

6836-252

8/24/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 24 2010

Joanna Holcombe
Lonza Inc.
Boroline Road
Allendale, NJ 07401

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Phenocide 256**
EPA Registration Number: 6836-252
Application Date: May 25, 2010
Receipt Date: May 26, 2010

Dear Ms. Holcombe:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment

- Label Amendment: Update Storage and Disposal statements per PRN 2007-4

Conditions

Revise Label to Read:

- 1.) You must update your Precautionary Statements to read: "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
- 2.) The nomenclature for Rubella, Herpes Simples type 2, Influenza Type A/Mich, Avian Influenza, Felene leukemia and Infectious Bovine Rhinotracheitis is incomplete. You must add the term, virus such that it reads "Rubella Virus", etc. Revise your label accordingly.
- 3.) Since this product is utilized as a disinfectant as well as a fungicidal when treating trucks, footbaths, urinals, toilets, you must add the following directions for these sites with an appropriate heading:
 - a) **Fungicidal:** Phenocide 256 is an effective fungicide against *Trichohyton mentagrophytes* (agent causes athlete's foot fungus) and *Candidia albicans* in areas such a locker rooms, dressing rooms, shower And bath areas. Follow disinfection directions

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- b) **To disinfect Nail/Barber/Beauty Salons:** Mix $\frac{1}{2}$ oz. per gallon of water to disinfect hard nonporous instruments and tools. Use $\frac{1}{2}$ oz per gallon of water to kill Adenovirus type 2. completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution must be prepared daily or more often if solution becomes diluted. **Note:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.
- c) **To disinfect Foot Spas:** After using the foot spa, drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add [1/2 oz.] of for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the sides, [deck] [seat of chair lift] [any related equipment] and any uncovered surfaces on the [bath] [unit] [foot spa] with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the [unit] [bath] [foot spa] has been thoroughly disinfected, drain the solution from the [unit] [bath] [foot spa] and rinse the disinfected surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.
- d) **To disinfect Vehicles:** Apply $\frac{1}{2}$ oz per gallon of water to vehicles including mats, crates, cabs and wheels. Leave all treated surfaces wet for 10 minutes. Allow to air dry or wipe excess liquid with clean sponge or cloth.

4.) Add the following statement under the "Directions For Use" section: Fungicidal: Kills *Trichophyton mentagrophytes* (agent causes Athlete's Foot Fungus) in bathrooms, shower areas, and locker rooms. Follow Disinfection Directions

5.) ATCC has updated the nomenclature *Salmonella choleraesuis* to *Salmonella enterica*. Revise your label accordingly.

6.) **Deodorizing directions:**

Nursing Homes, Hospitals, Hotels, Schools: Using $\frac{1}{2}$ oz. in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals and air conditioner pans will eliminate odors.

7.) **Cleaning Solution:**

Dilute $\frac{1}{2}$ oz per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications.

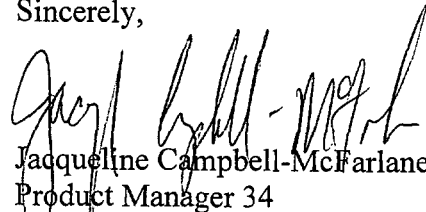
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General Comments

A stamped label with conditions is enclosed for your records. Submit a copy of your final printed label before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,



Jacqueline Campbell-McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: stamped label

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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
in EPA Letter Dated:
AUG 24 2010

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

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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.

(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 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.

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(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[†]
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

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

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

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[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 (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 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.

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.

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.

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[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

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(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Remain silent on burning;" therefore, no incineration language is provided for plastic containers.)

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.

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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic and Metal Containers:) Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)

(Note to reviewer: For Refillable Containers – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

Pesticide Storage:

Open dumping is prohibited. Store in original container in areas inaccessible to children.

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:

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

(Plastic or Metal Containers:) To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)