



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 18, 2022

Ruchi Naik
Lonza LLC
412 Mt. Kemble Avenue
Suite 200S
Morristown, NJ 07960

Subject: PRIA Label Amendment – Add virucidal disinfection and electrostatic sprayer claims
Product Name: DS6835
EPA Registration Number: 6836-442
Application Date: 05/13/2021
Action Case No.: 302080

Dear Ms. Naik:

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

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

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

Page 2 of 2
EPA Reg. No. 6836-442
Decision No. 302080

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

f/Terria Northern, Acting Product Manager 34
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Enclosure: Accepted stamped label

Note to Reviewer:
[Language in brackets [AAA] is optional or interchangeable]
{Language in braces {AAA} is for informational purposes and will not appear on the final label}

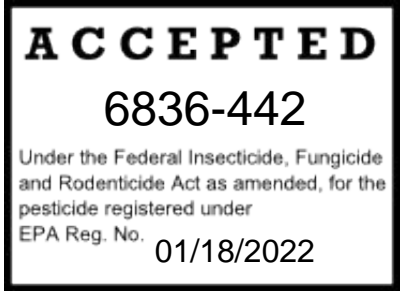
DS6835

[One-Step¹ Disinfectant⁴] / [Cleaner] [Virucide*] [Tuberculocide] [Deodorizer] [Deodorant] [Germicide²]
(Meets OSHA Blood borne Pathogen Standard for *HBV, *HCV & *HIV)

For [Health Care] [Hospital] [Industrial] [&] [Institutional] Use
[Unscented] [Fragrance Free]

[Kills Flu Virus*^{1,9}]
[Kills Germs²]

Active ingredient:	
Hydrogen peroxide.....	1.24%
Other ingredients:.....	98.76%
Total.....	100.00%



KEEP OUT OF REACH OF CHILDREN CAUTION

Manufactured by:
Lonza, LLC
412 Mt. Kemble Ave.
Suite 200S
Morristown, NJ 07960

EPA Reg. No. 6836-442
EPA Est. No. (as indicated on container)

Net Contents: (expressed as avoirdupois pounds and ounces) [g] [mL]
[Minimum Net Wt.]

[Barcode]
[DOT Symbols]
[Country of origin (insert country)]
[Manufactured in (insert country)]

{Note to Reviewer: for multi-packs}
[{insert #}] [Bonus] [Twin] [pack]

Precautionary Statements**Hazards to Humans and Domestic Animals**

CAUTION. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

First Aid

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

{*Optional Emergency contact information*}

[For emergency information on [product, usage, etc.], call [1-XXX-XXX-XXXX], Monday through Friday, 9 a.m. to 5 p.m. After 5 p.m. call your poison control center at 1-800-222-1222.]

{Note to reviewer: Pages 3-13 are considered optional marketing language. }

{Note to reviewer: The following claims containing "New" may only be used for a period of six months after EPA's approval of a revised or alternate formula, beginning when the product is first sold or distributed.}

- Breakthrough package
- Introducing [new]
- New [and Improved!]
- New [Convenient] [Amazing] Package

FRESHNESS AND ODOR ELIMINATION CLAIMS:

- Deodorizer [Odor Neutralizer]
- Leaves a [light] [clean] [fresh] scent without added fragrance
- No fragrance added

USAGE CLAIMS:

- For [Hospitals] [Healthcare] [Institutional] [and Industrial Use]
- For [one-step⁴] [daily] use on [environmental] [non-critical] [semi-critical] medical surfaces¹ [in hospitals and other healthcare facilities].
- May be used to clean and disinfect sinks, faucets, fixtures, bathrooms, restrooms, tubs, and showers.
- May be used for cleaning of showers, tubs, shower doors and nonporous curtains, and fixtures, and exterior surfaces of toilets.
- Multi-purpose¹
- Multi-surface¹
- Step-saving, [time-saving], [cost-saving] formula
- Suited for everyday use
- Versatile, Convenient formula

CLEANING CLAIMS:

