

47371-192

11/23/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 23 2009

Joanna Holcombe
Senior Commercial Regulatory Services Associate
H&S Chemicals Division
c/o Lonza Inc.
Allendale, NJ 07401

Subject: Lonza Formulation HWS-32
EPA Registration No. 47371-192
Notification Date: November 02, 2009
EPA Receipt Date: November 03, 2009

Dear Ms. Holcombe:

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

Proposed Notification

- Adding H1N1 label claims per EPA guidance

General Comments

Based on a review of the material submitted, your notification to add H1N1 label claims per EPA guidance is acceptable. A copy has been inserted in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I

CONCURRENCES Antimicrobials Division (7510P)

SYMBOL								
SURNAME								
DATE								

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

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.

For use in tanning salons.

For use on [tanning beds], [and] [tanning equipment].

Formulation HWS-32 is effective at controlling mold and mildew odor on mattresses, pillows and shower curtains.

Use Formulation HWS-32 in the laundry to control odors on musty bedding and linens. Test on a small inconspicuous area before using.

Use Formulation HWS-32 on mildew stains in damp areas such as bathrooms, showers, kitchens, basements and laundry rooms.

Use Formulation HWS-32 in work areas such as tool rooms and garages for odor control and light duty cleaning.

Use Formulation HWS-32 to remove odors caused by flooding and smoke from fires.

Use Formulation HWS-32 leaves a clean fresh scent.

Formulation HWS-32 provides long lasting freshness against tough (pet) odors from litter boxes and pet accidents.

Formulation HWS-32 (Kills) (Eliminates) (Removes) (Destroys) avian influenza A (H5N1) on pre-cleaned environmental surfaces

Formulation HWS-32 (Kills) (Eliminates) (Removes) (Destroys) *[Insert pathogen or pathogens from lists on pages 5 and 6]* on (pre-cleaned) environmental surfaces

Formulation HWS-32 (Kills) (Eliminates) (Removes) (Destroys) (Germs) (Bacteria) (Viruses*) (on (pre-cleaned) environmental surfaces)

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

(AREAS OF USE:)	
Use Formulation HWS-32 in:	
Airplanes	Mobile homes
Airports	Ships
Ambulances	Taxis
Boats	Trailers
Buses	Trains
Campers	Transportation terminals
Cars	Trucks (Box Trucks)
Emergency (Police) (EMS) (Fire) (Rescue) vehicles	

Kills (Effective against) (99.9% of) Influenza A that causes the flu.

(Note to reviewer. The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.)



or

(NSF Listed)

(insert 6-Digit NSF Listing Number here)

(Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.)



(Any Kosher Symbol such as:)

(Kosher)

120924

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

(TYPES OF SURFACES:)	
Use Formulation HWS-32 on washable hard, nonporous surfaces of:	
Appliances, exteriors of	Sealed granite
Bathroom fixtures	Sealed limestone
Bathtubs (Fiberglass)	Sealed marble
Cabinets	Sealed slate
Cages	Sealed stone
Chairs	Sealed terra cotta
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps	Sealed terrazzo
Conductive flooring	Stainless steel
Counters (countertops)	Upholstery, vinyl and plastic
Countertop laminates	Woodwork, finished
Desks	
Doorknobs	Non-critical medical device surfaces:
Floors	Beds [Medical] [Hospital]
Foot Spas	Bed frames
Garbage cans	Bed rails
Highchairs	Crutches
Kennel runs	Defibrillators
Microwave ovens, exteriors of	Gurneys
Outdoor furniture except cushions and wood frames	Non-critical [hospital] [medical] equipment surfaces
Refrigerators, exteriors of	[Medical] Examining tables
Refrigerated storage and display equipment	[Medical] [Hospital] Lamps
Telephones	[Medical] [Hospital] Scales
Other hard nonporous surfaces made of:	
Glazed ceramic	Resuscitators
Glazed enameled surfaces	Stands
Glazed porcelain	Stretchers
Laminated Surfaces	Stethoscopes
Metal	Walkers
Plastic (such as polystyrene or polypropylene)	Wheel chairs

(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 enterica* 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.

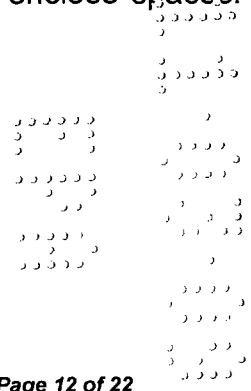
TOILET BOWLS [/ URINALS]: Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first preclean to remove heavy soil, then remove or expel over the inner 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 4 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.

To control the growth of mold and mildew on large inflatable non-porous plastic and rubber structures (animals, promotional items, moonwalks, obstacle course play and exercise equipment): Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 4 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. Ventilate buildings and enclose spaces. Do not use equipment until treatment has been absorbed, set or dried.



CLEANING AND DISINFECTING HARD NONPOROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORS):

Preclean equipment if heavily soiled to ensure proper surface contact. Add 4 oz. of Formulation HWS-32 to one gallon of water. Gently mix for a uniform solution. (Use 16 oz per gallon of water to kill Adenovirus Type 7). Apply solution to hard, nonporous surfaces of the respirator with a brush, coarse spray device, sponge, or by immersion. Thoroughly wet all surfaces to be disinfected. Treated surfaces must remain wet for 10 minutes. Remove excess solution from equipment prior to storage. Comply with all OSHA regulations for cleaning respiratory protection equipment (29 CFR §1910.134).

***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 and 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. (Use 16 oz per gallon of water to kill Adenovirus Type 7). 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 (can) 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.

