



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**February 29, 2008**

Georgia Anastasiou  
Lewis & Harrison LLC  
Agent for Lonza, Inc.  
122 C Street, NW / Suite 740  
Washington, DC 20001

Subject:      Product Name: Phenocide 256  
                 EPA Reg. Number: 6836-252  
                 Application Date: December 3, 2007  
                 Receipt Date: December 6, 2007

Dear Ms. Anastasiou:

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

**Proposed amendment:**

- Revised labeling

**General comment:**

Note that when submitting efficacy data to support certain claims, the ATCC numbers must be listed on the following location options:

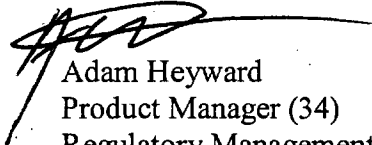
- On the data matrix, or
- On the master labeling (as optional text) with the listing of the organisms claims, or
- As the final page of the master label (as optional text).

**Other comments:**

A stamped copy of the label is enclosed for your record.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6422 or by e-mail at [heyward.adam@epamail.epa.gov](mailto:heyward.adam@epamail.epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or by email at [grigsby.stacey@epamail.epa.gov](mailto:grigsby.stacey@epamail.epa.gov) during the hours of 8:00 am to 4:00 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,



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

Enclosure: (stamped label)

# PHENOCIDE 256

## GERMICIDAL DETERGENT

Cleans, Disinfects & Deodorizes  
Pleasant Fragrance

- PSEUDOMONACIDAL
- FUNGICIDAL
- STAPHYLOCIDAL
- TUBERCULOCIDAL
- \*VIRUCIDAL

Active Ingredients:

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

**KEEP OUT OF REACH OF CHILDREN**

**DANGER / PELIGRO**

See [left] [right] [back] [side] panel for Precautionary Statements and First Aid.

EPA Reg. No. 6836-252

EPA Est. No. (insert EPA Establishment no. Here)

Net Contents: (insert container size here)

**Lonza Inc.**  
**90 Boroline Road**  
**Allendale, NJ 07401**

**ACCEPTED**  
**with COMMENTS**  
**EPA Letter Dated:**  
**FEB 29 2008**

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

**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.

**ENVIRONMENTAL HAZARDS**

This product is toxic to fish.

*(If the container size is 5 gallons or greater, the following Environmental Hazards statements will be added:)*

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.

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

Phenocide 256 is a multi-purpose germicidal detergent proven effective by the AOAC Use-Dilution Method in 400 ppm hard water (calculated as  $\text{CaCO}_3$ ) in the presence of 5% organic bioload (Fetal Bovine Serum).

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

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.

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

Phenocide 256 is effective against the following pathogenic organisms:

**(Bacteria:)**

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

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

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 (1/2) 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 1/2 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.

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 256, 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.

**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.

**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 1/2 ounce per gallon of water.

**\*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.



**[VETERINARY], [ANIMAL CARE] and [ANIMAL LABORATORY] FACILITIES/ [ZOOS] / [PET SHOPS] / [KENNELS] AND [FARM PREMISE] DISINFECTION / [VIRUCIDAL] DIRECTIONS:**

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries pens, stalls and etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all (troughs, racks and) feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of ½ oz. of **Phenocide 256** per 1 gallon of water [*or equivalent dilution*] for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. [*For "Veterinary Practice..."*] Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

*(Alternate Numbered Format)*

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries pens, stalls and etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.
3. Empty all (troughs, racks and) feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water.
4. Saturate surfaces with a use-solution of ½ oz. of **Phenocide 256** per 1 gallon of water [*or equivalent dilution*] for a period of 10 minutes. Wipe or allow to air dry.
5. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure.
6. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. [*For "Veterinary Practice..."*] Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse.
7. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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

## **PHENOCIDE 256**

### **GERMICIDAL DETERGENT**

#### **LIVESTOCK, TURKEY, AND POULTRY HOUSE DISINFECTANT**

DILUTION: 1:256

ONE-HALF [ ½ 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.

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

EPA Reg. No. 6836-252

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

### 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: 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.