- An effective counter cleaner¹
- Clean more with less
- Clean surfaces¹ at your fingertips
- Cleaner
- Cleaning
- Cleaning just got a whole lot easier
- Cleans
- Cleans [away] [up] dirt, dust and hair
- Cleans [sealed grout]
- Cleans and disinfects⁴ in one step¹
- Cleans to a [Sparkle] [Shine]
- Cuts through [tough] [dried on] [dirt] [stains] [messes] [grease] [grime] [soils]
- Fast drying
- For [light touch ups] [quick clean-ups]
- For a Powerful Clean
- For everyday messes¹
- [Great] [Designed] [Built] [Tough] [Textured Design] for your Toughest Messes
- [Great] [Designed] [Built] for Tough [Messes] [Cleaning]
- [Great] for [Spring] [Bathroom] [Patient room] Cleaning
- Greasy messes
- Great for cleaning around the toilet
- Handles daily clean-ups with no need for additional sprays, sponges or buckets.
- [Heavy] [light] duty [jobs]
- Helps you finish cleaning
- Keeps day care centers clean.^{1, 8}
- Makes [your job] [cleaning] [easier] [easy].
- [Multi-purpose][everyday][daily] kitchen cleaning¹ [touch-up]

CLEANING CLAIMS (cont.):

- No [mixing] [mess] [and / or fuss] [no muss].
- Powerful cleaner for kitchen and bath
- Powers through [tough messes] [the dirt] [the grime]
- Easy clean-ups
- Removes soap scum
- Removes the grime [to give you] [so you have] [more time]
- The convenient way to keep your home looking “just cleaned”
- Touch Up
- Tough cleaning [made easy] [made easier] [at your fingertips]
- Tough cleaning without the tough cleaning smell
- Tough Enough to Clean a Classroom¹
- Tough enough to do the bigger cleaning jobs.
- Traps [&] [and] locks away [dirt] [grease] [messes] [crumbs] [hair] [lint] [dust] [dirty greasy messes]
- Traps and locks grease and grime
- Uses the cleaning power of hydrogen peroxide

CLEANING AND ODOR ELIMINATION CLAIMS:

- A fresh take on tough cleaning
- An effective way to clean and deodorize against odor-causing bacteria.
- Deodorizes
- Don't just mask odors –neutralizes them
- For a cleaner, fresher [home¹] [house¹], great for [all around] the [house¹] [home¹] [kitchen¹] [bath¹]
- [Neutralizes] odors [and freshens] on contact
- Power[s] through [tough] [messes] [dirt] [and grease] and [help[s]] neutralize[s] odors
- Powers through odor
- Tough on odor

VALUE CLAIMS:

- Assorted] [Mixed] [Special] [Variety] [Multiple] [Multi] [Canister] [Bundle] [Pack]
- Bonus Size
- Convenient [size]
- Guaranteed³ [to clean longer] [use fewer bottles]
- Large Size, Small Size, Bonus Pack
- Spring Cleaning [Special] [Value] [Bonus] [spray bottle pack]
- Travel [Size] [pack]
- Value Size
- Variety Pack

SURFACE SAFETY CLAIMS:

- Compatible with most surfaces¹
- Non-scratch[ing]
- Not recommended for use on computer or television monitor screens.
- Not recommended for use on [or] [avoid contact with] copper and brass surfaces
- Will not scratch

OTHER CLAIMS:

- Call (Insert phone number)
- Comments?
- Do not use for personal cleansing.
- Fragrance Free
- Quality Guaranteed³
- Questions? call [1-XXX-XXX-XXXX]
- Ready to Use
- Save time with DS6835 [!]

ANTIMICROBIAL CLAIMS:

- 1 minute acting [disinfectant⁶] [antimicrobial⁶]
- All around the house¹ [disinfecting] [cleaning formula]
- [Antibacterial] [Antimicrobial] [Disinfectant] with Hydrogen Peroxide [active ingredient]
- [Antimicrobial] [antibacterial] [disinfecting] [spray] [formula]
- [Clean and] [disinfect] [household] surfaces¹ in [just] 1 minute⁶[!]
- [Clean and] [disinfect] in just [1] [one] minute⁶
- [Clean and] [disinfect] surfaces¹ in [just] 1 minute⁶[!]
- Cleans and [disinfects] [without scratching] [surfaces1]
- Cleans and [disinfects] in one [easy] step
- Convenient 1 minute⁶ hospital disinfectant
- Cuts [tough] grease, kills bacteria⁵
- Daily Surface¹Cleaner
- [Designed] [Built] for disinfecting and cleaning everyday
- [Designed] [Built] for Everyday [Disinfecting] [Cleaning]
- [Disinfect] any room in the house¹
- [Disinfect] (Refer or list areas of use listed on label)
- [Disinfect] [Surfaces¹] [Your House¹] [Your Kitchen¹] [Your Bathroom] [Daily] [Everyday]
- Disinfects surfaces¹ by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in one step]
- [Disinfect] the surfaces¹ of (refer or list from surfaces listed on label)
- [Disinfect] [Your Desk] [Your Office] [Your Room] [Daily] [Everyday]
- [Disinfect] your household¹ surfaces (*refer or list from surfaces listed on label*)
- Disinfects (insert from approved list of pathogens) in [just] 1 minute⁶
- Easy to use 1 minute⁶ hospital disinfectant
- [Easy] way to disinfect⁴ [in one step¹]
- Effective against SARS-Related Coronavirus 2¹ [SARS-CoV-2] [USA-WA1/2020] [in 30 seconds]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2¹ [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2¹ [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2¹ virus, the cause of COVID-19
- Effectively disinfects household surfaces¹
- Everyday Surface¹Cleaner
- Great for Everyday [Disinfecting] [Cleaning]
- Hospital Disinfectant
- Hydrogen peroxide [Antibacterial] [Antimicrobial] [Disinfectant]
- Hydrogen Peroxide [based]
- Kills [99.9%] [of] [MRSA] [Methicillin-Resistant Staphylococcus Aureus] [Norwalk virus]
- Kills 99.9% of Germs² [Bacteria] [and] [Viruses*]
- Kills bacteria

