

6836-252

12/4/2008

1/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 4, 2008

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

Subject: Notification in Accordance with PR Notice 98-10
Phenocide 256
EPA Registration Number: 6836-252
Application Date: November 14, 2008
Receipt Date: November 20, 2008

Dear Ms. Anastasiou:

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

Proposed Notification:

- Revision of the Storage and Disposal statement per PR Notice 2007-4

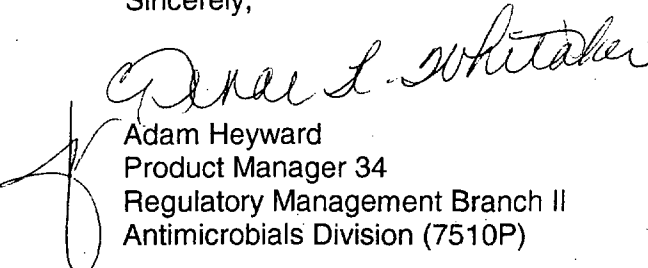
General Comment:

Based on a review of the material submitted, the following comments apply.

The notification application is acceptable.

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,


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

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 6836-252	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Phenocide 256	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Lonza, Inc. 90 Boroline Rd. Allendale, NJ 07401 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

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 to revise the storage and disposal language.
in accordance with PR-Notice 2007-4.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 740, Washington, DC 20001	Title Agent for Lonza, Inc.	Telephone No. (Include Area Code) 202-393-3903 x19
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Lonza, Inc.	
4. Typed Name Georgia Anastasiou	5. Date November 14, 2008	

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

November 14, 2008

HAND DELIVERED

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

ATTENTION: Adam Heyward
Product Manager (34)

SUBJECT: Lonza, Inc.
Phenocide 256 (EPA Reg. No. 6836-252)
Notification in accordance with PR-Notice 2007-4

Dear Mr. Heyward:

As agent for Lonza, Inc., I am submitting a notification for the product, **Phenocide 256 (EPA Reg. No. 6836-252)**. The purpose of this notification is to revise the storage and disposal language in accordance with PR-Notice 2007-4 and correct the Pesticide Storage language for over 1 gallon. The Pesticide Storage language on the EPA Stamped label dated 2/29/08 was inadvertently changed.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C Sec. 1001 to willfully make any false statements to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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

- a) Application for Pesticide Notification;
- b) One (1) copy of the label with changes highlighted; and,
- c) Two (2) copies of the label.

Thank you for your assistance with this submission. If you have any questions please feel free to contact me at 202-393-3903 ext. 19 or georgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

Georgia Anastasiou
Agent for,
Lonza, Inc.

cc: Kari Mavian (LONZA, Inc.)

4/15
PHENOCIDE 256

GERMICIDAL DETERGENT

Cleans, Disinfects & Deodorizes
Pleasant Fragrance

- PSEUDOMONACIDAL
- TUBERCULOCIDAL
- FUNGICIDAL
- *VIRUCIDAL
- STAPHYLOCIDAL

Active Ingredients:

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

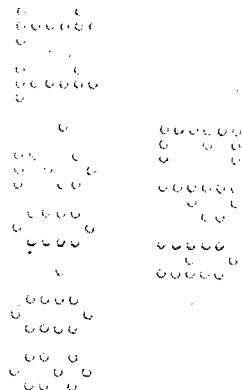
KEEP OUT OF REACH OF CHILDREN

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



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**PRECAUTIONARY STATEMENT:
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.

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(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.

(Note to reviewer: () 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

[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.

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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 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.

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[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.

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, Container is one gallon or less, Label has Household and Residential Uses only:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

13/15
(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household and Residential)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon.)

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 Containers:) Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. If not tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(Metal Containers:) Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. If not tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT cut or weld metal containers.

(Note to reviewer: For Refillable Containers, Container is over one gallon.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Refillable container. Refill this container with *[this product]* only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller.

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.

FINAL CONTAINER DISPOSAL

Clean container promptly after emptying. 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 remaining contents from container for use according to use directions and triple rinse promptly after emptying. 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.