



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 3, 2018

Jonathan Walsh
Regulatory Assurance Manager
Lonza Inc.
412 Mount Kemble Avenue
Suite 200S
Morristown, NJ 07960

Subject: Notification per PRN 98-10 – Remove Non-Food Qualifier
Product Name: DS-6640
EPA Registration Number: 6836-385
Application Date: 10/05/2018
Decision Number: 545120

Dear Mr. Walsh:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

If you have any questions, you may contact Terria Northern at 703-347-0265 or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Zeno Bain", written over a horizontal line.

for

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

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}

DS-6640

NOTIFICATION

6836-385

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/03/2018

One-Step Ready to Use Disinfectant

Disinfectant – Cleaner – Mildewstat - Virucide* - Deodorizer

for Hospitals, Household, Institutional, Commercial and Industrial Use

[Bactericidal against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella enterica [in 3 minutes]]

[Virucidal against HIV-1, Influenza A/Hong Kong, and Norovirus]

{Note to reviewer: each scent below may also be represented by a graphic depicting the corresponding scent with the exception of apple which will be submitted to the Agency for review.}

[Citrus] [Floral] [Pine] [Fresh] [Mint] [Clean] [Lemon] [Scent] [Fragrance] [Odor] [Unscented] [Fragrance Free]

Active ingredient:

Hydrogen peroxide..... 1.22%

Other ingredients:..... 98.88%

Total..... 100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 6836-385

EPA Est. No. (as indicated on container.)

Net Contents (as indicated on container.)

[DOT Symbols]

[Country of origin (*insert country*)]

[Manufactured in (*insert country*)]

[Barcode]

[QR Code]

[Price]

Manufactured by:

LONZA Inc.

412 Mount Kemble Avenue

Suite 200S

Morristown, NJ 07960

{Note to Reviewer: Pages 2 – 6 are considered optional marketing language:}

Marketing Claims

{Disinfectant claims} DS 6640 [this product] [is] [a] [an]:

- 3 minute acting [disinfectant] [antimicrobial]
- 3 minute hospital disinfectant
- [Antibacterial] [Antimicrobial] [Disinfectant] with Hydrogen Peroxide [active ingredient]
- Convenient 3 minute hospital disinfectant
- Disinfects (*insert from approved list of pathogens*) in [just] 3 minutes
- Disinfects in one step
- Formulated Hydrogen Peroxide [disinfectant]
- Hard surface¹ [antimicrobial] [antibacterial] [disinfectant]
- Hospital Disinfectant tested using the current AOAC Germicidal Spray Test method in 3 minute[s] [contact time]
- Hydrogen Peroxide [based]
- Hydrogen peroxide [Antibacterial] [Antimicrobial] [Disinfectant]
- [Kills] [Eliminates] [Removes] [Destroys] [Fights] [Germs²] [Bacteria] [Viruses*] (*Insert pathogen or pathogens from list on page 8*) on [pre- cleaned] environmental surfaces¹ [in [just] 3 minutes]
- Kitchen³, Bathroom, Household Disinfectant Cleaner.
- [One-step] [Hospital Use] disinfectant, cleaner that is effective against a broad spectrum of bacteria and is virucidal* [including HIV-1, when used as directed].
- Proven "one-step" disinfectant - cleaner - virucide* - fungicide which is effective in the presence of 5% serum contamination [in 3 minute(s)] [contact time].
- Provides hospital disinfection in [just] 3 minute(s) [contact time]
- Virucidal* [including: [Herpes Simplex Type 2] [Herpes], [HIV-1] [HIV], and [Influenza A/Hong Kong] [Influenza]]

{Sanitizer claims} DS 6640 [this product] [is] [a] [an]:

- 1 minute ~~[non-food]~~ sanitizer³
- Convenient [1 minute] ~~[non-food]~~ sanitizer³
- ~~[Non-food]~~ Sanitizer³ [against] [Enterobacter aerogenes] [and] [Staphylococcus aureus] in [just] 1 minute
- Provides ~~[non-food]~~ sanitization³ in [just] 1 minute [contact time]
- Sanitizer with Hydrogen Peroxide

Free From Claims

- [Bleach] [Chlorine] Free
- Contains no [Bleach] [Chlorine]
- Dye Free {for formulation without dye only}
- Fragrance Free {for formulation without fragrance only}

¹ Hard, non-porous surfaces

² Kills *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and Norovirus

³ Non-food contact surfaces

DS 6640

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Cleaning Claims

- Cleaner
- Cleans
- [Convenient] Ready To Use [Formula] [Cleaner]
- Cuts [through] [tough] grease and grime
- Inhibits [the growth of] [mold] [and] [mildew]
- Leaves [your house with] a [*insert fragrance from list*] scent.
- Removes soap scum
- Scrub Free