DS6835

EPA Reg. No. 6836-442

EPA Submission 2021-05-13

ANTIMICROBIAL CLAIMS (cont.):

- Kills [household] [kitchen] [bathroom] bacteria¹
- [Kills] [Destroys] germs² [in] [just] [1 minutes⁶]
- Kills coronavirus^{1,10} that causes COVID-19
- Kills [99.999%] [five logs] of *Candida auris* on hard, non-porous surface
- [Kills] [and] [inactivates] 99.999% of *Candida auris* on hard, non-porous surfaces
- [Kills][Effective against] *Candida auris* on hard, non-porous surfaces
- [Kills] [Effective against] the virus^{1,10} that causes COVID-19
- [Kills] [Eliminates] 99.9% SARS-Related Coronavirus¹ [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]
- [Kills] Germs² [*Influenza A Virus, the Flu Virus] [Bacteria] [Bacteria and Viruses*] [Viruses*]
- Kills [Germs²] [*Influenza Type A Virus, the Flu Virus] [Bacteria] [Viruses*]
- Kills germs²
- [Kills] [Removes] [Destroys] (*Insert pathogen or pathogens from lists on pages 12*) [on environmental surfaces¹]
- [Kills] [Removes] [Destroys] [Fights] [Germs²] [Bacteria] [Viruses*] (*Insert pathogen or pathogens from list on page 12*) on environmental surfaces¹ [in [just] 1 minute⁶]
- [Kills] [Removes] [Destroys] 99.9% of bacteria
- [Kills] [Removes] [Destroys] 99.9% of bacteria, leaves [leaving] surfaces¹ [clean and] disinfected
- Kill MRSA & Flu Virus^{*,1,9!}
- Kills the Flu Virus^{*,1,9}
- Kills the coronavirus^{1,10} that causes COVID-19
- Kills the virus^{1,10} that causes COVID-19
- Kills [99.9% of] SARS-CoV-2¹, which causes COVID-19
- Kitchen, Bathroom, Household Disinfectant Cleaner¹
- Leaves surfaces¹ clean and disinfected
- [One-step¹] [Hospital Use] disinfectant⁴ that is effective against a broad spectrum of bacteria and is virucidal* [including *HIV-1, when used as directed].
- Proven one-step¹ disinfectant⁴ - virucide* - which is effective [in 1 minute⁶] [contact time].
- Proven to kill *Candida auris* [*C. auris*] [in 10 minutes] on hard, non-porous surfaces
- [Proven to] kill[s] coronavirus^{1,10}
- [Proven to] kill[s] the virus^{1,10} that causes COVID-19
- Provides hospital disinfection in [just] 1 minute⁶ [contact time]
- Kills antibiotic resistant organisms¹¹
- Reduce cross contamination between treated surfaces¹
- Remove [99.9% of] [Bacteria] [Germs²] [from] [Surfaces¹][Bathroom] [Office]
- Restroom disinfectant
- Surface¹ [antimicrobial] [antibacterial] [disinfectant]
- The convenient way to [disinfect] your household surfaces¹
- The smart [way to] clean [and disinfect]
- This product will clean and disinfect surfaces¹
- Virucidal* [including: [Herpes Simplex Type 1 Virus] , [HIV-1] [HIV], and [Influenza A (ATCC VR-544)]
- [With proven] Antibacterial Action

