



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 18, 2019

Sara Seltzer
Registration Specialist
Diversey, Inc.
P.O. Box 19747
Charlotte, NC 28219

Subject: PRIA Label Amendment – Add Biofilm and Emerging Pathogen Claims
Product Name: Avert Sporidical Disinfectant Cleaner
EPA Registration Number: 70627-72
Application Date: December 12, 2018
Decision Number: 558218

Dear Ms. Seltzer:

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, please contact Wanda Henson by phone at (703) 308-6345, or via email at henson.wanda@epa.gov

Sincerely,

A handwritten signature in black ink, appearing to read "D. Fuller", with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

Avert

Sporicidal Disinfectant Cleaner

(For Institutional Use)

(Kills C. Diff (C. diff) spores(!))

ACTIVE INGREDIENT:	
Sodium hypochlorite	1.312%
OTHER INGREDIENTS:	98.688%
TOTAL:	100.000%

1.25% available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER

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.

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 for treatment advice.

IF INHALED: Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

IF SWALLOWED: Call 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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR FURTHER TREATMENT ADVICE.

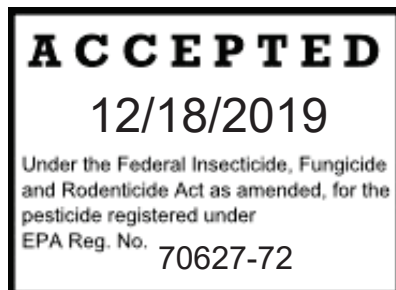
[Note to Reviewer: Working Emergency Number Will be Printed Here]

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.

(See additional precautionary statements on back (side) (left) (right) (panel) (of) (label) (below).)

Net Contents:



(Made in (Product of) _____)

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(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

(MARKETING CLAIMS:)

[Note to reviewer: Diversey will use one or more of the following optional Marketing Claims on product labels, as space permits.]

- Cleans (Cleaner), (and) Deodorizes (Deodorant) (Deodorizer), Disinfects (Disinfectant), *Virucidal (*Virucide), Fungicidal (Fungicide)
- Sporicidal disinfectant against (Clostridium difficile) (C. diff) (C. difficile) spores
- (Designed) For daily use (Use for) daily (or) (discharge) (cleaning) (in Healthcare)
- Multi-surface cleaner disinfectant
- Cleans, disinfects, and deodorizes in one labor saving step.
- Efficient. Cuts cleaning time.
- Makes cleaning easier
- Cleans everyday messes
- Non-abrasive (formula) (product)
- Will not leave grit or soap scum on surfaces
- Convenient
- Does not require (the hassle of) dispensing systems.
- Fragrance-free
- The smell of clean
- No added (perfume) (fragrance) (and) (or) (dye)
- No harsh (alcohol) (vinegar) (and) (or) (peracetic acid) smell
- Contains 12,500 ppm of (chlorine) (Contains 12,500 ppm of sodium hypochlorite)
- Recyclable (bottle) (product container)
- Bleach-based formula means no quat-binding concerns (with wiping)
- Clean & disinfect hard non-porous surfaces (easily)
- Cleans and disinfects
- Clean(s) and deodorize(s)
- Cleans effectively
- Cleans hard-to-remove stains
- Clean you expect
- Cleans, deodorizes and disinfects
- Deodorizer (Odor Counteractant) (Odor Neutralizer)
- Convenient
- Convenient & easy cleaning all around (the) (office) (business) (workplace)
- Cuts grease
- Cuts the toughest grime and grease without scratching surfaces
- Easy / Effective
- For everyday use (in (institutional) (and) (industrial) facilities)
- For hard, non-porous surfaces
- For use in critical care areas (where control of the hazards of cross-contamination between treated surfaces is of prime importance)
- For use (in) (Hospitals) (and) (Health Care) (settings) (as a multi-purpose disinfectant cleaner)
- For your toughest bathroom messes
- Help make your (the) *[insert any use site from use site section]* Avert Clean
- Efficiently (eliminates) (removes) (bad) (mal)odors
- Quaternary ammonium compound-free (No quaternary ammonium compounds)
- Use on hard, non-porous surfaces only. (Test wipe on a small inconspicuous area first)

