



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 13, 2018

Megan P. Priest
Regulatory Consultant
Decon7 Systems, LLC
8541 East Anderson Drive
Suite 106
Scottsdale, AZ 85255

Subject: PRIA Label Amendment – Adding Efficacy Claims
Product Name: D7 Part 1
EPA Registration Number: 89833-3
Application Date: 07/25/2018
Decision Number: 543104

Dear Ms. Priest:

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.

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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, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,



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

Enclosure

D7 Part 1 Master Label

D7 Part 1

For use as a disinfectant, virucide[^], fungicide, deodorizer, and food contact sanitizer* on hard, non-porous surfaces in Ambulances, Police/Fire Departments, Hospitals, Nursing Homes, Homes, Hotel & Motels, Industrial/Institutional Buildings, Schools, Poultry/Beef/Swine Farm, and Harvesting Equipment.

Only for use when added to D7 Part 2 (EPA Reg. No. 89833-4) and D7 Part 3.

Part 1

ACTIVE INGREDIENTS:

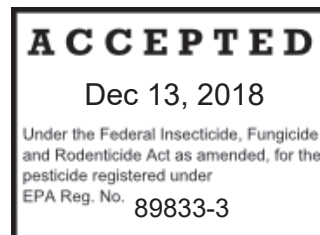
Alkyl (40% C₁₂, 50% C₁₄, 10% C₁₆) dimethyl benzyl ammonium chloride3.2%

INERT INGREDIENTS:.....96.8%

TOTAL.....100.0%

E.P.A. Reg. No. 89833-3

E.P.A. Est. No. XXX



**KEEP OUT OF THE REACH OF CHILDREN
DANGER**

FIRST AID
IF ON SKIN: 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.
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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth to mouth, if possible. Call poison control center or doctor for further treatment advice.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-424-9300

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

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE: Causes skin burns. Causes substantial but temporary eye injury. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield or safety glasses. When mixing and loading, wear a chemical resistant apron. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using the toilet or using tobacco. Remove and wash contaminated clothing before reuse.

D7 Part 1 Master Label

ENVIRONMENTAL HAZARDS

{For containers less than 5 gallons in size, use the below statement}

For small spills, flush with copious amounts of water.

{For containers equal to or larger than 5 gallons in size, use the below statement}

For small spills, flush with copious amounts of water. Do not discharge effluent containing these products into lakes, streams, ponds, estuaries, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing these products to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional office of the U.S. Environmental Protection Agency.

{Note to Reviewer: The below surfaces, use sites and marketing claims are optional}

[PRODUCT APPLICATIONS]

This product can be applied through foaming apparatus, low-pressure sprayers, mopping, and soaking systems. Follow manufacturers' instructions when using this equipment.

This formulation is for use on hard, non-porous surfaces in:

- Hospitals, medical and dental offices and clinics, healthcare facilities, nursing homes, physician offices, operating rooms/theaters, radiology rooms, isolation wards, quarantine areas, clean room environments, hospices, and medical research facilities.
- Patient care rooms & facilities, recovery rooms, Emergency Rooms, X-ray cat labs, exam rooms, newborn nurseries, neonatal units, orthopedics, respiratory therapy, surgi-centers, labs, out-patient surgical centers, blood collection rooms, central supply, housekeeping & janitorial rooms, ophthalmic/optometric facilities.
- EMS & fire facilities, emergency vehicles, ambulances, ambulance equipment/surfaces, police cars, fire trucks.
- Day care centers and nurseries, sick rooms, elder care centers, kindergartens, and preschools.
- Acute care institutions, alternate care institutions, home healthcare institutions.
- Life care retirement communities, elder care facilities.
- Restaurants*, restaurants and bars*, bars*, kitchens*, taverns*, cafeterias*, institutional kitchens*, fast food operations* and food storage areas*.
- Supermarkets, convenience stores, retail and wholesale establishments, department stores, shopping malls, gift shops, video stores, bookstores, dressing rooms and laundries, photocopy centers, bicycle shops, auto repair centers.
- Computer manufacturing sites, toy factories.
- Food establishments*, coffee shops*, donut shops*, bagel stores*, pizza parlors*, liquor stores*, gentleman's clubs, hookah lounges, casinos.
- Crime scenes and funeral homes, morgues, mortuaries, burial vaults, mausoleums, autopsy rooms (not for use on medical devices), cadaver processing areas.
- Police stations, courthouses, correctional facilities, jails, prisons, municipal government buildings, penitentiaries, correctional institutions, bus stations, train stations.
- Institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels, and transportation terminals, maintenance vehicles.
- Public restrooms, public facilities, waysides, travel rest areas, shower rooms, shower stalls, bathrooms, shower and bath areas.
- Hotels, motels, hostels, dormitories.
- Kitchens*, bathrooms and other household areas.
- Homes, condos, apartments, vacation cottages, summer homes.
- Institutions, schools and colleges, commercial and industrial institutions, churches, classrooms, community colleges, universities, athletic facilities and locker rooms, exercise rooms, exercise facilities, gyms, gymnasiums, fieldhouses, yoga studios.
- Cosmetic manufacturing facilities, medical device manufacturing facilities, biotechnology firms, pharmaceutical manufacturing facilities, warehouses.