DS6835:

- Deodorizes by killing [microorganisms] [bacteria] that cause offensive odors.
- Effectively controls malodors.
- is a [one-step¹] [hospital] disinfectant⁴ that is effective against a broad spectrum of bacteria
- is a proven "one-step¹" disinfectant⁴ is formulated for use in daily maintenance programs with a balance of detergents and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- [Kills] [kitchen¹] [bathroom] [household¹] bacteria
- Will disinfect, clean and deodorize surfaces¹ 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
- Will not leave grit or soap scum

DS6835

EPA Reg. No. 6836-442
EPA Submission 2021-05-13

Cross-contamination is of major [housekeeping] concern. **DS6835** have been formulated to aid in the reduction of cross-contamination on treated surfaces¹ [in the home, schools, institutions and industry.]

Use **DS6835**:

- as a disinfectant on surfaces¹
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and exterior toilet bowl surfaces¹
- to clean and disinfect finished floors, sinks and tubs
- to clean and disinfect surfaces¹ of gym equipment, exercise machines, wrestling mats and gymnastic equipment
- to clean and disinfect personal [safety] [protection] equipment¹, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. Rinse all equipment that comes in contact with skin before reuse with clean warm water [about 120°F], and allow to air dry. [Precaution: Cleaning at 120°F temperature will avoid overheating and distortion of the personal [safety] [protection] equipment that would necessitate replacement.]

[AREAS OF USE:]

Use **DS6835** on surfaces¹ in:

Bathrooms Children's room Homes [households] Kitchens Living room Day care centers ⁸ Nurseries ⁸ Bars Cafeterias Commercial Kitchens Convenience stores Food processing plants Food storage areas Institutional kitchens Restaurants USDA inspected food processing facilities Airplanes Airports Ambulances Boats Cruise Ships Buses Campers Cars [Emergency Medical] Transport Vehicles Emergency [Police] [EMS] [Fire] [Rescue] vehicles Mobile homes Ships Taxis Trailers Trains Transportation terminals Ambulatory Care Centers Ambulatory Surgical Centers Anesthesia Rooms [Areas] Birthing Center CAT Lab Central Service Areas Central Supply Rooms [Areas] Critical Care Units Dental offices Dialysis Clinics [Facilities] Doctor's Offices Donation Centers [blood][plasma][semen] Examination Rooms or Areas	Emergency Rooms [ER] Eye Surgical Centers Home Health Care [Settings] Hospices Hospital Beds Hospital Environmental Services (EVS) Hospitals ICU Areas Isolation Areas Laboratories Long Term Care Facilities [Medical] [Neonatal] [Pediatric] Clinics Medical Offices Neonatal Intensive Care Units (NICU) New born nursery Nursing homes Nursing's Stations Skilled nursing facilities Operating Rooms Ophthalmic Offices Orthopedics Out-Patient [Surgical Centers (OPSC)] [Clinics] [Facilities] Patient Care Areas Patient Rooms [Areas] Pediatric Intensive Care Units (PICU) Pharmacies Physician's Offices Psychiatric Facilities Public [Care] Areas Radiology [X-Ray] Rooms X-ray equipment Recovery Rooms Rehabilitation Centers Respiratory Centers Respiratory Therapy Rooms [Areas] Sick rooms Surgery Rooms Surgical Centers Surgery and Surgical Intensive Care Unit (SICU) Veterinary Clinics Waiting Rooms [Areas] Camp grounds Playground equipment
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[AREAS OF USE (cont.):]

Use **DS6835** in:

Athletic facilities Barber shops Business and office buildings Colleges Correctional facilities Dressing rooms Exercise facilities Factories Family Rooms [Dens] Health clubs Food Service Establishments Hotels Institutional facilities Institutions Laundry rooms Locker rooms Lodging Establishments	Manufacturing Facilities Motels Office Building Pet Shops Playrooms Prisons Public facilities Public rest rooms Reception Recreational Facilities Restrooms Retail Businesses Salons Schools Shower and bath areas Universities
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[TYPES OF SURFACES:]

Use DS6835 on washable hard, nonporous surfaces of:

