

6836-252

9/24/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, DC 20460



OFFICE OF
 PREVENTION, PESTICIDES
 AND TOXIC SUBSTANCES

September 24, 2003

Robert Sloan
 Sr. Regulatory Services Associate
LONZA, Inc.
 17-17 Route 208
 Fair Lawn, NJ 07410

Subject: **Phenocide 256**
 EPA Registration No. 6836-252
 Application Dated August 18, 2003

Dear Mr. Sloan:

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

Proposed Amendments:

- Response to PR Notice 2001-1
- Revise Precautionary statement
- Revise Storage and Disposal statements

Label Comments:

1. Correct typo in the Pesticide Storage text. "Open dumping....children to read "Do not reuse...container."
2. Add the statement, "This product is toxic to fish" at the beginning of the environmental hazard paragraph.

General Comment:

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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Renae A. Whitaker
Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or clothing. Wear goggles or face shield and protective gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water, or feed.

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 SWALLOWED: Call a 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.

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 PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

(If container size is 5 gallons or greater, use the following Environmental Hazards statements:)

ENVIRONMENTAL HAZARDS

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.

PHENOCIDE 256

GERMICIDAL DETERGENT

Cleans, Disinfects & Deodorizes
Pleasant Fragrance

PSEUDOMONACIDALSTAPHYLOCIDAL
*VIRUCIDAL FUNGICIDAL TUBERCULOCIDAL

Active Ingredients:

o-benzyl-p-chlorophenol.....	9.5%
o-phenylphenol.....	9.5%
Inert Ingredients:	81.0%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER / PELIGRO

(See side panel for additional precautionary and practical treatment statements.)

Net Contents: _____

EPA Reg. No. 6836-252

EPA Est. No. _____

LONZA INC.
17-17 ROUTE 208
FAIR LAWN, NJ 07410

ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 24 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
6836-252

Phenocide 256 is a multi-purpose germicidal detergent proven effective by the AOAC Use-Dilution Method in 400 ppm hard water (calculated as CaCO_3) in the presence of 5% organic bioload (Fetal Bovine Serum).

Phenocide 256's formula disinfects, cleans, and deodorizes in one labor-saving step.

Phenocide 256 is effective against the following pathogenic organisms:

(Bacteria:)

Pseudomonas aeruginosa
Salmonella choleraesuis
Staphylococcus aureus

Enterobacter aerogenes

†*Enterobacter cloacae*

***Enterococcus* sp.

Escherichia coli

Klebsiella pneumoniae

Mycobacterium bovis

†*Proteus mirabilis*

Providencia rettgeri

Pseudomonas cepacia

***Pseudomonas maltophilia*

Salmonella typhi

Salmonella typhimurium

Serratia marcescens

Shigella flexneri

†*Enterococcus faecalis*

Streptococcus pyogenes

**Tested against antibiotic resistant strain only.

† Tested against both standard ATCC strains and antibiotic resistant strains.

(Viruses:)

*Adenovirus Type 2

*Herpes Simplex Type 2

*HIV-1 (AIDS virus)

*Human rhinovirus Type 38

*Influenza Type A/Mich

*Polio I virus

*Rubella

*Vaccinia

(Fungi:)

Candida albicans

Trichophyton mentagrophytes

(Animal Viruses:)

*Avian Influenza

*Canine parvovirus

*Feline picornavirus

*Infectious Bovine Rhinotracheitis

*Newcastle Disease Virus

Use on hard, nonporous surfaces such as floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring and lavatory fixtures.

For use in hospitals, nursing homes, schools, colleges, medical and dental offices, farms, hog farms, equine farms, poultry and turkey farms, federally inspected meat and poultry plants, tack shops, kennels, pet shops, veterinary clinics, and animal life science laboratories. This includes barns, calf pens, laying operations, breeder operations, hatcheries, agricultural buildings and premises, live haul equipment, trucks, foot baths, and meat and poultry processing plants.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner. Before use of this compound, food products and packaging materials must be removed from the room and carefully protected. After use of this compound, all surfaces must be thoroughly rinsed with potable water.

USDA: For use in federally inspected meat and poultry plants on all surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.

USDA: For use in federally inspected meat and poultry plants as an antimicrobial agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DILUTION: 1 to 256 One-Half (½) oz. per Gallon

DIRECTIONS FOR USE

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

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following two 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 preclean 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.

TO DISINFECT: Use ½ oz. of Phenocide 256 per gallon of water for a minimum contact time of 10 minutes in a single application. Remove gross filth and heavy soil deposits, then thoroughly wet surfaces. Phenocide 256 is extremely versatile and can be applied with a mop, sponge, or cloth as well as soaking or used as a holding solution. Prepare fresh solution daily, or more often if the use solution becomes visibly soiled, cloudy or diluted.

Rinsing is not necessary on floor surfaces unless floors are to be waxed or polished.

Tuberculocidal effectiveness is in 10 minutes at 20°C.

HATCHERY: Can be used for cleaning, disinfecting and deodorizing floors, walls and equipment throughout the hatchery. This includes incubators, setters, and racks. Add ½ ounce per gallon of water. Hot or cold water may be used. Remove loose waste, gross filth, and heavy soil deposits prior to disinfecting. Repeat with fresh solution to disinfect.

***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 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 protective gloves, gowns, face masks, or eye coverings must be worn during all cleaning of body fluids, blood, and decontamination procedures.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Phenocide 256.

CONTACT TIME: HIV-1 (AIDS virus) is inactivated after one (1) minute of contact at room temperature (20 to 25°C). Use a 10 minute contact time for other viruses and bacteria claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

LIVESTOCK, TURKEY, AND POULTRY HOUSE DISINFECTANT

DILUTION: 1:256 One-Half (1/2) Ounce per Gallon

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. Immerse 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.
8. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(If container size is one gallon or less, use the following Storage and Disposal statements:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Rinse and discard in trash or recycle if allowed.

(If container size is greater than one gallon, use the following Storage and Disposal statements:)

STORAGE AND DISPOSAL

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

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children. 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 for guidance.

Container Disposal: Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.