



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 29, 2019

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

Subject: PRIA Label Amendment – Review Product Chemistry and Revise Precautionary Statements
Product Name: NuGen IID-32
EPA Registration Number: 6836-386
Application Date: March 12, 2019
Decision Number: 549034

Dear Ms. Rosario:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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Decision No. 549034

with FIFRA section 6. If you have any questions, you may contact Joseph Daniels at (703) 347-8669 or via email at Daniels.joseph@epa.gov

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

{Note to reviewer:

Items in brackets [AAA] are optional and may/may not be included on final label.

Items in braces {AAA} are for information purposes and will not appear on final label}

NUGEN® 1ID-32

One-Step Germicidal† Cleaner and Deodorant

DISINFECTANT
STAPHYLOCIDAL¹
FUNGICIDAL
*VIRUCIDAL

PSEUDOMONACIDAL²
BACTERICIDAL
MILDEWSTATIC

ACCEPTED

07/29/2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 6836-386

[FLORAL] / [CITRUS] / [FRESH] / [CLEAN] / [LEMON] / [PINE] / [MINT]
[scent] [fragrance] [odor] [scented]

Active Ingredients:

Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate.....1.516%

Other Ingredients:98.484%

Total 100.000%

DANGER [PELIGRO]

KEEP OUT OF REACH OF CHILDREN

See [left] [side] [right] [back] panel for Precautionary Statements

EPA Reg. No. 6836-386

EPA Est. No. (insert EPA Est. No. here)

Net Contents (as indicated on container)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[BARCODE]

Manufactured by:

LONZA Inc.

412 Mount Kemble Avenue

Suite 200S

Morristown, NJ 07960

¹staphylococcus aureus and staphylococcus epidermis

²pseudomonas aeruginosa

NUGEN 1ID-32

EPA Reg. No. 6836-386

EPA Stamped Label 2018-11-26

EPA submission 2019-03-12

{Note to reviewer: Language in [] is optional or interchangeable}

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Poly-ethylene, or Polyvinyl Chloride (PVC), or Viton, selection Category A). Wear a minimum NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; or a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; or a NIOSH-approved powered air purifying respirator with HE filters. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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 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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact 1-800-222-1222, the poison control center, for emergency medical treatment information.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

{Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statement will be used:}

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.

{Note to reviewer: the following is considered optional marketing language:}

A multi-purpose, germicidal[†] detergent effective in the presence of a moderate amount of organic soil [5% serum].

Bleach-free

Cleans, disinfects, and eliminates odors.

Continuous Odor Removal

[Deodorizes and] has a clean, fresh scent

Destroys [mold] odors at the source.

Disinfecting [Multi-Purpose] Cleaner

Disinfects [and / or] cleans [and / or] deodorizes in one [labor saving] step when used according to the directions for disinfection.

Doesn't just mask odors, it eliminates them.

Eliminates [smoke] [pet] [mold] odors.

Eliminates tough [floor] dirt and germs[†]

[Good for] [use on] finished wood surfaces

Help is on the way

Makes 32 gallons *{on the 1 gallon label}*

Meets OSHA Bloodborne Pathogen standard for HIV

Mold Odor Destroyer

Multi-purpose [or] Floor cleaner [and/or] disinfectant

No smeary residue

[†]**Note to reviewer:** *If a supplemental label is using the “Germs” claim, per the EPA Guidance on use of the term “Germs” in order to make an unqualified “germ” claim the supplemental label must list all 3 of the major classes of organisms: Virus, Bacteria, Fungi and label must bear disinfectant directions. In order to make a qualified “germ” claim the supplemental label must be a broad spectrum disinfectant and list additional claims against one of the following two major classes of organisms: Fungi or Viruses and must bear disinfectant directions. The front panel of the label for a qualified claim must contain a designator [such as **] that refers the user to the qualified statements that describes the type of germ the product is efficacious against. An unqualified claim can appear on front or back panel and does not require a designator.*

{Note to reviewer: the following is considered optional marketing language:}

Use **NUGEN® 1ID-32** in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal or food will be depicted in graphics.}

Bathrooms
Homes [households]
Kitchens

Dental offices
Hospitals
Medical Offices [Clinics]
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Federally inspected meat and poultry plants
Food processing plants
Food storage areas
Institutional kitchens
Restaurants
[USDA] [Federally] inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons

Public facilities
Public restrooms
Schools
Shower and bath areas
Salons [Beauty]
Universities

Camp grounds
Playground equipment

Animal laboratories
Dairy farms
Farms [Farm premises]
Hog farms
Kennels
Pet animal quarters
Pet shops
Poultry farms
Poultry houses
Turkey farms
Veterinary clinics
Zoos

Airplanes
Airports
Boats
Buses
Campers
Cars
Emergency vehicles
Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

{Note to reviewer: the following is considered optional marketing language:}

(TYPES OF SURFACES:)

Use **NUGEN® 1ID-32** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

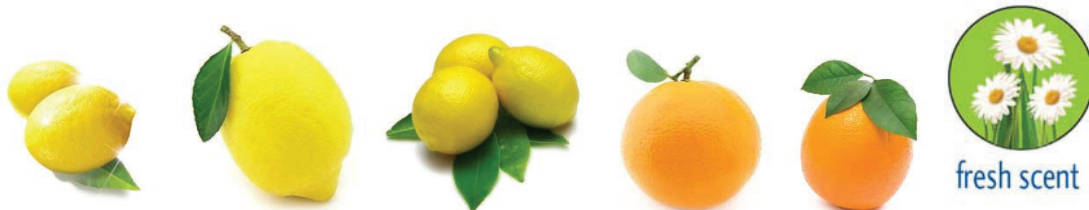
Appliances, exterior surfaces
Basins (empty)
Bathroom [lavatory] fixtures
Bathtubs
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and
refrigeration equipment and heat pumps
Conductive flooring
Counters [countertops]
Desks
Doorknobs
Fiberglass Bathtubs
Fiberglass Sinks
Floors
Garbage cans
Highchairs
Kennel runs