Air Vent Exteriors	Exam tables
Amalgamators	Exercise equipment (BH)
Anesthesia Cart	Faucet Handles
Anesthesia machines	Faucets
Apheresis machines	Fetal monitor carts
Appliances	Finished floors
Autoclaves	Floors
Bathroom fixtures [Doorknobs]	Footboards
Bathtubs [Fiberglass]	Garbage cans
Bedpans	Glass
Bed frames	Gurneys
Bed rails	Hard Nonporous Hospital [Medical] Surfaces
Beds [Medical] [Hospital]	Headboards
[Bedside] Commodes	High Touch Surfaces
Bedside Tables	Infant incubators
Bill [bed] [blanket] [spot lights]	Instrument Stands
Blood glucose meters	Isolettes
BP Cuffs	IV Stands [Poles]
Cabinet[s] [Handles]	Keyboards
Cages	Kitchen cupboards
Callboxes	Lab benches
Car seat	Laminate flooring
Cardiac gym equipment	Lift equipment [mechanicals][seats]
Carts [Medication Carts]	Light switches
Chairs	Linoleum
Charging Stations	[Medical] Examining tables
Circumcision tables	[Medical] [Hospital] Lamps
Closet Handles	[Medical] [Hospital] Scales
Computer keyboards	Microscope
Computer Peripherals	Microwave ovens — exteriors
Computer Tables	Mobile Workstations
Cords	Mouse pads
Counters [countertops]	Neonatal Warmers
Crutches	Non-critical [hospital] [medical] equipment surfaces
C-section delivery case carts	Non-porous Mattresses
Cupboards	Non-Wooden Outdoor [patio] furniture except cushion and wood frames\
Defibrillators	Nurse Call [Button][Devices]
Dental chairs	Ophthalmoscopes
Dental unit instrument trays	Otosopes
Desks	Over-bed Tables
Diagnostic Equipment	Oxygen hoods
Diaper changing [tables][counters]	Paddles
Diaper pails	Patient Monitoring Equipment
Docking Stations	Patient Slides
Doorknobs	Patient Support and Delivery Equipment
Dopplers	Phlebotomy Trays
Epidural cart	Phone Cradle
Equipment Surfaces	Physical Therapy Equipment Surfaces
Equipment tables	

[TYPES OF SURFACES (cont):]

Pipe Exteriors	Stoves ⁷ [stovetops ⁷]
Portable Scales seat	Stretchers
Pulp testers and motors	Support Bars
Pulse oximeters	Syringe infusion pumps
Refrigerated storage and display equipment ⁷	Tables, [picnic tables] [Examination Tables]
Refrigerators - exteriors	Tanning Beds
Rescue tools	Tele boxes and wires [Monitor Technician][Nursing]
Resuscitators	Telemetry equipment
Scales	Telephones
Sealed floors	Thermometers
Shopping cart handles	Tiles, glazed
Shower [Fixtures]	Toilet Seats,Handles,Fixtures
Shower stalls	Toilet bowl exterior surfaces
Showers	Transport monitors
Side Rails	Trash Cans
Sinks [bathroom, kitchen]	Tubs
Slit Lamps	Ultra-sound transducers and equipment
Spine back boards	Vaginal delivery case carts
Spine Backboards	Ventilator
Stands	Walkers
Stethoscopes	Walls
Stools	Wash Basins
Storage areas	Wheel chairs
	[Animal/Veterinary items]
Other hard nonporous surfaces made of:	Animal equipment
Acrylic	Animal crates
Finished woodwork	Automatic feeders
Formica®	Buckets
Glass	Brushes
Glazed ceramic	Cages
Glazed enameled surfaces	Counters
Glazed porcelain	Desks
Metal	Dog runs
Plastic [such as polystyrene or polypropylene]	Examination tables
Sealed granite	Exterior surfaces of fountains
Sealed marble	External surfaces of [veterinary equipment] [watering appliances]
Sealed quartz	Farm vehicles
Sealed stone	Feed racks [trucks]
Stainless steel	Fencing
Upholstery- vinyl and plastic	Food baths
	Gates
Plastic Mattress Covers	Gathering equipment (guiding)
Power Cords	Grooming equipment
PVC Tubing	Handling equipment
Remote Controls	Pens
	Stalls
	Veterinary care centers

[Insert Brand name] is registered in the United States and Trademark Office to *[Insert Company Name]*.

[Insert Brand name] is a registered trademark of *[Insert Company Name]*

[Formica® is a registered trademark of the Diller Corporation]

[Note: Do not use on unpainted wood, natural marble or brass.]