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. (Use 16 oz per gallon of water to kill Adenovirus Type 7). 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 scrub all treated surfaces that come into contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

For Heavy Duty Cleaning and / or Odor Control: When greater cleaning is desired, use 8 - 16 oz. of Formulation HWS-32 per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

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 deionized 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.

Formulation HWS-32 is effective at eliminating odors on porous surfaces such as drapes, carpets, bedding, shower curtains and non-porous surfaces such as walls and floors. Excellent for fire restoration.

Other suggested Uses: Homes, Veterinary Clinics, Fish Markets, Kennels, Trash Compactors, Offices, Beauty Salons, Locker Rooms, Health Spas, Conference rooms, Elevators, Smoking Areas, Lounges, Day Care Centers, Dry Cleaners, Theaters, Farms, Auditoriums and Churches.

Deodorizing directions:

Nursing Homes, Hospitals, Hotels, Schools, Restaurants: Using 4 oz. in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes

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and air conditioner pans will eliminate odors.

Mopping Solutions, Automatic Scrubbers: Use 4 oz. per gallon of cleaning solution to eliminate undesirable odors.

Laundry: 4 oz. per load added during the final rinse cycle deodorizes all offensive odors.

Air Freshener/Automotive Uses: 16 oz. per gallon of water will effectively neutralize damp musty odors caused by mildew in storage areas, basements, closets and bathrooms. Effective on smoking and cooking odors (garlic, fish, onions, etc.). Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

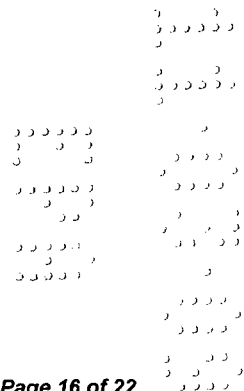
Carpets: 4 oz. per gallon of shampoo solution eliminates odors associated with urine, vomit, smoke, and mildew. Reapply after cleaning for freshening effects. Allow to dry.

RV Holding Tanks: Toilet waste: cover bottom of holding tank with water and add 4 oz. If odors return before time to empty, simply add 4 oz. to the tank. Kitchen waste: 1/2 oz. of **Formulation HWS-32** to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 16 - 24 oz. per gallon of water for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow 10 minutes contact time. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Backup, Water, Smoke Damage: Use 8 - 16 oz. per gallon of water. Spray over affected areas before and after cleaning and extraction. Allow ten minutes contact time. Use proper ventilation; open windows.

Cleaning Solution: Dilute 4 oz. per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications.



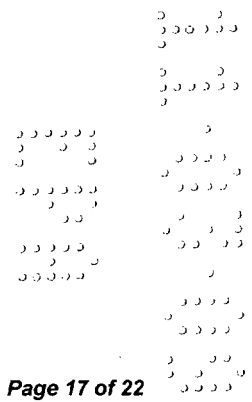
WATER, SMOKE DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA AND FUNGI FOR HOME, INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE:

This product is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, concrete, brick, trim and frame lumber, tackless strip and paneling. Using appropriate dilution, saturate the affected materials with enough product to remain wet for at least 10 minutes.

Sewer Backup and River Flooding: During mitigation procedures, dilute 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Concrete, Brick, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Dilute 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain wet for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

Special instructions For Cleaning Carpet Against Odor Causing Bacteria: Use this product in industrial and institutional areas such as homes, motels, hotels, nursing homes, schools, and hospitals. Use on wet-cleanable synthetic fibers. Do not use on wool. Vacuum carpet thoroughly prior to cleaning. Test fabric for colorfastness. **For portable extraction units:** Mix 4 oz. of concentrate per gallon of water. **For truck mounted extraction machines:** Mix 4 – 8 oz. of concentrate per gallon of water and meter at 4 gallons per hour. **For rotary floor machines:** Mix 4 oz. of concentrate per gallon of water and apply at the rate of 300 – 500 sq. ft. per gallon. Do not mix this product with other cleaning products. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment. After using the product, set the carpet pile and protect the carpet from furniture legs and bases while drying. Do not over-wet. If applied to stain resistant nylon carpet, apply a fabric protector according to the manufacturer's directions.



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

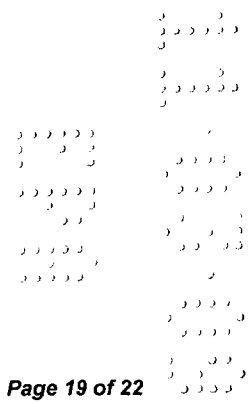
STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate



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

STORAGE AND DISPOSAL

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

Pesticide Storage:

Store in original container in areas inaccessible to children. Open dumping is prohibited.

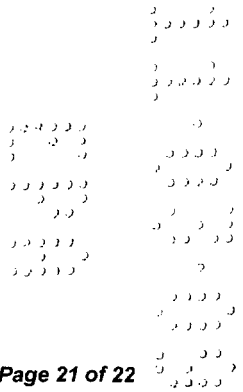
Pesticide Disposal:

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

FINAL CONTAINER DISPOSAL

Clean container promptly after emptying. Cleaning the container before final disposal is the responsibility of the person disposing of the container

(Plastic or Metal Containers:) To clean the container before final disposal empty remaining contents from container for use according to use directions and triple rinse promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times.



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SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary container label will be used only when the product is diluted in accordance with the use directions)

FORMULATION HWS-32

(EPA Reg. No. 47371-192)

Active Ingredients:

Didecyl dimethyl ammonium chloride..... 1.27%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride.....0.85%

Inert Ingredients:..... 97.88%

Total:100.00%

The product in this container is diluted as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the restroom. Remove and wash contaminated clothing before reuse.

Follow the directions for use on the pesticide label when applying this product