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

- Cleans hard, non-porous water washable surfaces!
- Cleans (removes) (destroys) stains
- Cleans (tough) grease and grime (and) (institutional) (soils) (fast)
- Cleans (tough) soap scum
- Convenient, (effective) (efficient) (&) easy cleaning
- Effective daily cleaner
- Effective against soap scum
- For a cleaner, fresher [*insert any use site(s) from Use Site section*]
- For multiple cleaning tasks
- Intense cleaning action
- Keeps day care centers clean
- No mixing
- Powerful clean
- Powers away tough stains (stuck on dirt)
- (Efficient) (effective) (and) easy cleaning everywhere
- Removes tough stains
- (Specially) (Specifically) designed to dissolve (penetrate) the toughest (stubborn) soils
- Use daily to prevent the build-up of dirt and grime
- Antimicrobial (Cleaner)
- Bactericidal (Cleaner)
- Sporicidal disinfectant (Cleaner)
- *Virucidal (Cleaner)
- Fungicidal (Cleaner)
- Fungicidal disinfectant against *C. auris*
- Meets OSHA Bloodborne Pathogen Standards
- Complies with surface disinfection requirements of OSHA('s) Bloodborne Pathogens Standard
- No fragrance added (No added fragrance)
- Broad-Spectrum (Multi-Purpose) (Multi-Surface) ([†]Bactericidal) (*Virucidal) ([‡]Fungicidal) (Disinfectant) (Activity) (Cleaner)
- Controls the spread of [*insert organism name(s) from list in Efficacy Claims section*] on treated hard, non-porous environmental surfaces
- Controls (Eliminates) odor-causing bacteria
- Cleans as it disinfects
- (Disinfects) (Kills germs) for a deep-down clean
- Disinfectant (disinfecting) hard non-porous surface cleaner
- Disinfects against [*insert organism name(s) from list in Efficacy Claims section*]
- Disinfects environmental hard non-porous surfaces
- Disinfects hard, non-porous environmental surfaces
- Dual action formulation providing broad spectrum activity against; [‡]fungi, *viruses, and [†]bacteria
- Cleans and deodorizes all around the [*insert any use site from use site section*].
- Cleans, deodorizes and kills listed bacteria all around the [*insert any use site(s) from Use Site section*]. (Just let surface remain wet for 1 minute.)
- Effective against flu virus (Influenza A)
- Effective in 1 minute against [*insert organism name(s) from list in Efficacy Claims section*]
- Effectively disinfects hard, non-porous surfaces
- Effectively disinfects in the presence of organic soil
- Exhibits effective virucidal activity: kills Influenza A/Hong Kong and Herpes Simplex Type 2

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- Exhibits effective virucidal activity: kills [insert any virus name from Efficacy Claims section]
- Kills bacteria (and viruses) (fungi)
- Kills bacteria (and viruses) (on hard, non-porous surfaces) in 1 minute
- Cleans while it kills (destroys) germs
- Kills (Effective against) cold virus on hard, non-porous surfaces
- Kills (Effective against) flu virus on hard, non-porous surfaces
- Kills (Effective against) cold and flu virus on hard, non-porous surfaces
- Kills odor-causing bacteria
- This product controls biofilm and slime deposits
- Kills 99.9999% of bacteria (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) in biofilms on a hard, non-porous surface
- Kills a minimum of 99.9999% of bacteria (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) in biofilms
- Formulated to kill 99.9999% of bacteria (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) in biofilms
- Kills biofilm bacteria (*Pseudomonas aeruginosa* and *Staphylococcus aureus*)
- Penetrates biofilms, killing the bacteria (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) (living there) (in the biofilm)
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] is designed to provide effective cleaning and disinfection in areas where it is of prime importance in controlling the cross contamination on treated pre-cleaned, hard, non-porous, inanimate surfaces.
- An effective biocide that aids in the removal of non-public health biofilms and non-public health slime-forming microorganisms
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] controls non-public health biofilm and slime deposits
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] is effective in controlling sulfate reducing bacteria, general aerobic bacteria, including microorganisms that contribute to biofilm formation
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] cleans and disinfects [insert organism name(s) from list in Efficacy Claims section] including ESKAPE pathogens - *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter aerogenes*, Multi-Drug Resistant (MDRO)
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] kills ESKAPE organisms with a 1 minute kill time.
- (This product) (Avert) (Avert Sporicidal Disinfectant) [insert marketed product name] cleans and disinfects, killing ESKAPE organisms with a 1-minute dwell time.
- Kills ESKAPE bacteria (in 1 minute)

