UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Lonza, Inc. 17-17 Route 208 Fair Lawn, NJ 07410

WOV 2 8 2000

Subject:

Lonza Formulation S-38

EPA Registration No. 6836-73 Amendment Date: 6/02/00 EPA Receive Date: 6/02/00

Attention:

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Ms. Ruth Trager

The amendment, referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), to add organisms and upgrade the label language is acceptable provided you make the label changes listed below before you release this product for shipment.

EFFICACY

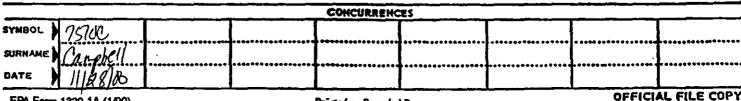
The submitted efficacy study, MRID No.451469-02, demonstrates this product's effectiveness as a disinfectant against Acinetobacter baumannii (ATCC 19606) when diluted at 2 oz. per gallon of water at 20°C in the presence of 400 ppm synthetic hard water and 5 % fetal bovine serum for 10 minutes.

The submitted efficacy study, MRID No. 451469-03, demonstrates this product's effictiveness as a disinfectant against Staphylococcus aureus, CDC HIP 5836. VISA when diluted at 2 oz. per gallon of water at 20°C in the presence of 400 ppm synthetic hard water and 5 % fetal bovine serum for 10 minutes.

LABEL RECOMMENDATIONS

Since the claim for use ultrasonic baths (p.2 right column) states that this product is formulated for "use only on non-critical instruments," this phrase should also appear in the ultrasonic bath directions.

On April 11, 2000, The Agency published PR Notice 2000-3, First Aid Statements for Pesticide Product Labels. You will need to revise your "First Aid" statements accordingly. It is the Agency's goal to have all the product labels revised by October 1, 2001.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

☆GPO: 2000 - 187-381

A copy of the stamped label is enclosed for your records. Please submit one copy of the final printed label before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

TAZAKUS IU HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold evelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be

(If container size is 5 gallons or larger, 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.

(If container size is one gallon or less, use the following Storage and Disposal Statements:)

STORAGE AND DISPOSAL

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

(if container size is greater than one gallon, use the following Storage and Disposal Statements:)

STORAGE AND DISPOSAL

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

Do not store on side. Avoid creasing or impacting of side walls. PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or 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

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

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

(For Bag-in-Box Containers:) Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FORMULATION S-38

One Step Disinfectant - Cleaner - Sanitizer -Fungicide - Mildewstat - Virucide* - Deodorizer with Organic Soil Tolerance for Homes, Hospitals, Institutional, Commercial. Farm and Industrial Use

> Acid-Free Cleaner Acid-Free Disinfectant

Citrus / Floral / Fresh / Clean / Pine / Mint / Lemon (Odor)(Scent)(Fragrance)

Formulated for effective poultry premise sanitation Formulated for effective swine premise sanitation Formulated for effective farm premise sanitation

Active Ingredients:

Octyl decyl dimethyl ammonium chloride 1 140% 0.456% Dioctyl dimethyl ammonium chloride 0.684% Didecyl dimethyl ammonium chloride Alkyl (C₁₄, 50%; C₁₂, 40%; C₁₆, 10%) 1.520% dimethyl benzyl ammonium chloride 96.200%

Inert (Other) Ingredients: 100.000% Total

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

SEE LEFT / SIDE / RIGHT / BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 6836-73

EPA Est. No. (as indicated on container) Net Contents: (insert container size here)

> Manufactured by: LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

> > ACCEPTED with COMMENTS in EPA Letter Dated:

NOV 28 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Rec. No. 6836-73

Lonza Formulation S-38 EPA Reg. No. 6836-73

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Fungicide, and Recommender. amended, for the pesticide, registered under EPA Reg. No. 6836 - 73 Cross-contamination is of major housekeeping concern. LONZA FORMULATION S-38 has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry.

LONZA FORMULATION S-38 is recommended for use in inedible processing areas, non processing areas and or exterior areas in official establishments operating under the Federal meat, poultry, egg shell grading and egg products inspection programs

LONZA FORMULATION S-38 is a one-step disinfectant-cleaner that is effective against a broad spectrum of bacteria, is *virucidal (including HIV-1), fungicidal and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION S-38 is a proven "one-step" cleaner – disinfectant – sanitizer - fungicide – mildewstat – virucide* in the presence of moderate amounts of organic soil.

When used as directed, LONZA FORMULATION S-38 will clean and deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans, garbage storage areas, and other places where bacterial growth can cause mal odors.

LONZA FORMULATION S-38 is recommended for use in hospitals, homes, medical and dental offices, medical related facilities, clinics, nursing homes, sick rooms, day care centers, nurseries, public rest rooms, institutions, schools, colleges, athletic facilities, camp grounds, public facilities, food processing plants, Federally inspected meat and poultry plants, dairy farms, hog farms, poultry and turkey farms, kennels, pet animal quarters, zoos, pet shops, animal laboratories, food storage areas, kitchens, bathrooms, restaurants and bars, cafeterias, institutional kitchens, convenience stores, airports, transportation terminals, hotels and motels, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, vehicles, buses, trains and taxis.

