

6836-253

08/23/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

AUG 23 2010

Joanna Holcombe
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Phenocide 128
EPA Registration Number: 6836-253
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

Update storage and Disposal language per PR Notice 2007-4

Conditions

Revise the label as follows:

- 1.) Relocate the "Personal Protective Equipment", "User Safety Requirements," and "User Safety Recommendations," sections on page 2 to appear after the "Precautionary Statements." Also delete the "User Safety Recommendations" heading because it isn't in compliance with PR Notice 2000-5, Mandatory Labeling. The User Safety Requirements heading is acceptable for both sections.
- 2.) Qualify fiberglass as a hard nonporous surface on page 3 by stating "*sealed*" fiberglass. Also, qualify outdoor furniture as hard nonporous surface on page by adding the disclaimer, "*except for wooden frames and cushions.*"
- 3.) Qualify that non-food contact surfaces are being treated in refrigerators on page 3 by stating refrigerator "*exteriors.*"
- 4.) The nomenclature for *Salmonella choleraesuis* must be updated to read "*Salmonella enterica*" on page 4.

5.) The nomenclature for Herpes Simplex 1, ~~Cytomegalovirus~~, Avian Influenza, Feline leukemia

and Infectious Bovine Rhinotracheitis is incomplete on page 4. You need to indicate that the

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microorganisms are viruses by stating "Herpes Simplex Type 2 *Virus*, *Vaccinia Virus*, *Avian Influenza Virus*, *Feline leukemia Virus*, and *Infectious Bovine Rhinotracheitis Virus*."

6.) Since the product makes hard surface cleaning and deodorizing claims on page 1, add the following heading above the "To Disinfect" directions on page 6:

Cleaning/Deodorizing: Apply 1 oz per gallon of water to hard nonporous surfaces with cloth, mop, sponge, or sprayer. Allow surface to air dry.

7.) Revise the last statement under the "To Disinfect" directions on page 6 and the 6th statement under the "Livestock, Turkey, and Poultry House Disinfectant" directions on page 8 to be in compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.

8.) Since this product is utilized as a disinfectant as well as fungicidal when treating trucks, footbaths, urinal, toilets, you must add the following directions for these sites with an appropriate heading:

- a) **Fungicidal:** Phenocide 128 is an effective fungicide against *Trichophyton mentagrophytes* (agent causes athlete's foot fungus) and *Candidia albicans* in areas such as locker rooms, dressing rooms, shower and bath areas. Follow disinfection directions.
- b) **Toilet/Urinal Disinfection:** Remove gross filth prior to disinfection. Empty toilet/urinal. Apply 1 oz per gallon of water to with a cloth, toilet brush, sponge or mechanical sprayer. Brush over exposed surfaces and under the rim. Allow surfaces to remain wet for 10 minutes. Then flush.
- c) **Footbaths:** After using footbath, drain and refill with fresh water to just cover intake valve or highest jet. Apply 1 oz per each gallon of fresh water added. Start the pump to circulate the solution. Wash down the sides, seat of chair, related equipment, and uncovered surfaces with a sponge, cloth, or brush. Treated surfaces must remain wet for 10 minutes. After the foot spa has been thoroughly disinfected, drain the solution from the unit and rinse surfaces with fresh water. Wipe dry with a clean cloth/sponge or allow to air dry. Repeat after each use.
- d) **Salon/Barber Instruments and Tools Disinfection:** Preclean heavily soiled instruments and tools prior to disinfection. Completely immerse combs, brushes, razors, scissors, blades, plastic rollers, manicure and other salon/barber instruments and tools for 10 minutes. Rinse thoroughly with water and dry before reuse. Fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel sheers 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.

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- e) **Vehicles:** Apply 1 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.

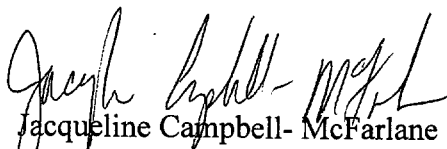
9.) Revise the 3rd-6th statements under the "Hatchery" directions on page 7 by stating "Remove chickens/chicks, loose wastes, gross filth, and heavy soil deposits prior to disinfecting. Preclean in accordance with Cleaning and Deodorizing directions. Apply 1oz per 1 gallon of water to hard nonporous surfaces. Leave all treated surfaces wet for 10 minutes. Allow to air dry or wipe excess liquid with cloth or sponge".

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission 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 128

GERMICIDAL DETERGENT
Cleans, Disinfects & Deodorizes
Pleasant Fragrance

- PSEUDOMONACIDAL
- FUNGICIDAL
- STAPHYLOCIDAL
- TUBERCULOCIDAL
- *VIRUCIDAL

ACTIVE INGREDIENTS:

o-benzyl-p-chlorophenol 4.75%
 o-phenylphenol 4.75%

OTHER INGREDIENTS: 90.50%
 Total..... 100.0%

This product contains the active ingredients o-phenyl phenol and o-benzyl phenol, each at 0.42 lbs./gal.

KEEP OUT OF REACH OF CHILDREN

DANGER / PELIGRO

(See side / right/ left/ back panel for additional precautionary and First Aid statements.)

NET CONTENTS _____
 EPA Reg. No. 6836-253
 EPA Est. No. _____

Lonza Inc.
 90 Boroline Road
 Allendale, NJ 07401

ACCEPTED
 with **COMMENTS**
 in EPA Letter Dated:

AUG 23 2010

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. **6836-253**

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

**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.

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

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

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 CaCO₃) 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: () 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)

(Note to reviewer: () 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.

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

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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 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 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.

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

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

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this product. Bactericidal strength 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 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.

***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, 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)

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

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)

(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 ¼ 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: Language in () is optional or interchangeable)

(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.)

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