

47371-89

02-09-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.
90 Boroline Road,
Allendale, NJ 07401

FEB 9 2010

SUBJECT: Formulation AE-90
EPA Registration Number: 47371-89
Application Date: January 8, 2010
Receipt Date: January 11, 2010

Dear Ms. Holcombe:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 2007-4.

- Update the Company address;
- Update pathogen names; and
- Update the Storage and Disposal language per PR Notice 2007-4.

Based on a review of the submitted information, this notification is acceptable. *Salmonella enterica* reflects the pathogen name with ATCC; in Herpes simplex virus type 2, virus is written with "small v" not "capital V". Your proposed label language is in agreement with PR Notice 2007-4. This notification will be made part of the record for this file.

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

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

7510P: T. Lantz.		CONCURRENCES					
SYMBOL							
SURNAME	T. Lantz						
DATE	2/9/2010						

EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section 1

1. Company/Product Number 47371-089	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Formulation AE-90	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) H&S Chemicals Division c/o Lonza Inc. 90 Boroline Road Allendale, NJ 07401 <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.)

Not Subject to PRIA

Label Notification to update Storage and Disposal language per PR Notice 2007-4.

PLEASE READ COVER LETTER FOR DETAILS.

This notification is consistent with the provisions of PR-Notice 98-10 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 18 U.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 98-10 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.

Signature: Joanna Holcombe

Date: 1-8-10

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Package wgt. container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Other _____	
				<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9297
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.		Date Application Received (Stamp)
2. Signature <u>Joanna Holcombe</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date January 8, 2010	

Via FedEx

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIFY)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201-696-3470
joanna.holcombe@lonza.com

Joanna Holcombe
January 8, 2010

**CONTAINS CONFIDENTIAL BUSINESS INFORMATION PROTECTED FROM DISCLOSURE
UNDER FIFRA §10**

**SUBJECT: Formulation AE-90, EPA Reg. No. 47371-089
Application for Label Notification**

Dear Ms Noble:

I am submitting an application to accomplish the following for the above named product:

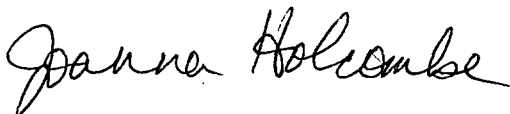
- Update the company address;
- Update pathogen names; and
- Update the Storage and Disposal language per PR Notice 2007-4.

Please find the enclosed documents in support of this notification:

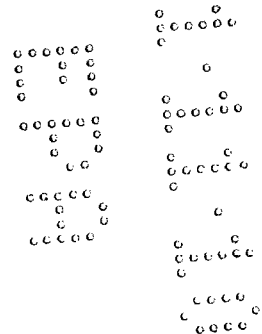
- Application for Notification;
- One copy of the proposed label with changes highlighted; and
- Two copies of the proposed label

If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,
Lonza Inc.



Joanna Holcombe
Sr. Commercial Regulatory Services Associate



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FORMULATION AE-90

One-step Disinfectant, Cleaner, and Deodorant

BACTERICIDAL FUNGICIDAL
MILDEWSTATIC *VIRUCIDAL

A ready-to-use, multi-purpose formula effective in the presence of a moderate amount of soil (5% organic serum) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Trichophyton mentagrophytes*, *Herpes simplex Virus type 2, and *HIV-1 (AIDS virus).

Active Ingredients:

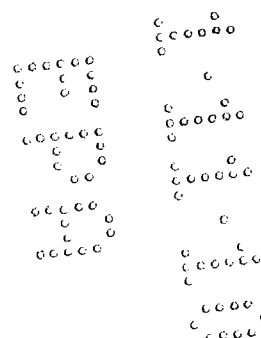
n-Alkyl (C₁₄ 60%, C₁₆ 30%, C₁₂ 5%, C₁₈ 5%)
 dimethyl benzyl ammonium chloride 0.09%
n-Alkyl (C₁₂ 50%, C₁₄ 30%, C₁₆ 17%, C₁₈ 3%)
 dimethyl ethylbenzyl ammonium chloride 0.09%
Other Ingredients: 99.82%
Total 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 47371-89
EPA Est. No. (as indicated on container)
Net Contents: (as indicated on container)

H&S Chemicals Division,
c/o Lonza Inc.
90 Boroline Road, Allendale, NJ 07401



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

CAUTION Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray. Wash thoroughly with soap and water after handling.

PHYSICAL AND 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.

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 eye.