DS6835 is a one-step¹ [Hospital] disinfectant⁴ and Bactericidal [tested according to the modified germicidal spray test]:

{or}

DS6835 [is effective against] [Kills] [Removes] [Destroys]:

[Bacteria]:

Pseudomonas aeruginosa [ATCC 15442]

Salmonella enterica [ATCC 10708]

Staphylococcus aureus [ATCC 6538]

Acinetobacter baumannii [ATCC BAA-1709]

Enterobacter aerogenes [ATCC 13048]

[New Delhi metallo-beta-lactamase 1 [NDM-1] producing] *Enterobacter cloacae* [CDC 1000654]

Vancomycin Resistant *Enterococcus faecalis* [VRE] [ATCC 51575]

Enterococcus faecium [ATCC 6569]

Escherichia coli [ATCC 11229]

Escherichia coli O157:H7 [ATCC 35150]

Klebsiella pneumoniae [ATCC 4352]

Carbapenem Resistant *Klebsiella pneumoniae* [CRE] [*K. pneumoniae*] [ATCC BAA-1705]

[New Delhi metallo-beta-lactamase 1 [NDM-1] producing] *Klebsiella pneumoniae* [CDC 1000527]

Vancomycin Resistant *Staphylococcus aureus* [VRSA] [NARSA VRS1]

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

[Mycobacterium (TB)]

Mycobacterium bovis BCG (TB) at 21 °C [ATCC 35743]

[Fungi:]

Candida auris [AR-BANK#0381 from CDC] in 10 minutes

[Viruses*:]

*Adenovirus Type 5 [ATCC VR-5] [Strain Adenoid 75]

*Hepatitis B Virus [HBV]

*Hepatitis C Virus [HCV] [ATCC VR-1422] [BVDV]

*Herpes simplex type 1 Virus [ATCC VR-733] [Strain F(1)]

*HIV-1 [Strain HTLC-IIIB]

*Human Rotavirus [ATCC VR-2018] [Strain WA]

*Influenza A Virus [ATCC VR-544] [Strain A/8/68]

*Norovirus [*Norwalk Virus] [ATCC VR-782]

*Rhinovirus type 37 [ATCC VR-1147] [Strain 151-1]

*SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19]

[Animal Viruses*:]

*Canine Parvovirus [ATCC VR-2017] [Strain Cornell-780916-80] in 5 minutes

*Feline Calicivirus [ATCC VR-782]

*Minute virus of mice [ATCC VR-1346] [Strain Prototype (p)] in 5 minutes

{Note to Reviewer: This product qualifies for the following emerging pathogen claims against large non-enveloped or enveloped viruses. The claims shall not appear on marketed (final print) product labels.}

EMERGING VIRAL PATHOGEN STATEMENT

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the direction for use for the following organisms on the label:
Enveloped Viruses	Norovirus [ATCC VR-782]
Large Non-Enveloped Viruses	Norovirus [ATCC VR-782]
Small Non-Enveloped Viruses	Canine Parvovirus [ATCC VR-2017]

[DS6835] [Brand Name] [This Product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **[DS6835] [Brand Name] [This Product]** can be used against [name of emerging virus] when used in accordance with the directions for use against [Norovirus (ATCC VR-782)] [Canine Parvovirus (ATCC VR-2017)] 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]. **[DS6835] [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 (ATCC VR-782)] [Canine Parvovirus ATCC VR-2017] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

DIRECTIONS FOR USE

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

Packaging Related Statements

{Note to Reviewer: Appropriate language can be selected from this section, depending on packaging, but is not required.}

{For bottles with induction seal:} Unscrew cap, remove seal and place the [trigger] [sprayer] on the bottle.

{For bottles with sprayer:}

To Operate:

[Open hinged cover of sprayer and snap into opening on top.]

[Turn nozzle [counterclockwise] to ["spray"] ["stream"] [setting].]

[Adjust [nozzle] to desired pattern.]

{For containers with top pump dispensing mechanism:}

[To Open:] [To Operate:] [To Unlock:] Twist [rotate] [top] [pump] [head] [counter][clockwise].

[To Close:] [To Lock:] [Twist] [rotate] [pump] [head] [counter] [clockwise].

{Optional Directions for Product Supplied in Refill and Refillable Bottles:}

Refill only with this product.

To Refill [Spray Bottles]: Remove trigger sprayer from empty bottle.

[Pour:] Unscrew cap [and remove seal] on refill container and pour contents directly into empty bottle. [Use a funnel to minimize [product spills] [waste]. Pour product into spray bottle over sink or tub basin. [Use:]

[Replace trigger sprayer and return to use.] [Replace cap and use as you normally would.]