(ADDITIONAL CLAIMS:)

This product cleans, disinfects, and deodorizes hard, nonporous inanimate (environmental) surfaces (and patient care equipment) in one step with no rinsing required (after use), pre-cleaning for *C. auris* and *C. diff* required. This product is a (one-step,) (broad spectrum,) (hospital,) disinfectant (germicidal) cleaner and deodorizer (odor counteractant) designed for general cleaning, disinfection and deodorizing of hard, nonporous surfaces. (Designed for (non-critical) hard, nonporous surfaces in healthcare.) (It quickly) Removes (bathtub ring,) blood, body fluids, dirt, fungus, food residue, fecal matter, grime, laboratory stains, soils, stains, urine and other organic matter commonly found (on hard, nonporous, inanimate (environmental) surfaces) (patient care equipment)) (in hospitals and healthcare facilities) (where housekeeping is of prime importance in controlling the hazard of cross-contamination). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

Using approved Standard Quantitative Disk Carrier Test Method (under Good Laboratory Practices, (GLPs)), in the presence of soil and 4 (four) minute contact time, this product kills (and) (inactivates) spores of *Clostridium difficile* (ATCC 43598) on hard, nonporous surfaces.

(When used as directed, this product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic-resistant bacteria, *viruses, and fungi).) Using approved AOAC test methods (under Good Laboratory Practices, (GLPs)), in the presence of 5% serum load and 1 (one) minute contact time, this product kills *[insert organism name(s) from list in Efficacy Claims section]* on hard nonporous (inanimate) (environmental) surfaces: *[insert any use site(s) from Use Site section]*

(USE SITES:)

(Avert Sporicidal Disinfectant Cleaner) (Avert Sporicidal Disinfectant) (Avert) (This product) can be used in the following areas:

(Medical Facilities/Surfaces:)

- alternative care facilities,
- ambulances or (emergency medical) transport vehicles,
- ambulatory care centers (ASCs); ambulatory surgery centers,
- anesthesia rooms,
- assisted living facilities,
- (acute) (and) (long-term) care facilities,
- backboards,
- (hospital) (patient) beds, bedrails, bedframes, bed springs,
- bedpans,
- bedside (overbed) tables,
- blood pressure cuffs,
- blood pressure monitors
- CAT laboratories,
- cabinets,
- call buttons (boxes),
- (crash) (medication) carts,
- counters (countertops),
- central service areas,
- central supply rooms,
- clinics,
- critical care units,
- computerized axial tomography equipment (CATs),
- chemotherapy hoods,
- cellular phones,
- chairs,
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- dental clinics (offices),
- dental curing lights,
- dental operator surfaces,
- desktops,
- diagnostic equipment,
- dialysis clinics (facilities),
- docking stations,
- (blood) (plasma) donation centers,
- doors,
- examination (exam) rooms (areas),
- exam tables,
- emergency rooms (ERs) (areas),
- exterior surfaces of autoclaves,
- exterior surfaces of dialysis machines,
- exterior of glucometers,
- exterior surfaces of (medical) equipment,
- exterior surfaces of magnetic resonance imaging equipment (MRIs),
- (hard, nonporous) edges of privacy curtains,
- eye surgical centers,
- faucets,
- fixtures,
- footboards,
- gurneys,
- handheld electronic devices,
- handles,
- headboards,
- high touch surfaces,
- IV stands (poles) and exterior surfaces of pumps,
- health care facilities,
- high-touch surfaces,