D7 Part 1 Master Label

- Health clubs, spas, tanning salons, tanning spas/beds, footbath surfaces, massage/facial salons, hair/nail/pedicure salons, barber/beauty shops, salons, tattoo parlors. Not for use on needles or other skin piercing instruments.
- Museums, art galleries, post offices, performance/theater centers, banks, libraries, movie houses, bowling alleys.
- Recycling centers.
- Empty humidifier water tanks.
- Campgrounds, playgrounds, recreational facilities, picnic facilities, sports arenas, sports complexes.
- Food processing plants*, USDA inspected food processing facilities*, farms*, dairy farms*, hog farms*, equine farms, poultry and turkey farms* and egg processing plants*, meat/poultry processing plants*, meat/poultry producing establishments*, mushroom farms*, rendering plants, canneries*, caterers*, bakeries*, meat packing plants*, hide and leather processing plants.
- Processing facilities for fish, milk, citrus, wine, fruit, vegetable, ice cream, and potatoes and beverage plants*.
- Tobacco plant premises and equipment*.
- Veterinary clinics, animal life science laboratories, animal laboratories, animal research centers, animal quarantine areas, animal holding areas, animal breeding facilities, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, equine farms, pet shops, tack shops, operating rooms, washing areas, waiting rooms, examination rooms and other animal care facilities.
- Farmhouses, barns, sheds, tool sheds, barns, cattle barns, swine barns, sheep barns, horse barns, brooder houses, seed houses.
- Household and automotive garages, boats, ships, barges, watercraft, campers, RVs, trailers, mobile homes, cars, automobiles, trucks, delivery trucks, boxcars, tankers, tank trucks, buses, trains, taxis, helicopters and airplanes.
- Cruise lines, cruise ships, airline terminals, airports, shipping terminals, public transportation, transportation terminals.
- Commercial florist and flower shops.
- Basements, cellars, bedrooms, attics, living rooms and porches.

This product can be used on washable hard, non-porous surfaces such as:

- Food preparation and storage areas*.
- Kitchen equipment* such as trash compactors.
- Countertops*, countertop laminates*, stovetops*, sinks*, tub surfaces, Slurpee® machines*, shelves, racks, carts.
- Exterior surfaces of appliances; refrigerators, microwave ovens and ice machines*.
- Hospital beds, bed railings, bedpans, gurneys, traction devices, MRI, CAT, examining tables, instrument trays in patient care areas of hospitals, scales, paddles, wheelchairs, hard, non-porous surfaces of cervical collars and neck braces, spine backboards, stretchers, unit stools, CPR training mannequins*, curing lights, light lens covers, slit lamps, operating room lights, operating tables, oxygen hoods, dental chairs/countertops, examination tables, X-ray tables, washing areas, anesthesia carts, surfaces of empty whirlpools, surfaces of empty footbaths.
- Empty ultrasonic baths, empty whirlpools, empty whirlpool bathtubs.
- Highchairs*, baby cribs, diaper changing stations, infant bassinets / cribs / warmers / incubators, folding tables, hampers, laundry pails.
- Shower stalls, shower doors and curtains, bathtubs and glazed tiles, chrome plated intakes, toilets, toilet seats, toilet bowls above the water line, toilet bowl surfaces, urinals, empty diaper pails, portable and chemical toilets and latrine buckets, glazed porcelain, glazed tile and restroom fixtures, floors, sink basins, drain covers, bathroom fixtures.
- Glass, laminated surfaces, metal, stainless steel, glazed porcelain, glazed ceramic, sealed granite, sealed marble, plastic, (such as polycarbonate, polyvinylchloride, polystyrene or polypropylene), sealed limestone, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, chrome and vinyl, Plexiglas®, vanity tops.