Microwave ovens, exterior surfaces
Outdoor furniture (except cushions and wood
frames)
Refrigerators, exterior surfaces
Refrigerated storage and display equipment
Showers
Shower stalls
Sinks [bathroom, kitchen]
Stoves [stovetops]
Tables, [picnic tables]
Telephones
Toilets
Toilet stalls
Toilet bowl surfaces
Tubs
Tiles, glazed
Urinals
Walls

Other hard nonporous surfaces made of:

*Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Metal
Painted surfaces
Plastic (such as polystyrene or polypropylene)
Sealed stone
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished

{Note to reviewer: The following is an optional graphic that will be used to illustrate the scent.}



* Formica® is a registered trademark of The Diller Corporation

{Note to reviewer: The following are optional graphics that will be used to illustrate possible use sites.}



toilet
baño



garbage area
área de basura

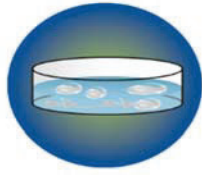


shower
ducha

{Note to reviewer: The following are optional graphics that will be used to illustrate odors to be controlled.}



smoke
humo



mold & mildew
moho y hongos



pet carrier
portador del
animal doméstico

{Note to reviewer: the following is considered optional marketing language:}

Effective [as a disinfectant] against the following pathogens:

[Bacteria]

Enterobacter aerogenes (ATCC 13048)

Escherichia coli (ATCC 11229)

Klebsiella pneumonia (ATCC 4352)

Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica (ATCC 10708)

Serratia marcescens (ATCC 14756)

Shigella flexneri (ATCC 12022)

Shigella sonnei (ATCC 11060)

Staphylococcus aureus (ATCC 6538)

Staphylococcus aureus - Methicillin-Resistant [MRSA] (ATCC 700699)

Staphylococcus epidermidis (ATCC 12228)

Streptococcus pyogenes [Strep] (ATCC 19615)

[Viruses:]

*Herpes simplex Type 1 Virus [Herpes]

*Influenza A Virus [Influenza]

*HIV-1 [(AIDS virus)]

[Fungi:]

Trichophyton interdigitale [Athlete's Foot Fungus] [A cause of ringworm]

DILUTION: 1:32 4 fl. oz. per gallon of water [474 ppm Active Quat]

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

[AVISO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL USE DIRECTIONS

APPLICATION: For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 4 fl. oz. [1/2 cup] of the concentrate per 1 gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware, dishes or appliance interior surfaces as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

Rinsing of floors is not necessary unless they are to be waxed or polished.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following 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.

{Note to reviewer: Alternate Directions for use:}

General Cleaning:

Mix 4 fl. oz [1/2 cup] per 1 gallon of water.

To Disinfect and Clean [throughout your home]:

Mix 4 fl. oz [1/2 cup] per 1 gallon of water. Let stand for a minimum of 10 minutes before wiping. For heavily soiled surfaces, a precleaning step is required.

For tough jobs:

Pour directly on sponge or soil. Let stand for a minimum of (contact time) before wiping. Rinse thoroughly with clean water.

For surfaces that may come in contact with food, potable water rinse is required.

USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: [Prepare diluted solution as outlined in directions above.] To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove the heavy soil, then [remove or expel over the inner trap the residual bowl water] or [empty bowl]. Pour in 3 fl. oz. of the diluted solution. [Swab the bowl completely using a scrub brush or mop] [Brush bowl completely], making sure to get under the rim. Let stand for a minimum of 10 minutes [or overnight], then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 4 fl. oz. [1/2 cup] per 1 gallon solution for a contact time of at least 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL DIRECTIONS: **NUGEN® 1ID-32** is an effective fungicide against *Trichophyton interdigitale* [the athlete's foot fungus] [a cause of ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

MILDEWSTATIC DIRECTIONS:

[Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops.] Apply solution [4 fl. oz. [1/2 cup] per 1 gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

***KILLS HIV-1 [AIDS VIRUS] ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV1] [associated with AIDS].

Special Instructions for Cleaning and Decontamination Against *HIV-1 [*AIDS Virus] of Surfaces / Objects Soiled With Blood / Body Fluids.

Personal Protection: Clean-up must always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of **NUGEN® 1ID-32**.

Contact Time: Leave surface wet for 5 minutes [at 25°C] [77°F] [room temperature]. Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria claimed.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing must be disposed of according to federal, state, and local regulations for infectious waste disposal.

FARM PREMISE, LIVESTOCK, TURKEY AND POULTRY HOUSE DISINFECTANT DIRECTIONS:

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. 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.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Prepare diluted solution [as outlined in directions above] [4 fl. oz. per 1 gallon of water].
6. Saturate all surfaces with the diluted solution for a period of at least 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 animals or employ equipment until treatment has been absorbed, set, or dried.
9. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automated feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.

**VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS
DISINFECTION DIRECTIONS:**

For cleaning and disinfecting hard, nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 4 oz. of **NUGEN® 1ID-32** per 1 gallon of water *[or equivalent dilution]* for a period of at least 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 surfaces that come in contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

HEAVY-DUTY CLEANING DIRECTIONS:

Use [2 fl. oz. of **NUGEN® 1ID-32** per 24 fl. oz of water] [8 to 12 fl. oz. of **NUGEN® 1ID-32** per 1 gallon of water] to clean heavily soiled areas.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

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.

{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

{For Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in original container in areas inaccessible to children.

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. Wrap empty container and put in trash.

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.