Odor elimination claims

- Clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- Deodorizer
- Deodorizes [by killing microorganisms that cause offensive odors.]
- [Effective against] [Kills] odor causing bacteria
- [Eliminates][Neutralizes] odors [and freshens]
- Effectively controls malodors.
- Is formulated for use in daily maintenance programs with a balance of detergents, antimicrobials and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- Leaves a clean [*insert fragrance from list*] scent.
- Provides long lasting freshness against tough [pet] odors such as odors from litter boxes and pet accidents.
- Tough on odors

Usages claims

- For homes, Institutional and Industrial Use
- For [indoor] [and] [outdoor] household surfaces¹
- For use [away from home] [in public places] [all around the house¹]
- Is a [versatile] disinfectant for hard, non-porous contact surfaces
- Multi-purpose
- Multi-surface¹

Value claims

- Is effective and economical.
- Saves time [with 3 minute disinfection]

DS 6640 [This product] is a Hospital Disinfectant, tested using the current AOAC Germicidal Spray Test method and to the ASTM Virucidal test method for disinfection on inanimate surfaces.

DS 6640 [This product] is effective as a disinfectant against:

[Bacteria]:

Pseudomonas aeruginosa [ATCC 15442]

Staphylococcus aureus [ATCC 6538]

Salmonella enterica [ATCC 10708]

Enterobacter aerogenes [ATCC 13048]

Escherichia coli [ATCC 11229]

Klebsiella pneumoniae [ATCC 4352]

Methicillin Resistant *Staphylococcus aureus* [MRSA] [ATCC 33592]

[Viruses*:]

*Herpes Simplex Type 2 [Herpes] [ATCC VR-734, Strain G]

*HIV-1 [Strain HTLC-III_B]

*Influenza A/Hong Kong [Influenza] [ATCC VR-544, Strain A/Hong Kong/8/68]

*Norovirus [ATCC VR-782]

[Animal Viruses*]

Feline Calicivirus [ATCC VR-782]

DS 6640 [this product] is a sanitizer for hard, non-porous (kitchen, bathroom and household) non-food contact surfaces:

Enterobacter aerogenes

Staphylococcus aureus

EMERGING VIRAL PATHOGENS { *These claims shall not appear on marketed (final print) product labels.* }

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an... ..follow the directions for use for the following organism on the label:

Enveloped virus

Feline Calicivirus, (ATCC VR-782)/ Norovirus

Large, non-enveloped virus

Feline Calicivirus, (ATCC VR-782)/ Norovirus

[DS 6640] [Brand Name] [This Product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **[DS 6640] [Brand Name] [This Product]** can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus [Norwalk Virus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

OR

[Name of illness/outbreak] is caused by [name of emerging virus]. **[DS 6640] [Brand Name] [This Product]** kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus [Norwalk Virus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

[AREAS OF USE:]

Use **DS 6640** on hard, non-porous surfaces 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

Clinics
Dental offices
Health Care Facilities
Hospitals
Medical Offices
Medical Related Facilities
Nursing homes
Sick Rooms

Bars
Cafeterias
Convenience stores
Institutional kitchens
Restaurants

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

Motels
Playground Equipment
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons (Beauty)

Airplanes
Airports
Ambulances
Boats
Buses
Campers
Cars
Emergency (Police) (EMS) (Fire) (Rescue) vehicles
Mobile homes
Railcars
Taxis
Trailers
Trains
Transportation terminals
Trucks (Box Trucks)
Ships

Day care centers
Nurseries

[TYPES OF SURFACES:]

Use DS 6640 [this product] on washable hard, non-porous, non-food contact 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.}

Exteriors of Appliances
Bathroom fixtures
Bathtubs [Fiberglass]
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps⁴
Conductive flooring
Counters [countertops]
Countertop laminates
Desks
Doorknobs
Exhaust Fans
Fiberglass Sinks, Tubs and Showers
Floors
Garbage cans
Highchairs
Litter Boxes
Microwave oven exteriors
Outdoor furniture
Picnic Tables
Refrigerator exteriors
Showers
Shower Stalls
Sinks [bathroom] [kitchen]
Stoves [Stovetops]⁴
Tables
Telephones
Toilet exteriors
Toilet bowl exteriors
Toilet bowl surfaces
Tubs
Tiles, glazed
Ultrasonic baths
Urinal exteriors
Walls

Non-critical [hospital] [medical] equipment surfaces:

Beds [Medical] [Hospital]
Bed frames
Bed rails
Crutches
Defibrillators
Gurneys
[Medical] Examining tables
[Medical] [Hospital] Lamps
Rescue tools
Resuscitators
[Medical] [Hospital] Scales
Stands
Stretchers
Stethoscopes
Walkers
Wheel chairs

Other hard non-porous surfaces made of:

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

⁴ Use when surface is at room temperature

DS 6640

EPA REG. NO. 6836-385

EPA Submission 2018-10-05

Si no sabes el inglés, solicite instrucciones a su supervisor antes de usar el product.

DIRECTIONS FOR USE

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

[**To operate:** Turn nozzle to on position and spray.]

