

6836-252

08-21-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**August 21, 2007**

Ana Rodriguez-Koster  
Lewis & Harrison Consultants  
Agent for  
Lonza, Inc.  
122 C. Street, NW, Suite 740  
Washington, DC 20001

Subject: Notification Application Per PR Notice 98-10  
**Phenocide 256**  
EPA Registration No. 6836-252  
Application Date: July 31, 2007  
Receipt Date: August 2, 2007

Dear Ms. Rodriguez-Koster:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification:**

- Minor label revision

**General Comment:**

Based on a review of the material submitted, the following comment applies:

The notification application is acceptable and has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or by email at [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov) or Lisa McKelvin at (703) 308-7496 or by email at [mckelvin.lisa@epa.gov](mailto:mckelvin.lisa@epa.gov).

Sincerely,

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

# LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740  
Washington, D.C. 20001  
telephone 202.393.3903  
fax 202.393.3906

July 31, 2007

VIA FEDERAL EXPRESS

Document Processing Desk [NOTIF]  
Office of Pesticide Programs (7504P)  
U. S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**ATTENTION:** Adam Heyward  
Product Manager, Team 34

**SUBJECT:** Lonza, Inc.  
Phenocide 256 (EPA Reg. No. 6836-252)  
Notification of Minor Label Change per PR Notice 98-10

Dear Mr. Heyward:


On behalf Lonza, Inc., I am submitting a Notification of minor label change for their end-use product, **Phenocide 256 (EPA Reg. No. 6836-252)**. The purpose of this Notification is to remove the statement "This product contains sodium nitrite" from the product label. The Agency had requested addition of this statement in its letter dated 6/15/2006 (Attachment 1). However, as stated in your e-mail message dated 6/18/2007 (Attachment 2), request for the inclusion of this statement was an Agency oversight given that the product does not contain sodium nitrite. As a result, I am submitting this Notification to delete this language from the label.

Enclosed please find the following documents in support of this Notification:

1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10;
2. One (1) copy of the proposed product label, with changes highlighted; and,
3. One (1) clean copy of the proposed product label.

Thank you for your assistance with this submission. If you have any questions, please call me at 202-393-3903 x.17 or e-mail me at [alkoster@lewisharrison.com](mailto:alkoster@lewisharrison.com).

Sincerely,



Ana Rodriguez-Koster  
for,  
Lonza, Inc.

Enclosures

cc: Bob Sloan, Lonza, Inc.



**EPA**

United States  
Environmental Protection Agency  
Washington, DC 20460

- ☐ Registration  
☐ Amendment  
☒ Other: Notification

OPP Identifier Number  
**265394**

**Application for Pesticide - Section I**

1. Company/Product Number  
**6836-252**

2. EPA Product Manager  
**Adam Heyward**

3. Proposed Classification

4. Company/Product (Name)  
**Phenocide 256**

PM#  
**Team 34**

☒ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)  
**Lonza, Inc.  
90 Boroline Road  
Allendale, NJ 07401**

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(1), my product is similar or identical in composition and labeling to:

EPA Reg. No. \_\_\_\_\_

Product Name \_\_\_\_\_

**PLEASE DIRECT ALL CORRESPONDENCE TO  
"CONTACT POINT" LISTED BELOW**

☐ Check if this is a new address

**Section - II**

☐ Amendment - Explain below.

☐ Final printed labels in response to Agency letter dated \_\_\_\_\_

☐ Resubmission in response to Agency letter dated \_\_\_\_\_

☐ "Me Too" Application

☒ Notification - Explain below.

☐ Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**NOTIFICATION OF MINOR LABEL CHANGE PER PR NOTICE 98-10**

**Notification of MINOR LABEL CHANGE in Accordance With PR Notice 98-10**

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 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Ana Rodriguez-Koster

Date: 7/31/07

**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes\*  
☐ No

Unit Packaging

☐ Yes  
☐ No

Water Soluble Packaging

☐ Yes  
☐ No

2. Type of Container

☐ Metal  
☐ Plastic:  
☐ Glass  
☐ Paper  
☐ Other (Specify)

**\*Certification must  
be submitted**

If "Yes" No. per  
Unit Packaging wgt. container

If "Yes" No. per  
Package wgt. container

3. Location of Net Contents Information  
☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions  
☐ On Label  
☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph  
☐ Paper glued  
☐ Stenciled  
☐ Other \_\_\_\_\_

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: **Ana Rodriguez-Koster, Lewis and Harrison, LLC**  
**122 C St, NW Suite 740**  
**Washington, DC 20001**

Title: **Agent for Lonza, Inc.**

Telephone No. (Include Area Code): **(202) 393-3903 ext. 17**

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete, and I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

Ana Rodriguez-Koster

3. Title: **Agent for Lonza, Inc.**

4. Typed Name

**Ana Rodriguez-Koster, Lewis & Harrison LLC**

5. Date

**7/31/2007**

6. Date Application  
Received  
(Stamped)

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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.

### 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.

## PHENOCIDE 256

### GERMICIDAL DETERGENT

Cleans, Disinfects & Deodorizes  
Pleasant Fragrance

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

### 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

### NOTIFICATION

Date Reviewed: 2/10/07

Reviewed By: S. M. Kelly

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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.

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

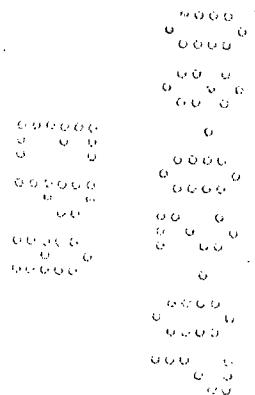
Use on hard, nonporous surfaces such as floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring and lavatory fixtures.

For use in hospitals, nursing homes, 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.



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**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.

*(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.

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).

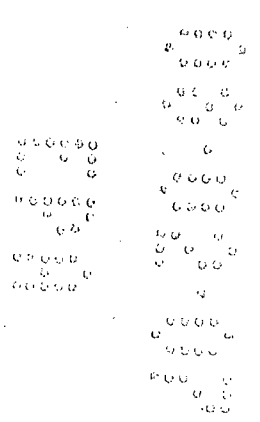
**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.**

**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.



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## 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.

(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.