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

- home health care (settings),
- hospices,
- hospitals,
- infant incubators,
- isolettes,
- instrument trays,
- (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs),
- isolation rooms (areas),
- IV stands (poles),
- exterior surfaces of IV pumps,
- laboratories,
- laboratory settings,
- laptops,
- laundry rooms,
- long-term care facilities (homes),
- loupes,
- mammography equipment,
- medical facilities,
- (medical) (physicians') (doctors') offices,
- mobile devices (electronic equipment),
- mobile workstations,
- (neonatal) (newborn) nurseries,
- nursing homes,
- operating rooms (theaters),
- operating room tables, (lights,) (light switches,) (wall mounted controls), (and exterior surfaces of equipment,)
- ophthalmic offices,
- outpatient (surgical) centers (clinics) (OPSCs) (facilities),
- orthopedics,
- pagers,
- patient care (monitoring) equipment,
- patient support and delivery equipment,
- patient rooms,
- phlebotomy trays,
- phones, phone cradles and phone accessories,
- (physical) (patient) therapy rooms,
- procedure rooms,
- pulse oximeters,
- psychiatric facilities,
- radiology (X-Ray) rooms (areas),
- reception areas,
- recovery rooms,
- rehabilitation centers,
- remote (portable) controls (controllers),
- skilled nursing facilities,
- scales,
- sequential compression devices,
- side rails,
- sinks,
- slit lamps,
- (mayo) (instrument) (ring) stands,
- stethoscopes,
- stools,
- stretchers,
- support bars,
- surgery rooms,
- tables, (exam tables),
- tablet PCs,
- telephones,
- exterior surfaces of toilets, (portable toilets,)
- toilet grab bars (handholds),
- traction devices and patient slings,
- exterior surfaces of (PVC) (equipment) tubing,
- urinals,
- waiting rooms (areas),
- walls,
- wash basins,
- wheelchairs,
- weighing devices/equipment,
- X-Ray equipment

[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to pre-clean and/or disinfectant the following semi-critical items prior to terminal sterilization:]

- anesthesia equipment,
- respirators, respiratory equipment, respiratory therapy equipment,
- ultrasound transducers (and/or probes).

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(General Institutional Facilities/Surfaces:)

(Animal/Veterinary Facilities/Animal Housing Facilities):

(Cross-contamination is a major Infection Prevention concern.) (This product has been developed to aid in the reduction of cross-contamination (not only in hospitals (and healthcare facilities), but also) in:)

- exterior surfaces of air vents covers,
- airports,
- animal hospitals,
- animal housing facilities,
- animal treatment facilities,
- animal life science laboratories,
- athletic facilities,
- bathrooms,
- bus (depots) (stations),
- casinos,
- cabinets,
- cages,
- chairs,
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- counters (countertops),
- correctional facilities,
- cruise ships,
- day care centers
- desktops,
- docking stations,
- doors,
- elder care centers
- exercise equipment,
- faucets,
- feeding and watering equipment,
- fixtures,
- floors (flooring),
- food service,
- funeral homes,
- handheld electronic devices,
- handles,
- health clubs,
- high touch surfaces,
- hotels (motels),
- institutions,
- locker rooms,
- kennel runs,
- laptops,
- mobile devices (electronic equipment),
- mobile workstations,
- office buildings,
- pagers,
- pet shops,
- playgrounds,
- phones, phone cradles and accessories,
- public buildings,
- public restrooms,
- recreational facilities,
- retail businesses,
- schools (colleges, and universities),
- sinks,
- stools,
- tables,
- tablet PCs,
- telephones,
- train (depots) (stations),
- transportation terminals (facilities),
- tubs,
- exterior surfaces of toilets,
- urinals,
- veterinary clinics,
- walls,
- wash basins

(It is designed) For (daily) (use) (cleaning) (disinfecting) (on) (of) (medical) (hard, nonporous inanimate (environmental) surface (materials)) (Compatible with): acrylic, baked enamel surfaces, Corian[®], glass, glazed ceramic (tile), glazed porcelain, glazed tile, laminated surfaces, sealed mirror stone, painted surfaces, plastic (surfaces), sealed quarry tiles, sealed granite, sealed marble, stainless steel, finished terrazzo and vinyl.

Not recommended for use on (or) (avoid contact with): aluminum, brass, chipped enamel, clear plastic, copper, finished floors, natural marble, painted surfaces, and silver. (Not for use on soft, porous surfaces such as clothing, fabrics, textiles, paper surfaces, and unfinished wood.)

Note: This product is compatible with the listed materials. If product is intended to be used on other surfaces, it is recommended to test product by applying to a small discrete area to determine compatibility before proceeding with its use.