D7 Part 1 Master Label

- Tables, chairs, desks, folding tables, workstations, bed frames, lifts, washable walls, cabinets, doorknobs and garbage cans/pails, trash barrels, trash cans, trash containers, cuspidors and spittoons.
- Enameled surfaces, painted (finished) woodwork, Formica®, plastic upholstery.
- Sealed foundations, steps, plumbing fixtures, finished baseboards and window sills.
- Exhaust fans, HVAC systems ductwork, refrigerated storage and display equipment, coils and drain pans of air conditioning and refrigeration equipment and heat pumps. (These surfaces should be at room temperature before application of the product.)
- Large, inflatable, non-porous plastic and rubber structures such as animals, promotional items, moonwalks, slides, obstacle course play and exercise equipment.
- Non-wooden picnic tables and outdoor furniture (not for use on cushions and wood frames).
- Tattoo equipment. (Not for use on needles or other skin piercing instruments.)
- Playground equipment.
- Automobile interiors.
- Maintenance equipment.
- Telephones and Telephone booths.
- External Lenses Vision correction including eyeglasses (not for use on contact lenses), protective eyewear, goggles, light lens covers.
- Optical instruments/implements.
- Hair clippers, cutting implements, plastic rollers, washable nail files.
- Hard hats, headphones.
- Kennel runs, cages, kennel/cages floors, conductive flooring, examination tables, veterinary x-ray tables.
- Hatchers, setters, trays, racks, egg flats, walls, floors, ceilings, poultry boxes, egg cases, vans and trash containers, seed houses, feeder bowls*, water bowls*, exterior of water feed lines (rinse after application is recommended).
- Wrestling, dance, cheer and gymnastic sealed mats, athletic training tables, physical therapy tables, exercise equipment.
- Drinking fountains*.
- Windows and mirrors.

{Additional Marketing Claims:}

[ANTIMICROBIAL CLAIMS:]

Antibacterial

Antimicrobial

Bactericide

Bactericidal

Broad spectrum bactericidal activity

Broad-spectrum disinfectant

Cleaner, disinfectant and deodorizer

Disinfectant

Disinfects [and] [Sanitizes*]

Disinfects [and] [&] [deodorizes]

Effectively cleans and disinfects all hard, nonporous surfaces

Effectively treats biofilms caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Food contact sanitizer*

Formulated to kill 99.9999% of bacteria† in biofilm

Fungicide

Fungicidal

Germicidal

Hospital disinfectant

Is a multi-purpose disinfectant

Is efficacious

Is a proven disinfectant and cleaner

D7 Part 1 Master Label

Kills 99.9999% of bacteria† in biofilm on a hard, non-porous surface.
Kills a minimum of 99.9999% of bacteria† in biofilm
Kills bacteria
Kills biofilm bacteria†
Kills, removes and destroys germs, bacteria and viruses on hard, non-porous surfaces.
Kills fungi
Kills germs
Kills (*insert organism(s) from approved organism listing for this product*)
Kills viruses^
Kills *Salmonella enterica*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.
Penetrates biofilm, killing the bacteria† living there
Reduces at least 99.9999% of bacteria† growing in biofilm
Sanitizes*
Virucidal^
Virucide^

Pseudomonas aeruginosa, *Salmonella enterica*, and *Staphylococcus aureus* are bacteria found where food is prepared and stored. Food contact surfaces must be rinsed with potable water after application.