{For Refill container:}

Unscrew cap [, remove seal] and transfer your trigger to this bottle.

GENERAL DISINFECTION [/ *VIRUCIDAL] [/ Candida auris] DIRECTIONS: Spray 6 - 8 inches from hard, non-porous surface, until non-porous surface surfaces are thoroughly wet. Do not breathe spray. Treated non-porous surface surfaces must remain visibly wet for 1 minute⁶. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 30 seconds.] Wipe dry with a clean cloth, sponge, mop or towel, or allow to air dry.

{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.

Special Instructions for Cleaning Prior to Disinfection against Candida auris

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

To Use as a [One-Step¹] Disinfectant⁴:

1. Pre-clean visibly soiled areas.
2. Spray 6 – 8 inches from surface¹, making sure to wet thoroughly.
3. Allow surface to remain visibly wet for 1 minute⁶. *{Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 30 seconds.]*
4. Wipe surface dry. [If streaking is observed, wipe with a clean, damp [microfiber] [cloth] [or] [paper towel]]
5. [Allow to air dry.]

To Clean and Disinfect Bathtubs, Shower Stalls and Other Large, Open Areas¹ with Floor Drains:

1. Pre-clean visibly soiled areas.
2. Spray 6 – 8 inches from surfaces of floors, walls and ceilings making sure not to over spray. Allow surfaces to remain visibly wet for 1 minute⁶.
3. [Scrub using a deck brush or other coarse material as necessary.]
4. Rinse surfaces thoroughly and let air dry.

[NOTE: Floors will be slippery when wet or contaminated with foreign materials.]

To Pre-clean Instruments Prior to Terminal Sterilization/High Level Disinfection:

1. Place instruments into a suitable container.
2. Spray this product onto instruments¹ to thoroughly wet all surfaces.
3. Allow surface to remain visibly wet for 1 minute⁶.
4. Rinse instruments.
5. Follow with an appropriate disinfection process.

Note: Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

To Disinfect Non-Critical, Pre-cleaned Instruments:

1. Instruments must be thoroughly pre-cleaned to remove excess organic debris, rinsed, and rough dried. (Clean and rinse lumens of hollow instruments before spraying with this product).
2. Spray all surfaces¹ of instruments with this product until thoroughly wet.
3. Allow surface to remain visibly wet for 1 minute⁶.
4. Wipe with a clean, damp cloth or paper towel and allow to air dry.

Note: Non-critical medical items are those that only come into contact with intact skin.

To Clean and Disinfect Manikins Used in CPR Training:

- Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces.
- Disassemble the manikin as directed by manufacturer's instructions. Spray surface with this product until thoroughly wet. Allow surface to remain visibly wet for 1 minute⁶ and rinse with potable water.

To Disinfectant Surfaces¹ in Pharmaceutical and Cosmetic Processing Facilities:

1. Pre-clean visibly soiled areas.
2. Spray 6-8 inches from surface¹ until surface is thoroughly wet.
3. Allow surfaces to remain visibly wet for 1 minute⁶.
4. Rinse with sterile water.
5. Wipe with a dry, clean cloth and let air dry.

To Clean and Disinfect Barber and Beauty/Manicure Instruments and Tools:

1. Pre-clean visibly soiled items.
2. Spray all surfaces of pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other hard, non-porous instruments with this product until thoroughly wet.
3. Allow surface to remain visibly wet for 1 minute⁶.
4. Rinse the surfaces thoroughly with water.
5. Let air dry before reuse.

To Disinfect Surfaces¹ of Non-Circulating Footbaths:

DS6835

EPA Reg. No. 6836-442

EPA Submission 2021-05-13

1. Drain: Drain the water [from] [the] [unit] [basin] [bowl] and remove any visible debris.
2. Clean: Thoroughly clean all surfaces with [this product] [soap] [detergent], then rinse with water and drain.
3. Apply: Spray this product 6 – 8 inches from surface¹. Allow surface to remain visibly wet for 1 minute⁶.
4. Scrub: Brush or swab thoroughly.
5. Rinse [cleaned] [treated] [surfaces] with fresh water and drain.

***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]. Hepatitis C Virus (HCV) or Hepatitis B Virus (HBV).

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 **DS6835**. **DS6835** [this product] can be used for this purpose.

Contact time: Leave hard, non-porous surface to remain visibly wet for 1 minute for HIV-1. Use appropriate contact time as listed on label for all other viruses[,] [and] bacteria claimed.