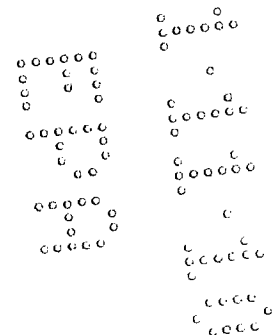
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

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

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

(Note to reviewer: The following is considered optional marketing language:)

- Broad-spectrum activity.
- Hospital-use disinfectant effective against *Staphylococcus aureus* (Staph), and *Pseudomonas aeruginosa* (*Pseudomonas*).
- Non-acid and non-abrasive; will not etch or scratch delicate surfaces.
- Effective against *HIV-1 (AIDS virus) and *Herpes simplex Virus type 2.
- Controls mold and mildew.
- Dissolves soap scum and foams away dirt.
- Disinfects, cleans, and deodorizes in one labor-saving step.
- Contains no CFCs or other ozone depleting substances
- Federal regulations prohibit CFC propellants in aerosols
- Deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins and cans, basements, restrooms, and other areas prone to odors caused by micro-organisms).
- When used as directed, demonstrates effective disinfection against *Staphylococcus aureus*, *Salmonella enterica* and *Pseudomonas aeruginosa*, thus meeting AOAC Use Dilution Test requirements for hospital disinfectant. Efficacy tests have demonstrated that it 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, nonporous surfaces commonly contacted by bare feet.



DIRECTIONS FOR USE

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

SHAKE BEFORE USING

GENERAL USE DIRECTIONS: For use in households, basements, restrooms, hospitals, nursing homes, institutions, offices, schools, colleges, airports, hotels, motels, greenhouses, and kennels. Disinfects, cleans, and deodorizes non-porous, inanimate surfaces such as floors, walls, metal surfaces, stainless steel surfaces, plastic surfaces (such as polypropylene, polystyrene, etc.), plastic/vinyl chairs, glazed porcelain, garbage cans, laundry chutes (opening and the surfaces within 12-24 inches of the opening), bathroom fixtures, sink tops, shower stalls, exterior bowl surfaces, empty basins, knobs, handles, railings, tables, chairs, telephones, bathrooms, bathtubs, hampers, cabinets, bed springs, vehicles (ships, trains, and airplanes), and many other similar public and residential surfaces which could harbor and transmit dangerous microorganisms.

TO CLEAN: Shake can. Spray evenly over surface, allowing sufficient time for the foam to penetrate heavy soil deposits. Wipe off. Chrome fixtures may be rinsed for high shine.

TO DISINFECT: Clean surface thoroughly as instructed above. Then apply a thin coat of foam, making sure to cover entire surface to be disinfected. Allow foam to remain for at least 10 minutes, then wipe off or allow to air dry.

(For labels that list medical premises and / or metal and / or stainless steel surfaces, one of the following statements must be used:)

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

or

This product is not for use on medical device surfaces.

MILDEWSTATIC INSTRUCTIONS: Follow the disinfection instructions above. Repeat application weekly or when growth reappears.

FUNGICIDAL DIRECTIONS: Kills Trichophyton mentagrophytes (the cause of athlete's foot fungus) on environmental surfaces. For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities on surfaces such as floors and shower stalls. Follow disinfection directions.

***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 / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

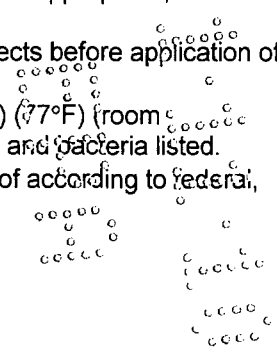
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

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

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

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 5 minutes at (25°C.) (77°F) (room temperature). Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood / body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.



DIRECTIONS FOR FOOD PROCESSING ESTABLISHMENTS:

For use on non-food, contact surfaces such as floors, walls, tables, empty garbage bins and cans. When used in food processing establishments, cover or remove all food and packaging materials, remove all gross soils, saturate all surfaces with the spray product, scrub to loosen all soils, allow to soak for 10 minutes, and thoroughly rinse all wetted and cleaned surfaces with potable water.

TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

Empty toilet bowl or urinal. Remove gross filth before disinfection. Thoroughly clean exposed surfaces with soap or detergent. Shake can. Apply a thin coat of foam, making sure to cover entire surface to be disinfected. Brush or swab thoroughly, including under the rim, allow foam to remain for at least 10 minutes, then flush.

DISINFECTION DIRECTIONS FOR KENNELS AND OTHER AREAS THAT HOUSE ANIMALS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a thin coat of foam for a period of 10 minutes. Saturate all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure with a thin coat of foam for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

(Note to reviewer: Container is a Nonrefillable aerosol can)

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in areas inaccessible to children. Do not reuse empty container.

Container Disposal

Do Not Puncture or Incinerate!

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency for disposal instructions.

