

47371-192

11/19/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 19 2004

Mr. Robert Sloan
 Sr. Regulatory Services Associate
 H & S Chemical Division c/o LONZA, Inc.
 17-17 Route 208
 Fair Lawn, NJ 07410

SUBJECT: Formulation HWS-32
 EPA Registration Number: 47371-192
 Applications Dated: May 19, 2004
 Receipt Date: May 24, 2004

Dear Mr. Sloan:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- update label language
- add public health and non-public health pests

Label Comments

Make the following changes to your labeling:

A. Make the following revisions to page four:

1. You have added the site: "Foot Spas" to your label. As such, add the following set of directions for use:

"Disinfection of Hard, Non-Porous Surfaces in Footbaths: *To remove body oils, dead tissue, soil and all other buildups or organic matter on inanimate surfaces after using the footbath, drain the water and thoroughly clean all hard, non-porous surfaces with soap or detergent, then rinse with water. Saturate surfaces with a use solution of 4 ounces per gallon of water (or equivalent use dilution) to exposed surfaces with a cloth, mop, sponge or sprayer. For spray applications,*

CONCURRENCES							
SYMBOL	7510C						
SURNAME	J. Lock						
DATE	11/19/04						

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use a coarse spray device. Do not breathe spray. Brush or swab thoroughly and allow solution to stand for 10 minutes. After the unit has been thoroughly disinfected, rinse all surfaces with fresh water. Do not use equipment until treatment has been absorbed, set or dried."

2. Add the following statement to your label as per the last stamped label for this product: *"This product must not be used to clean or disinfect the following food contact surfaces: utensils, glassware, and dishes."* Your product is for use in restaurants, kitchens, homes and other similar sites and you have added new surfaces to this label, several of which can be used to describe materials from which dishes are commonly made: "glazed porcelain" and "glazed ceramic." Disinfectants are not to be used on food contact surfaces such as utensils, glassware and dishes even with a potable water rinse.

3. As per your last requested notification for this product, revise the "Mildewstatic Instructions" as follows: "...Apply use-solutions of 4 ounces per gallon of water..."

B. Make the following revisions to page six:

1. Revise your directions for Veterinary Practice/Animal Care... to be in agreement with DIS/TSS-18 as follows: *"...Thoroughly scrub all treated surfaces that come in contact with food, including equipment used for feeding and watering, with soap or detergent, and rinse with potable water before reuse."*

2. As per your last requested notification for this product, revise the "Citrus Canker Disease" directions to indicate the use of **deionized** water.

3. Revise your Storage and Disposal statement for containers of 1 gallon or less and the Pesticide Storage statement for containers larger than 1 gallon to be in agreement with the last stamped label and PR Notice 83-3 as follows: *"Store in original container in locked storage areas inaccessible to children..."*

4. Revise your Storage and Disposal statement for containers of 1 gallon or less to be in agreement with PR Notice 84-1 as follows: *"...Wrap and discard in trash or recycle."*

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c)(5) and section 4 (a) when the Agency requires all registrations of similar products to submit such data.

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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6)e. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosures: Stamped label
7510C:T.Lantz:11/19/04:47371-192a

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid contact with the skin. Harmful if inhaled. Avoid breathing spray. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

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.

(Note to reviewer: If container size is 5 gallons or greater, use the following Environmental Hazards statements:)

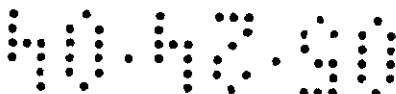
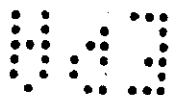
ENVIRONMENTAL HAZARDS

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 19 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-192



FORMULATION HWS-32

ONE-STEP DISINFECTANT

GERMICIDAL DETERGENT AND DEODORANT

Disinfectant	Pseudomonacidal
Staphylocidal	Salmonellacidal
Bactericidal	Fungicidal
Mildewstatic	*Virucidal

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

Active Ingredients:

Didecyl dimethyl ammonium chloride	1.27%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride	0.85%
Other Ingredients:	97.88%
Total:	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See [right] [left] [side] [back] panel for Precautionary
Statements and First Aid