This product contains no phosphorous.

LONZA FORMULATION S-38 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

LONZA FORMULATION S-38 improves labor results by effectively controlling malodors.

LONZA FORMULATION S-38 is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.

LONZA FORMULATION S-38 will not leave grit or soap scum.

LONZA FORMULATION S-38 is a versatile disinfectant and sanitizer for Veterinarian, Animal Care and Farm Premise applications.

LONZA FORMULATION S-38 is a sanitizer for hard porous and nonporous **non-food contact surfaces** at 1:256 dilution (½ oz. per gallon) according to the Sanitizer Test Method, modified in the presence of 300 ppm hard water and 5% organic serum against:

Klebsiella pneumoniae

Staphylococcus aureus

LONZA FORMULATION S-38 delivers non-acid disinfectant performance in an economical concentrate.

LONZA FORMULATION S-38 is a versatile cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).

LONZA FORMULATION S-38 delivers unsurpassed non-acid cleaning performance in an economical concentrate. Effective, yet economical, LONZA FORMULATION S-38 is a heavy-duty disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

LONZA FORMULATION S-38 is an alkaline pH disinfectant cleaner that cleans and deodorizes in one labor saving step.

LONZA FORMULATION S-38 can be used with a mop and bucket, trigger spray, sponge, or by soaking.

LONZA FORMULATION S-38 effectively controls odors.

LONZA FORMULATION S-38 cleans, shines, deodorizes and disinfects all nonporous household surfaces. Inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and smelling fresh.

LONZA FORMULATION S-38 is recommended for nonscratch cleaning of sinks, showers, and tubs, shower doors and curtains, glazed ceramic tiles, fiberglass, fixtures and toilet bowls.

LONZA FORMULATION S-38 is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION S-38 kills household germs; effective against Pseudomonas aeruginosa (pseudomonas), Staphylococcus aureus (staph), Streptococcus faecalis (strep), Influenza A/Brazil and Trichophyton mentagrophytes (Athlete's foot fungus).

LONZA FORMULATION S-38 is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors and other glass surfaces.

Use LONZA FORMULATION S-38 on the multi-touch surfaces responsible for cross-contamination and infection.

LONZA FORMULATION S-38 is recommended for use on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.

ACCEPTED with COMMENTS in EPA Leacr Dated:

NOV 2 8 2000

Under the Federal Insecticide, Fungicide, and Redenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836 - 73 Use LONZA FORMULATION S-38 on finished floors, high speed burnished floors, conductive flooring, walls, tables, chairs, kennel runs, cages, coils and drain pans of air conditioning and refrigeration equipment and heat pumps, bathroom bowls, basins, cabinets, fiberglass, formica®, vinvl and plastic upholstery, countertops, stove tops, sinks, appliances, refrigerators, urinals, toilet bowls, toilet bowl surfaces, door knobs and handles, glass surfaces including windows and mirrors.

LONZA FORMULATION S-38 is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area Chick Processing Area Egg Holding Area;

Tray Dumping Area

Chick Holding Room

Chick Loading Area

Setter Room

Hatchery Room

Poultry Buildings

LONZA FORMULATION S-38 is recommended for Swine

Premise Sanitation:

Farrowing Barns and areas Dressing Plants

Creep area

Waters and Feeders

Loading Equipment

Chutes

Hauling Equipment

Nursery Blocks

DIRECTIONS FOR USE

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

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.

Preparation of Use-Solution:

Disinfectant-Hospital- 2 oz. per gallon of water (1:64)Disinfectant- Non Medical- 1 oz. per gallon of water (1:128) Sanitizer - ½ oz. per gallon of water (1:256)For heavy-duty use, add 8 oz. of LONZA FORMULATION S-38 per gallon of water.

DISINFECTION / *VIRUCIDAL / FUNGICIDAL / MOLD & MILDEW CONTROL DIRECTIONS:

Apply use-solution of LONZA FORMULATION S-38 to hard. nonporous surfaces, thoroughly wetting all surfaces with a cloth, mop sponge or sprayer. If surfaces are visibly dirty preclean prior to disinfection / *virudical / fundicidal activity. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry. Prepare a fresh solution daily or when usesolution becomes diluted or soiled. Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product should not be used to clean utensils, glassware and

For spray applications, use a coarse spray device. Spray 6 -8 inches from surface; rub with a brush, sponge or cloth. Do not breathe spray.

For Hospitals, Medical and Dental Offices and Nursing Homes: At 2 oz. per gallon of water, the activity of LONZA FORMULATION S-38 has been evaluated in the presence of 5% organic serum by the AOAC use-dilution test and found to be effective against the following gram negative and gram positive organisms:

Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis Acinetobacter baumannii Brevibacterium ammoniagenes Enterobacter aerogenes

Klebsiella pneumoniae Salmonella schottmuelleri Pseudomonas cepacia Serratia marcescens Shigella dysenteriae Streptococcus faecalis

Escherichia coli

Enterococcus faecalis – Vancomycin-resistant (VRE) Staphylococcus aureus - Methicillin resistant (MRSA) Staphylococcus aureus - Vancomycin Intermediate Resistant (VISA)

For Schools, Public Rest Rooms, Athletic Facilities, Food Processing Plants, Food Storage Areas, Kitchens, Restaurants, Bars, Transportation Terminals, Hotels, Motels and Other Non-Medical Institutional and Industrial Hees.