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This product cleans, disinfects and deodorizes (common) hard, nonporous (hospital) (non-critical) (semi-critical) (medical) surfaces (patient care equipment) in one step (with no rinsing required), pre-cleaning is required when using against *C. diff* and *C. auris*. (Designed for (daily) use on (common) hard, nonporous (materials) (inanimate) (environmental) surfaces (patient care equipment) found in hospitals and other healthcare facilities.) (May be used to clean and disinfect sinks, faucets, fixtures, bathrooms, restrooms, tubs, and showers.) (For non-scratch cleaning of showers, tubs, shower doors and nonporous curtains, and fixtures, urinals, and exterior surfaces of toilets.) It can be used on the following: *[insert any use site(s) from Use Site section]*(found in (health care facilities) (and) (hospitals).) Do not use on glasses, dishes and utensils. In addition, this product will deodorize those areas that are generally hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, and any other areas that are prone to odors caused by microorganisms. (Disinfects, cleans, and deodorizes hard, nonporous surfaces in (restrooms,) (bathrooms,) (toilet areas,) (finished nonporous surfaces behind and under sinks and counters,) (garbage cans and garbage storage areas), and other places where bacterial growth can cause malodors.)

Note: Prior to use on electronic equipment or components, (please) refer to manufacturer's instructions (for appropriate use).

(Clostridium difficile efficacy statements:)

- Effective in 4 minutes against Clostridium difficile (*C. diff*) (*C. difficile*) spores.
- Broad spectrum (Proven) disinfectant (bactericide, *virucide, fungicide) with efficacy against Clostridium difficile (*C. diff*) (*C. difficile*) spores.
- Effective disinfectant cleaner (and Clostridium difficile sporicide) (for use in hospitals, ambulatory care centers, long term care facilities, and other healthcare facilities.)
- May be used as part of a comprehensive approach to Clostridium difficile (*C. diff*) (*C. difficile*) spore control.
- Designed for (killing) (controlling) Clostridium difficile (*C. diff*) (*C. difficile*) spores (on hard nonporous surfaces (and patient care equipment)) in hospitals (and other healthcare facilities).
- Effective (for daily use) against *[insert any organism from list of organisms on this label]* (multi-drug resistant organisms) (MDROs) (and Clostridium difficile (*C. diff*) (*C. difficile*) spores).
- Daily use product with (Clostridium difficile) (*C. diff*) (*C. difficile*) sporicidal disinfectant efficacy which allows for product standardization (reduces (reducing) cleaning complexity) (reduces the number of products needed) (eliminates the need for a separate sporicide).
- Daily defense against (Tough on) Clostridium difficile (*C. diff*) (*C. difficile*) spores.
- Kills Clostridium difficile (*C. diff*) (*C. difficile*) spores in 4 minutes.
- Tested Clostridium difficile (*C. diff*) (*C. difficile*) spores with soil load.

DIRECTIONS FOR USE:

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

(EFFICACY CLAIMS:)

^(†)BACTERICIDAL:

[Note to reviewer: Only one of the following statements will be on the product label]

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

(in the presence of 5% serum load and 1 (one) minute contact time on hard, non-porous environmental surfaces.) - or - (1 minute contact time) - or - (1 minute)		
(^(†)Bactericidal Activity):		
(Organism)	(ATCC Number)	(Contact Time)
^(†) <i>Staphylococcus aureus</i>	(ATCC 6538)	1 minute
^(†) <i>Pseudomonas aeruginosa</i>	(ATCC 15442)	1 minute
^(†) <i>Salmonella enterica</i> , formerly known as <i>Salmonella choleraesuis</i>	(ATCC 10708)	1 minute
^(†) <i>Campylobacter jejuni</i>	(ATCC 29428)	1 minute
^(†) <i>Escherichia coli</i>	(ATCC 11229)	1 minute
^(†) <i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
^(†) <i>Listeria monocytogenes</i>	(ATCC 19117)	1 minute
^(†) <i>Stenotrophomonas maltophilia</i>	(ATCC 25596)	1 minute
^(†) <i>Streptococcus pyogenes</i>	(ATCC 19615)	1 minute
(^(†)Antibiotic-Resistant (Strains of) Bacteria [list below]):		
^(†) <i>Acinetobacter baumannii</i> , Multi-Drug Resistant (MDRO)	(ATCC 19606)	1 minute
^(†) <i>Enterobacter aerogenes</i> , Multi-Drug Resistant (MDRO)	(ATCC 29751)	1 minute
^(†) <i>Enterococcus faecalis</i> , Vancomycin Resistant (VRE)	(ATCC 51575)	1 minute
^(†) <i>Enterococcus faecium</i> , Multi-Drug Resistant	(ATCC 51559)	1 minute
^(†) <i>Escherichia coli</i> , Carbapenem Resistant (CRE)	(CDC 81371)	1 minute
^(†) <i>Escherichia coli</i> , Extended-Spectrum Beta-lactamase (ESBL) producing	(ATCC BAA-196)	1 minute
^(†) <i>Klebsiella pneumoniae</i> , Carbapenem Resistant (CRKP)	(ATCC BAA-1705)	1 minute
^(†) <i>Klebsiella pneumoniae</i> , Extended-Spectrum Beta-lactamase (ESBL) producing	(ATCC 700603)	1 minute
^(†) <i>Klebsiella pneumoniae</i> , Multi Drug Resistant	(ATCC 51503)	1 minute
^(†) <i>Klebsiella pneumoniae</i> , NDM-1 positive	(CDC 1000527)	1 minute
^(†) <i>Pseudomonas aeruginosa</i> , Multi-Drug Resistant Metallo-beta lactamase (MBL) positive	(CDC 2012059)	1 minute
^(†) <i>Staphylococcus aureus</i> , Methicillin Resistant (MRSA)	(ATCC 33592)	1 minute
^(†) <i>Staphylococcus aureus</i> , Community Acquired Methicillin Resistant (CA-MRSA)	(NARSA NRS 384)(Genotype USA300)	1 minute
*VIRUSES (*VIRUCIDAL) (*VIRUCIDAL ACTIVITY): [Note to reviewer: Only one of the following statements will be on the product label]		
(in the presence of 5% serum load and 1 minute contact time on hard, non-porous environmental surfaces.) - or - (1 minute contact time) - or - (1 minute)		
(*Viruses (*Virucidal) (*Virucidal Activity)):		
(Organism)	(ATCC Number)	(Contact Time)
*Adenovirus Type 2	(ATCC VR-846, Strain Adenoid 6)	1 minute
*Adenovirus Type 4	(ATCC VR-4, Strain RI-67)	1 minute