EPA Reg. No. 47371-192

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

NET CONTENTS (insert container size here)

H&S CHEMICALS DIVISION

c/o LONZA INC.,

17-17 ROUTE 208, FAIR LAWN, NJ 07410

HLG/ALM/MSD
copy

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

- Concentrate [Concentrated]
- Neutral [Neutral pH]
- Disinfects [Disinfectant]
- Cleans [Cleaner]
- Deodorizes [Deodorizer]

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO_3) in the presence of a moderate amount of soil (5% organic serum) according to the AOAC Use-dilution Test. Disinfects, cleans and deodorizes in one labor-saving step.

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, zoos, federally inspected meat and poultry establishments, equine farms, tack shops, pet shops, airports, kennels, hotels, motels, poultry farms, turkey farms, dairy farms, hog farms, breeding establishments, grooming establishments, funeral homes and households.

Disinfects, cleans, and deodorizes the following hard, nonporous, inanimate surfaces: floors, walls, [non-medical] metal surfaces, [non-medical] stainless steel surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.).

Recommended for 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. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging material must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants, as a disinfectant 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.

Recommended for use in tanning salons.

Recommended for use on [tanning beds], [and] [tanning equipment].

Effective against the following pathogens:

[Bacteria:]

*Pseudomonas aeruginosa*¹
*Staphylococcus aureus*¹
Salmonella choleraesuis

Acinetobacter calcoaceticus
Bordetella bronchiseptica
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus faecalis-Vancomycin Resistant [VRE]
*Escherichia coli*¹
Fusobacterium necrophorum
*Klebsiella pneumoniae*¹
Legionella pneumophila
Listeria monocytogenes
Pasteurella multocida
Proteus mirabilis
Proteus vulgaris
Salmonella enteritidis
Salmonella typhi
Salmonella typhimurium
Serratia marcescens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus -Methicillin resistant - [MRSA]
Staphylococcus aureus-Vancomycin Intermediate Resistant - [VISA]
*Staphylococcus epidermidis*²
*Streptococcus faecalis*¹
Streptococcus pyogenes

¹ ATCC & antibiotic-resistant strain

² antibiotic-resistant strain only

[Viruses:]

*Adenovirus Type 4
 *Hepatitis B Virus [HBV]
 *Hepatitis C Virus [HCV]
 *Herpes Simplex Type 1
 *Herpes Simplex Type 2
 *Human coronavirus
 *HIV-1 [AIDS virus]
 *Influenza A / Hong Kong
 *Respiratory Syncytial Virus [RSV]
 *Rubella [German Measles]
 *Vaccinia

[Animal viruses:]

*Avian polyomavirus
 *Canine distemper
 *Canine parvovirus - at 16 oz. per gallon
 *Feline leukemia
 *Feline picornavirus
 *Infectious bovine rhinotracheitis
 *Infectious bronchitis [Avian IBV]
 *Pseudorabies [PRV]
 *Rabies
 *Transmissible Gastroenteritis virus [TGE]

[Fungi:]

Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

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

(AREAS OF USE:)

Use Formulation HWS-32 in:

Bathrooms
Homes [Households]
Kitchens

Dental offices
Health Care Facilities
Hospitals
Medical Offices
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Food processing plants
Food storage areas
Institutional kitchens
Restaurants
USDA 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 rest rooms
Schools
Shower and bath areas
Salons [Beauty] [Nail]
Tanning Salons

Camp grounds
Play ground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos

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

(TYPES OF SURFACES:)

Use Formulation HWS-32 on
washable hard, nonporous
surfaces of:

Appliances, exteriors of
Bathroom fixtures
Bathtubs [Fiberglass]
Cabinets
Cages
Chairs
Coils and drain pans of air
conditioning and
refrigeration equipment and
heat pumps

Conductive flooring
Counters [countertops]
Countertop laminates
Desks
Doorknobs
Floors
Foot Spas
Garbage cans
Highchairs
Kennel runs
Microwave ovens, exteriors of
Outdoor furniture
Refrigerators, exteriors of
Refrigerated storage and
display equipment