At 1 oz. per gallon of water, the activity of LONZA FORMULATION \$-38 has been evaluated in the presence of 5% organic serum by the AOAC use-dilution test and found to be effective against:

Staphylococcus aureus, Salmonella choleraesuis Escherichia coli

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*Virucidal Directions:

At 1 oz. of LONZA FORMULATION S-38 per gallon of water, LONZA FORMULATION S-38 was evaluated in the presence of 5% serum and found to be effective against the following viruses on inanimate hard non-porous environmental surfaces:

*Influenza A/Brazil *HIV-1 (AIDS virus) *Herpes Simplex Type 1 and 2

*Vaccinia

*KILLS HIV ON PRE-CLEANED 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 on inanimate 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 ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: Clean up should always be done wearing protective latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION S-38.

CONTACT TIME: Leave surface wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Fungicidal Directions:

At 1 oz. per gallon of water, LONZA FORMULATION S-38 is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities

Mold and Mildew Control Directions:

At 1 oz. per gallon of water, LONZA FORMULATION S-38 will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces. Allow to dry on surface. Repeat when mildew growth returns.

NON-ACID TOILET BOWL DISINFECTANT/CLEANER

DIRECTIONS: If surfaces are visibly dirty, pre-clean prior to disinfection / *virucidal / fungicidal activity.

From Concentrate: Add 1-2 oz. to the bowl water and mix. Brush over exposed surfaces including under the rim, allow to stand for 10 minutes and flush.

From Use-Solution: Empty toilet bowl or urinal and apply 1-2 oz. per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical spray. Allow to stand for 10 minutes and flush.

For Heavy Duty Use: Empty toilet bowl or urinal and apply 8 oz. per gallon use-solution to exposed surfaces, including under the rim, with a cloth, mop, sponge or sprayer. Allow to stand for 10 minutes and flush.

SALON / BARBER INSTRUMENTS AND TOOLS DISINFECTION DIRECTIONS:

Use 1 – 2 oz. of LONZA FORMULATION S-38 per gallon of water ($\frac{1}{4}$ – $\frac{1}{2}$ oz. per quart of water) (or equivalent dilution). Completely immerse pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other nonporous instruments so that surfaces remain wet for 10 minutes. Rinse thoroughly and dry before reuse. Change solution daily or when visibly dirty.

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, noncontaminated receptacle. Prolonged soaking may cause damage to metal instruments.

GLASS CLEANING / DEODORIZING DIRECTIONS::

Add ½ - 2 oz. of LONZA FORMULATION S-38 per gallon of water to clean and deodorize windows, mirrors and glass surfaces. Use a coarse spray device. Spray 6 - 8 inches from surface. Rub with a sponge or cloth. Do not breathe spray.

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use LONZA FORMULATION S-38 to disinfect hard nonporous objects compatible with Ultrasonic cleaning units. Add 1- 2 oz of LONZA FORMULATION S-38 per gallon of water. Pour fresh solution directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

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SANIITIZING NON FOOD CONTACT SURFACES: (such as floors, walls, and tables.). Add ½ oz. of LONZA FORMULATION S-38 per gallon of water. LONZA FORMULATION S-38 is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

LAUNDRY SANITIZER DIRECTIONS: This product sanitizes by controlling or reducing the growth of odor-causing bacteria when used on washable laundry items such as bed spreads, sheets, pillow cases, diapers, towels and other wet linens. Use 1 oz. per 25 lbs. of dry weight fabric. Dilute the appropriate amount of LONZA FORMULATION S-38 in one to two gallons of water, then add to the wash wheel in the final rinse. Laundered fabric may also be treated by soaking.

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:

Remove all animals and feeds from premises, trucks, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1 oz. of LONZA FORMULATION S-38 per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use 1 oz. of LONZA FORMULATION S-38 per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more.

Vehicles: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and LONZA FORMULATION S-38. Use 1 oz. of LONZA FORMULATION S-38 per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more.

Shoe Bath Sanitizer Directions: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof shoes and place in a 1 oz. per gallon of water solution for 60 seconds prior to entering area. Change the solution in the bath daily or when solution appears diluted or soiled.

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Dressing Plant Disinfectant Directions: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a 1 oz. per gallon of water solution. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

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

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables and 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. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1oz. of LONZA FORMULATION S-38 per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE DISINFECTION DIRECTIONS:

Remove all animals and feed from premises, vehicles and enclosures. 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. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1 oz. of LONZA FORMULATION S-38 per gallon of water (or equivalent dilution) for a period of 10 minutes. 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. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

For Bag - In - Box Containers:

How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:
-Fill bottle from dispenser.
Apply to surfaces as specified in directions above.

Mop Buckets:
Fill bucket from dispenser.
Set up "Wet Floor" signs.
Mop floor surface as specified in directions above

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