This product kills *Staphylococcus aureus* [(ATCC 6538)] [Staph], *Staphylococcus aureus* [(ATCC 6538)] [Staph] biofilm, *Salmonella enterica* [(ATCC 10708)] [Salmonella], *Escherichia coli* [(ATCC 11229)], *T. interdigitale* [(ATCC 9533)], *Aspergillus niger* [(ATCC 6275)], Avian Influenza A [(H3N2)] Reassortant Virus, Avian Influenza A [(H5N1)] Virus, Avian Influenza A [(H7N9)] Virus, Norovirus, *Listeria monocytogenes* [(ATCC 15313)], Porcine Epidemic Diarrhea Virus *Pseudomonas aeruginosa* [(ATCC 15442)], and *Pseudomonas aeruginosa* [(ATCC 15442)] biofilm.

Helps reduce cross-contamination on treated food and non-food contact kitchen surfaces listed on this label. A potable water rinse is required after application on food contact surfaces.

This product is an effective disinfectant against *Staphylococcus aureus* [(ATCC 6538)] [Staph], *Staphylococcus aureus* [(ATCC 6538)] [Staph] biofilm, *Salmonella enterica* [(ATCC 10708)] [Salmonella], *Pseudomonas aeruginosa* [(ATCC 15442)], and *Pseudomonas aeruginosa* [(ATCC 15442)] biofilm.

This product is an effective fungicide against *T. interdigitale* [(ATCC 9533)] and *Aspergillus niger* [(ATCC 6275)].

This product is an effective virucide against Avian Influenza A [(H3N2)] Reassortant Virus, Avian Influenza A [(H5N1)] Virus, Avian Influenza A [(H7N9)] Virus, Norovirus and Porcine Epidemic Diarrhea Virus.

This product is an effective sanitizer* against *Staphylococcus aureus* [(ATCC 6538)] [Staph], *Escherichia coli* [(ATCC 11229)] and *Listeria monocytogenes* [(ATCC 15313)].

This product is bactericidal according to the AOAC Use Dilution Method test on hard inanimate surfaces with a 10 minute contact time in the presence of a 5% fetal bovine serum organic soil load: *Staphylococcus aureus* [(ATCC 6538)] [Staph], *Salmonella enterica* [(ATCC 10708)] [Salmonella], *Pseudomonas aeruginosa* [(ATCC 15442)].

This product is effective against ([*Staphylococcus aureus* [(ATCC 6538)]] [and] ([*Pseudomonas aeruginosa* [(ATCC 15442)]])) biofilms with a 6 log reduction.

D7 Part 1 Master Label

Deodorizes
Deodorizer
Eliminates odors
Contains no abrasives so it won't scratch surfaces.

*A potable water rinse is required after application on food contact surfaces.

† *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

{Note to Reviewer: End of Optional Marketing Claims}

FOR USE AS A DISINFECTANT AGAINST THE FOLLOWING ORGANISMS WITH A 10 MINUTE CONTACT TIME:

Staphylococcus aureus [(ATCC 6538)] [Staph]
Salmonella enterica [(ATCC 10708)] [Salmonella]
Pseudomonas aeruginosa [(ATCC 15442)]

^FOR USE AS A VIRUCIDE AGAINST THE FOLLOWING ORGANISMS WITH A 10 MINUTE CONTACT TIME:

Avian Influenza A (H3N2) Reassortant Virus
Avian Influenza A (H5N1) Virus
Avian Influenza A (H7N9) Virus
Norovirus
Porcine Epidemic Diarrhea Virus

FOR USE AS A FUNGICIDE AGAINST THE FOLLOWING ORGANISMS WITH A 10 MINUTE CONTACT TIME:

T. interdigitale [(ATCC 9533)]
Aspergillus niger [(ATCC 6275)]

FOR USE AS A DISINFECTANT AGAINST THE FOLLOWING BIOFILMS WITH A 10 MINUTE CONTACT TIME:

Staphylococcus aureus [(ATCC 6538)] [Staph]
Pseudomonas aeruginosa [(ATCC 15442)]

