-1 (AIDS virus). **Kills Pandemic 2009 H1N1 Influenza A Virus (formerly called Swine Flu)**.

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.

FOR DISINFECTING For disinfecting, remove gross food particles and heavy soil deposits, then apply this product to walls, floors, garbage cans, and other hard (inanimate), nonporous surfaces, such as tables, chairs, countertops, sinks, bathroom fixtures, bedframes and showers with a coarse spray device so as to thoroughly wet surfaces for a contact time of 10 minutes. On surfaces which contact food, follow with a potable water rinse. This product is not for use on dishes, glassware or eating utensils. Let air dry or wipe dry. *Kills HIV-1 (AIDS virus) on precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings where 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 800 ppm of active quaternary) for a contact time of 5 minutes at room temperature (20-25°C). Use a ten(10) minute contact time for disinfection against all other bacteria, fungi, and viruses claimed (listed above). **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. **KITCHEN** Kitchen floors collect both traffic dirt and germs. Use this product anywhere greasy dirt is a problem. **BATHROOM** Great for cleaning and deodorizing basins, tubs, and tiles. Leaves everything bright and clean...kills odor-causing germs. Use this product where odors are a problem. **TO CLEAN AND DISINFECT TOILET BOWLS** Remove or expel over the inner trap residual bowl water prior to applying solution. Remove gross filth. Use 4 ounces in toilet bowl. Squeeze around bowl and under water rim. Then scrub thoroughly with brush making sure to get under the rim and let stand for at least 10 minutes, then flush. This product, when used as directed, will not harm white or colored bowls or inanimate, hard surfaces. Close cap on container after use. **SANITIZING NON-FOOD CONTACT SURFACES** Use on washable, hard, nonporous surfaces: walls, floors, tables without dilution. The product is effective against *Staphylococcus aureus* and *Enterobacter aerogenes* in the presence of 5% serum for specified hard, non-porous surfaces. Apply by mop, sponge, cloth or spray to thoroughly wet surfaces for a minimum contact time of 5 minutes. Wipe dry with a clean cloth or sponge, or allow to air dry. **MILDEWSTATIC INSTRUCTIONS** This formulation will effectively inhibit the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply solution by spraying the product, making sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears. 647941SA.0910

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **PESTICIDE STORAGE:** Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Open dumping is prohibited. Do not reuse empty container. **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 - (For containers 1 gallon or less):** Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available or offer for reconditioning if appropriate. **(For containers greater than 1 gallon):** Nonrefillable container. Do not reuse or refill this container. Clean promptly after emptying. Then offer for recycling if available or puncture and dispose in a sanitary landfill or by other procedures approved by state and local authorities. 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.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals.

CAUTION: Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

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

If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 inhaled	<ul style="list-style-type: none"> • 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.

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.