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

*Hepatitis A Virus	(Strain HM-175)	1 minute
*Hepatitis B Virus (HBV)		1 minute
*Hepatitis C Virus (HCV)		1 minute
*Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734, Strain G)	1 minute
*Human Coronavirus, (ATCC VR-740)	(ATCC VR-740, Strain 229E)	1 minute
*Human Immunodeficiency Virus, HIV-1 (AIDS Virus)	(Strain HTLV-III _B .)	1 minute
*Influenza A Virus (2009-H1N1) (Novel H1N1)	(Strain A/Mexico/4108/2009, CDC # 2009712192)	1 minute
*Norovirus, (Feline Calicivirus as the surrogate)	(Feline Calicivirus, ATCC VR-782 as the surrogate)	1 minute
*Poliovirus Type 1	(ATCC VR-1000)	1 minute
*Respiratory Syncytial Virus (RSV)	(ATCC VR-26, Strain Long)	1 minute
*Rhinovirus, Type 37	(ATCC VR-1147, Strain 151-1)	1 minute
*Rotavirus WA		1 minute
(*Veterinary Viruses:)		
*Avian Influenza A (H5N1)	(Strain VNH5N1-PR8/CDC-RG, CDC # 2006719965)	1 minute
*Canine Parvovirus	(ATCC RVR-2017, Strain Cornell-780916-80)	1 minute
*Feline Calicivirus	(ATCC VR-782)	1 minute
BIOFILM: (1 minute contact time) (1 minute)		
(Organism)	(ATCC Number)	(Contact Time)
<i>Staphylococcus aureus</i>	(ATCC 6538)	1 minute
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	1 minute
([±]) FUNGICIDAL: [Note to reviewer: Only one of the following statements will be on the product label] (This product is fungicidal against the pathogenic fungi, <i>Trichophyton interdigitale</i> (formerly <i>Trichophyton mentagrophytes</i>) (ATCC 9533) (the fungi that may cause Athlete's Foot) when used as directed on hard, non-porous surfaces.) - or - (in the presence of 5% serum load and 1 minute contact time on hard, non-porous environmental surfaces.) - or - (1 minute contact time) - or - (1 minute)		
(Organism)	(ATCC Number)	(Contact Time)
([±]) <i>Trichophyton interdigitale</i> (formerly <i>Trichophyton mentagrophytes</i>)	(ATCC 9533)	1 minutes
([±]) <i>Aspergillus niger</i>	(ATCC 6275)	1 minute
([±]) <i>Candida albicans</i>	(ATCC 10231)	1 minute
([±]) <i>Candida auris</i>	(CDC AR-0381)	1 minute