FOR USE AS A FOOD CONTACT SURFACE SANITIZER* AGAINST THE FOLLOWING ORGANISMS WITH A 1 MINUTE CONTACT TIME:

Listeria monocytogenes [(ATCC 15313)]
Escherichia coli [(ATCC 11229)]
Staphylococcus aureus [(ATCC 6538)] [Staph]

Directions for Use: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Mixing Instructions: Pour the complete contents of D7 Part 1 (EPA Reg. No. 89833-3), D7 Part 2 (EPA Reg. No. 89833-4) and D7 Part 3 which acts as a booster into a mixing container (plastic or glass), large enough to hold all components when completely mixed. Stir the solution until it is well mixed (15-20 seconds). The mixture is now ready to apply.

D7 Part 1, D7 Part 2, and D7 Part 3 (booster) are always sold in corresponding container sizes such that the use of the entire contents of each container will always result in the required product ratio of 49:49:2.

D7 Part 1 Master Label

(Note to Reviewer: For labels that list medical devices and/or stainless steel surfaces, one of the following FDA/EPA Memorandum of Understanding 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 can be used to pre-clean 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.

For Use as a ([Disinfectant] [Virucide^] [Fungicide] [Deodorizer]): Properly mix the D7 mixture according to mixing instructions. Apply the mixture to hard, inanimate, non-porous surfaces, thoroughly wetting the surface, with a cloth, mop, sponge or spray. For heavily soiled areas, a preliminary cleaning is required. If sprayed, use a coarse spray setting, spray 10" to 18" inches from the surface and do not breathe the spray. Keep the surfaces wet for 10 minutes. The mixture must be reapplied if it dries out or becomes diluted by any liquid during the 10 minute contact time. A potable water rinse is required after application on food contact surfaces.

For Use as a Cleaner and Disinfectant for Biofilms on Pre-Cleaned Hard, Non-Porous Surfaces: Properly mix the D7 mixture according to mixing instructions. Pre-clean surfaces to remove soil and filth. Wipe dry. Thoroughly wet pre-cleaned surface with the D7 mixture. Allow surface to remain wet for 10 minutes. The mixture must be reapplied if it dries out or becomes diluted by any liquid during the 10 minute contact time. Rinse thoroughly.

For Use as a Food Contact Surface Sanitizer: Properly mix D7 mixture according to mixing instructions. Once mixed, the combined D7 solution can be further diluted 1:5 by adding 1-part D7 mixture to 4-parts water. The product is now ready to apply by cloth, sponge, spray, soak, foaming or mopping to hard, inanimate, non-porous surfaces. For heavily soiled areas, a preliminary cleaning is required. The mixture must be reapplied if it dries out or becomes diluted by any liquid during the 1 minute contact time. A potable water rinse is required after application on food contact surfaces.

For Use as a General Deodorizer [Not for use in CA]: Properly mix the D7 mixture according to mixing instructions. Apply the mixture via spray, soak, foam or fog and let air dry to eliminate odors. When fogging to eliminate odors, apply 1 quart per 2000 cubic feet following fogger manufacturer's directions for use. If fogging, remove all people and animals from the area. Applicators must vacate area immediately following initiation of the fogging apparatus.

For Use as a Deodorizer for HVAC Systems Ductwork [Not for use in CA]: Properly mix the D7 mixture according to mixing instructions. Apply the mixture via spray or fog into system intake vents while system fan is running. Allow enough application time for mixture to contact air duct systems surfaces and repeat application as necessary. If fogging, remove all people and animals from the area. Applicators must vacate area immediately following initiation of the fogging apparatus.

D7 Part 1 Master Label

STORAGE AND DISPOSAL
DO NOT CONTAMINATE WATER, FOOD, AND FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product should be kept in the original container in a cool dry area. Store product container in an upright position. Avoid creasing or impacting of sidewalls.

PESTICIDE DISPOSAL: Pesticide wastes may be 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.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available and dispose of in a sanitary landfill, or by incineration.

Manufactured ([For] [By]):
Decon7 Systems, LLC.
8541 East Anderson Drive, Suite 106
Scottsdale, Arizona 85255

Net Contents:

Lot Number:

[Batch Code]