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

For use as a One-Step Cleaner and Disinfectant Against Bacteria and Viruses by Electrostatic Spraying¹:

Electrostatic spray application is for efficacy claims with a 1 minute contact time. This application method is not to be used to treat surfaces for *C. auris*, TB, or Canine parvovirus and Minute virus of mice claims.

- Ensure bystanders and pets are not present in the room during application.
- Clean visibly dirty surfaces prior to spraying.
- Wear a half face respirator with a chemical specific cartridge and a N95 filter, and eye protection (goggles, face shield or safety glasses) when spraying.
- Select a spray nozzle that produces spray droplet particles with a volume median diameter (VMD) $\geq 80 \mu\text{m}$.
- Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.
- Hold the sprayer nozzle 1-2 feet away from the target surface. Starting at the highest point and working down to the lowest point, spray target surfaces using a smooth methodical “S” pattern. To avoid leaving gaps in sprayed surfaces, overlap previously treated surfaces when moving onto subsequent sections.
- The target surface must remain visibly wet for {insert contact time}. Re-apply product as necessary to keep surface visibly wet for the duration of the contact time. Wipe surfaces dry (or rinse) (or allow to air dry).
- Allow the treated room to remain unoccupied for 15 minutes before reentering.

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses):

For cleaning and disinfecting the following surfaces¹: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities [including barns, pens, stalls, chutes, and barns] occupied or traversed by animals.
3. Empty [or cover] all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water.
5. Saturate all surfaces by spraying with product until thoroughly wet. To disinfect, all surfaces must remain visibly wet for 1 minute⁶.
6. Immerse or 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.

DS6835

EPA Reg. No. 6836-442

EPA Submission 2021-05-13

7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

To Clean and/or Deodorize:

Apply product by trigger sprayer to surfaces. [Wipe surfaces dry] [Rinse] [Allow to air dry]. Repeat for visibly soiled areas. For stubborn stains or visibly soiled areas or tougher jobs, allow product to penetrate [dirt] before wiping.

To Spot Clean: Spray and wipe clean with damp sponge [, mop] or cloth.

To Clean/Remove Soap Scum:

[Just] spray on [soils] and wipe off [with a dry paper towel or lint-free cloth or microfiber cloth or sponge]. No rinsing necessary. [For best results, use a dry paper towel or lint-free cloth or microfiber cloth or sponge.] Repeat for visibly soiled areas. [For stubborn stains or visibly soiled areas or tougher jobs, allow product to penetrate [dirt] [and] [or] [soap scum] before wiping.] [For best results, use regularly to prevent dirt and soap scum build up].

To Clean Surfaces [and] [or] [Small Areas of Floors]: Spray soiled area, then wipe clean.

To Spot Clean Carpet: Spray a light even coating [from 6 – 8 inches above] on soiled area of the carpet until damp. Gently blot area with a clean, damp, color-safe cloth. Repeat as needed [for stubborn stains]. Let air dry. Vacuum.

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

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

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.

End Notes:

¹ On hard, non-porous, non-food surfaces

² Kills *Pseudomonas aeruginosa* and *Staphylococcus aureus* and {choose one or more virus efficacy list}

³ If not satisfied, contact customer service at [email address] [phone number].

⁴ When directions for disinfection are followed

⁵ Pre-clean grease prior to disinfection.

⁶ {If Canine Parvovirus is on supplemental label then the following statement is required} 5 minute contact time is required for Canine Parvovirus efficacy claim, {if *Candida auris* is on supplemental label then the following statement is required} 10 minute contact time is required for *Candida auris* efficacy claim { If Minute virus of mice is on supplemental label then the following statement is required} 5 minutes contact time is required for Minute virus of mice efficacy claim}

⁷ Allow the surface to adjust to room temperature before disinfection.

⁸ Not to be used on high chairs

⁹ {for a supplemental label} Do not approve an end-use product label that makes a flu claim without Influenza virus (Influenza A Virus, Strain A/8/68, ATCC VR-544) claim on the label

¹⁰ SARS-CoV-2

¹¹ *Enterobacter cloacae* [NDM-1] [CDC 1000654], *Enterococcus faecalis* [VRE] [ATCC 51575], *Klebsiella pneumoniae* [CRE] [ATCC BAA-1705], *Klebsiella pneumoniae* [NDM-1] [CDC 1000527], *Staphylococcus aureus* [VRSA] [NARSA VRS1], *Staphylococcus aureus* [MRSA] [ATCC 33592]