Other hard nonporous surfaces
made of:
Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Laminated Surfaces
Metal
Plastic (such as polystyrene or
polypropylene)
Sealed granite
Sealed limestone
Sealed marble
Sealed slate
Sealed stone
Sealed terra cotta
Sealed terrazzo
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished

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

DILUTION: (1:32) 4 ounces per gallon of water
(660 ppm quat) 8 ounces per 2 gallons of water
 12 ounces per 3 gallons of water
 16 ounces per 4 gallons of water
 20 ounces per 5 gallons of water

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 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 devices prior to sterilization or high-level disinfection.]

(or)

This product is not for use on medical device surfaces.

DISINFECTION / CLEANING / DEODORIZING

DIRECTIONS: Remove heavy soil deposits from surface, then thoroughly wet surface with a use-solution of 4 ounces of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse spray or by soaking. For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the 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 allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished.

Food contact surfaces must be thoroughly rinsed with potable water.

(Note to reviewer: one of the following two statements will be used:)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Formulation HWS-32, 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] [for 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 use-solution daily or more often if the solution becomes visibly dirty or diluted.

TOILET BOWLS: Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first pre-clean to remove heavy soil, then remove or expel over the inner trap the residual bowl water. Pour in three ounces of the diluted solution. Swab the bowl completely using a scrub brush or mop, making sure to get under rim. Let stand for 10 minutes or overnight, then flush.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS: 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 use-solution of 2 ounces per gallon of water with a cloth, mop, sponge or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

***KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C 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 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 I (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV OR HCV OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

Personal Protection: Disposable protective gloves, gowns, face masks or eye coverings, as appropriate, must be worn during all cleaning of blood / body fluids and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (77°F) (room temperature). HBV and HCV are inactivated after a 10 minute contact time. Use a 10-minute contact time for all other viruses, fungi and bacteria listed.

Disposal of Infectious Materials: Blood / body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

[NAIL] [MANICURE] SALON [BARBER] INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] / [VIRUCIDE] / [FUNGICIDE] DIRECTIONS:

Mix 4 oz. of Formulation HWS-32 per gallon of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure, pedicure 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. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

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.

CLEANSING OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS: This product removes body secretions, soil, and blood, along with their accompanying malodor, from the surfaces and orifices of human remains. Using a sponge or washcloth, bathe the entire body with a use-solution of 4 ounces per gallon of water. A soft handbrush may be employed on surfaces other than the face. Use fresh solution for each (cadaver) remains or when solution becomes visibly dirty or diluted.

FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT

DILUTION: 1:32

4 ounces per gallon of water

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, vehicles, 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, then rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. 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.
7. Ventilate buildings, coops, cars, trucks, boats and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, then rinse with potable water before reuse.

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

For cleaning and disinfecting the following hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. 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 FORMULATION HWS-32 per 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. Ventilate buildings and other closed spaces. Thoroughly rinse all surfaces that come into contact with food, including equipment used for feeding or watering, with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried..

FOR CANINE PARVOVIRUS ACTIVITY:

Formulation HWS-32 is effective against Canine Parvovirus at 16 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

CITRUS CANKER DISEASE CONTROL

For prevention of Citrus Canker Disease through treatment of equipment. Effective against *Xanthomonas axonopodis* pv. citri (Citrus Canker Disease) at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous equipment taken into infested areas. Saturate surfaces with a 2:21 (1:10 1/2) use-dilution [12 1/8 oz. per gallon of water] [or equivalent dilution] [2000 ppm active quat] for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.

(Note to reviewer: If container size is one gallon or less, the following Storage and Disposal directions will be used.)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Rinse thoroughly, securely wrap empty container in several layers of newspaper, and discard in trash or recycle.

(Note to reviewer: If container size is greater than one gallon, the following Storage and Disposal directions will be used.)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store in original container in areas inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

[Plastic containers:] Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

[Fiber Drums With Liner:] Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

[Metal Container:] Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or dispose of by other procedures approved by state and local authorities.