

6836-253



1-31-2008
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 31, 2008

Georgia Anastasiou
Lewis & Harrison Consultants
Agent for **Lonza, Inc.**
c/o 122 C street, N.W., Suite 740
Washington, DC 20001

Subject: **Phenocide 128**
EPA Registration No. 6836-253
Application Date: November 30, 2007
Receipt date: December 4, 2007

Dear Ms. Anastasiou:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable with the following comments.

Proposed Amendments

- Label revision
- Specify strain of *Staphylococcus aureus* as "MRSA"
- Revise language for use directions
- Revise Storage and Disposal language per PR Notice 2007-4

General Comment

Please provide an updated data matrix with the submission. It is unknown whether or not ATCC numbers for all organisms appear on it. 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 may 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).


Future labeling amendments may be accomplished by submitting a copy of the electronic label. Refer to the following website for guidance on electronic submissions, including label:
http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub.

If you have any questions concerning electronic label submissions, please call Willie Abney at 703 308-1689 or refer to the following website for a list of contact personnel for more information: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

Submit three (3) copies of the final printed label bearing the above revision. A stamped copy of the accepted labeling is enclosed.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,


Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA Stamped labeling

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

DANGER Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or clothing. Avoid breathing spray mist.

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. 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. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

In case of an emergency call toll free CHEMTREC 1-800-424-9300. 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 less, 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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: Coveralls over long-sleeved shirt and long pants, socks and chemical-resistant footwear, goggles or face shield, and chemical resistant gloves (such as barrier laminate or butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton at ≥ 14 mils).

USER SAFETY REQUIREMENTS: Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

(Note to reviewer: Language in () is optional or interchangeable)

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

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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, medical and dental offices, schools, colleges, [beauty] [nail] salons, 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.

Phenocide 128 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).

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.

For use on washable hard nonporous surfaces such as appliances, bathroom fixtures, bathroom sinks, bathtubs, cabinets, chairs, conductive flooring, countertop laminates, countertops, desks, doorknobs, empty basins, enameled surfaces, exhaust fans, exterior bowl surfaces, floors, Formica[®], garbage cans, glazed porcelain tiling, highchairs, outdoor furniture, painted surfaces, picnic tables, refrigerators, shower stalls, showers, sinks, stovetops, tables, telephones, toilet bowl surfaces, toilet bowls, toilets, tubs and glazed tiles, urinals, vinyl and plastic upholstery, walls, washable walls, woodwork, and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, fiberglass, and plastic. 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.

(Note to reviewer: Language in () is optional or interchangeable)

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

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Phenocide 128's formula disinfects, cleans, and deodorizes in one labor-saving step. Phenocide 128 is effective against the following pathogenic organisms:

(Bacteria:)

- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Staphylococcus aureus
- Enterobacter aerogenes
- Enterobacter cloacae[†]
- Enterococcus sp.**
- Escherichia coli
- Klebsiella pneumoniae
- Staphylococcus aureus - Methicillin-Resistant [MRSA]
- Mycobacterium bovis
- Proteus mirabilis[†]
- Proteus vulgaris
- Providencia rettgeri
- Pseudomonas cepacia
- Pseudomonas maltophilia**
- Salmonella typhi
- Salmonella typhimurium
- Serratia marcescens
- Shigella flexneri
- Streptococcus faecalis[†]
- Streptococcus pyogenes

** Tested against antibiotic resistant strain only.

[†] Tested against standard ATCC strains and antibiotic resistant strains.

(Viruses:)

- *HIV-1 (AIDS virus)
- *Rubella
- *Adenovirus Type 2
- *Herpes Simplex Type 2
- *Human rhinovirus Type 38
- *Influenza Type A/Mich
- *Polio I virus
- *Vaccinia

(Fungi:)

- Candida albicans
- Trichophyton mentagrophytes

(Animal Viruses:)

- *Avian Influenza
- *Canine parvovirus
- *Feline leukemia
- *Feline picornavirus
- *Infectious Bovine Rhinotracheitis
- *Newcastle Disease Virus

(Note to reviewer: Language in () is optional or interchangeable)

[If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.] 7/12

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 128

ONE OUNCE 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 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.

GENERAL PRECAUTIONS AND RESTRICTIONS: Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application.

TO DISINFECT: Use 1 ounce of Phenocide 128 per gallon of water for a minimum contact time of 10 minutes in a single application. For disinfecting, remove gross filth and heavy soil deposits, then thoroughly wet surfaces. Phenocide 128 is extremely versatile and can be applied with a mop, sponge, or cloth as well as soaking or used as a holding solution. Thoroughly wet surfaces with the recommended use solution for at least 10 minutes. The recommended use solution is used once and discarded on a daily basis.

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

Tuberculocidal effectiveness is in 10 minutes at 20° C.

(Note to reviewer: one of the following two statements will be used:)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Phenocide 128, when diluted in 400 ppm hard water [via use of automatic dispensing devices], remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for (up to 7 days) (for up to one week) (for up to one month) (for up to 2 months) (for up to 3 months) (up to 4 months) (up to 5 months) (up to 6 months) (up to 7 months) (up to 8 months) (up to 9 months) (up to 10 months) (up to 11 months) (up to 12 months) (up to one year) when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

(or)

Prepare a fresh solution daily or more often if the use solution becomes visibly soiled, clouded or diluted.

(Note to reviewer: Language in () is optional or interchangeable)

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HATCHERY: Can be used for cleaning, disinfecting and deodorizing floors, walls and equipment throughout the hatchery. This includes incubators, setters, and racks. Add 1 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.

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. Use 1 ounce per gallon of water.

(Note to reviewer: Language in () is optional or interchangeable)

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***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 latex or vinyl 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 128.

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.

(Note to reviewer: Language in () is optional or interchangeable)

(Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used:)

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STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Offer for recycling if available or discard in trash.

(Note to Reviewer: For Nonrefillable Containers.)

Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. One of the following statements must be used for Refillable Containers.)

Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

OR

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose."

(Note to reviewer: Language in () is optional or interchangeable)

(Note to reviewer: If container is greater than one gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage:

Do not store on side. Avoid creasing or impacting of side walls.

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:

[Insert statements from below.]

(Plastic Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

(Metal Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(Note to Reviewer: For Nonrefillable Containers.)

Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. The following statement must be used for Refillable Containers.)

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose.

(Note to reviewer: Language in () is optional or interchangeable)

[Note to reviewer: May be used as an insert or hang tag or inserted on label.]

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PHENOCIDE 128

GERMICIDAL DETERGENT

LIVESTOCK, TURKEY, AND POULTRY HOUSE DISINFECTANT

DILUTION: 1:128

ONE OUNCE PER GALLON

DIRECTIONS FOR USE

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals, poultry and feeds from premises, vehicles, 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 or poultry.
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 or poultry, as well as forks, shovels, and scrapers used for removing litter and manure in the recommended use solution.
8. Ventilate buildings, coops, cars, boats, and other closed spaces in which the product has been used. 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.

(Refer to label for precautionary and practical treatment statements.)

EPA Reg. No. 6836-253

(Note to reviewer: Language in () is optional or interchangeable)