GENERAL CLEANING / DEODORIZING DIRECTIONS:

[Spray] [Apply to] soiled area then wipe clean. Repeat for heavily soiled areas.

DISINFECTION [/ *VIRUCIDAL] DIRECTIONS:

Spray 6 - 8 inches from surface, until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 3 minutes. Wipe dry with a clean cloth, sponge, mop or towel, or allow to air dry.

MOLD AND MILDEW CONTROL DIRECTIONS:

DS 6640 [This product] effectively inhibits the growth of mold and mildew, and the odors caused by them, when applied to hard, non-porous surfaces. Spray 6 - 8 inches from surface, until surfaces are thoroughly wet. Do not breathe spray. Allow to air dry on surface. Repeat every [7] [seven] days, or when [mold] [or] [mildew] growth returns.

{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.

NON-ACID TOILET BOWL AND URINAL CLEANER DIRECTIONS:

Apply **DS 6640** [this product] to exposed surfaces including under the rim with a sprayer. Use a [toilet] brush to scrub the bowl. Repeat and allow to stand for 1 minute, then flush.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES¹ / 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 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 must always be done wearing protective 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 **DS 6640** [this product].

CONTACT TIME: Leave surface wet for 3 minutes.

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

SALON/BARBER INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] / [VIRUCIDE* /]

DIRECTIONS:

Spray **DS 6640** [this product] on combs, brushes, plastic rollers, manicure and other salon instruments and tools and allow them remain wet for 3 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use.

Note: Stainless steel shears and instruments must be rinsed and dried and kept in a clean, non-contaminated receptacle. Prolonged contact with the disinfectant solution may cause damage to metal instruments.

TO SANITIZE AND DEODORIZE NON-FOOD CONTACT SURFACES: Spray **DS 6640** [this product] until thoroughly wet. Treated surfaces must remain wet for 1 minute. Wipe dry with a clean cloth, sponge, mop or towel, or allow to air dry. For heavily soiled areas, pre-cleaning is required.

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

For cleaning and disinfecting hard, non-porous surfaces: equipment used for animal food or water, 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 all surfaces by spraying with **DS 6640** [this product] and allow them to remain wet for 3 minutes. Spray 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. Wipe or allow to air dry. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, 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.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles, coops, crates and other 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 by spraying with **DS 6640** [this product] and allow them to remain wet for 3 minutes. Spray 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. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Wipe or allow to air dry. Ventilate treated buildings, vehicles, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.

HATCHERIES:

Use **DS 6640** [this product] to treat the following hard, non-porous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Saturate all surfaces by spraying with **DS 6640** [this product] and allow them to remain wet for 3 minutes. Then allow to air dry.

VEHICLES:

Wash all vehicle surfaces including mats, crates, cabs and wheels with water and soap or detergent. Saturate all surfaces by spraying with **DS 6640** [this product] and allow them to remain wet for 3 minutes. Then allow to air dry.

DRESSING PLANT DISINFECTANT DIRECTIONS:

Use to disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect all rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Scrub to loosen all soils. Saturate all surfaces by spraying with **DS 6640** [this product] and allow them to remain wet for 3 minutes, and then thoroughly rinse with potable water before operations are resumed.

Refill Directions:

Remove top from empty spray bottle.

Unscrew cap on refill bottle and pour contents directly into empty bottle until full. Replace trigger sprayer. If liquid remains in refill bottle, replace cap. Store for future use. Use product according to label directions.

{Note to reviewer: For Nonrefillable Containers, Ready to Use Household/Residential Use Products}

STORAGE AND DISPOSAL [Nonrefillable containers, household/residential users]

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

Pesticide Storage:

Store in original container in areas inaccessible to children.

Container Disposal:

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: Nonrefillable Containers, Ready-To-Use Products for Commercial/Institutional/Industrial Uses– no new container rinsing directions, not a dilutable per PRN 2007-4)

STORAGE AND DISPOSAL [Nonrefillable Containers, for Commercial/Institutional/Industrial users]

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.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container.

(Plastic Containers:) Triple rinse (or equivalent). 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). Offer for recycling if available or puncture and dispose of in sanitary landfill or by other procedures approved by state and local authorities.

{Note to Reviewer: Alternate Directions for Refillable Container - For Containers for Household and Residential Uses

STORAGE AND DISPOSAL [Refillable containers-Household and Residential Users]

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

Pesticide Storage:

Store in original container in areas inaccessible to children.

Container Disposal:

Do not reuse or refill this container except as described in the directions for use. Wrap [container] and put in trash or offer for recycling if available.

{or}

Do not reuse or refill this container except as described in the directions for use. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: Alternate Directions for Refillable containers - For Containers for commercial, industrial, and institutional use.}

STORAGE AND DISPOSAL [Refillable containers - For commercial, industrial, and institutional users.]

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.

Container Disposal:

Do not reuse or refill this container except as described in the directions for use.

(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 if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities.

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



(Any Kosher Symbol such as:)

(Kosher)