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

(Emerging Pathogens Claims)

(Avert Sporidical Disinfectant) (Avert) (This product) meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

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

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped Viruses	One of the following: Canine Parvovirus (ATCC VR-2017) Feline Calicivirus Hepatitis A Poliovirus Type 1 (ATCC VR-1562) Adenovirus Type 2 (ATCC VR-846) Adenovirus Type 4 (ATCC VR-4) Rotavirus (Strain WA)
Large, Non-Enveloped Viruses	One of the following: Canine Parvovirus (ATCC VR-2017) Feline Calicivirus Hepatitis A Poliovirus Type 1 (ATCC VR-1562)
Small, Non-Enveloped Viruses	Two of the following: Canine Parvovirus (ATCC VR-2017) Feline Calicivirus Hepatitis A Poliovirus Type 1 (ATCC VR-1562)

(Avert Sporidical Disinfectant) (Avert) (This product) has demonstrated effectiveness against viruses similar to *[insert name of emerging virus]* on hard, non-porous surfaces. Therefore, (Avert Sporidical Disinfectant) (Avert Sporidical Disinfectant) (Avert) (This product) can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es) from list above]* on (hard, non-porous surfaces). Refer to the (CDC or OIE) website at *[insert pathogen-specific website address]* for additional information.

[Insert name of illness / outbreak] is caused by *[insert name of emerging virus]*. (Avert Sporidical Disinfectant) (Avert) (This product) kills similar viruses and therefore can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es)]* on (hard, non-porous surfaces). Refer to the (CDC or OIE) website at *[insert pathogen-specific website address]* for additional information.

For Removal of Biofilm:

1. Pre-clean surfaces to remove gross or visible soil.
2. Thoroughly wet pre-cleaned surface.
3. Allow surface to remain wet for 1 minute.
4. Wipe dry, or allow surface to air dry.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer)

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) (kills) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors). (Deodorizes by killing microorganisms that cause unpleasant (offensive) odors on hard nonporous surfaces (where odors can develop).) (This product will deodorize hard nonporous surfaces (and places) (in or on) *[insert any of the above listed use sites and/or surfaces]* (where bacteria growth can cause (obnoxious) (offensive) (malodors)) (where odors can develop).) This product deodorizes areas that are hard to keep fresh smelling.

(See reference sheet for a complete list of claims (and additional directions for use.))

[Note to Reviewer: For labels that list medical devices as defined by the FDA.]

(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 blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

Not recommended for use on (or) (avoid contact with): aluminum, brass, chipped enamel, clear plastic, copper, finished floors, natural marble, painted surfaces, and silver.

Note: Prior to use on electronic equipment or components, unplug from electrical outlet, and ensure equipment is powered off.

Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

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

Cleaning Procedure: Pre-clean surfaces to remove soil and filth before disinfection by application with a clean cloth, mop, and/or sponge saturated with the sporicidal disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. 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 of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials 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.

Disinfection Procedure for *C. difficile*: Spray product to hard, nonporous inanimate (environmental) surfaces. Ensure surfaces are thoroughly wet. Allow surfaces to remain wet for 4 (four) minutes. Wipe surfaces (and let air dry).

For Use as a One-Step Cleaner/Disinfectant, Deodorizer, and Fungicide:

See special instructions for *C. diff* and *C. auris* claims.

1. Pre-clean-visibly soiled areas.
2. Spray product to hard, nonporous inanimate (environmental) surfaces.
3. Ensure surfaces are thoroughly wet. (Wipe or rub with (lint-free)(microfiber)(cleaning)cloth, (disposable wiper,)(sponge,)(brush,)(or)(hand mop)to spread product on surface.)
4. Allow surface to remain wet for one (1) minute.
5. Wipe dry, or allow surface to air dry.

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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 Materials 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.

***Kills HBV, HCV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) and 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 Hepatitis B Virus, Hepatitis C Virus and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable protective gloves (latex, nitrile, or vinyl gloves), gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

Contact Time: Allow surface to remain wet for 1 minute. For *Clostridium difficile* spores, allow to remain wet for 4 minutes.

Disposal of Infectious Materials: Blood and other body fluids, cleaning materials and clothing must be autoclaved and disposed of according to Federal, state and local regulations for infectious waste disposal.

Animal Housing Facilities (Including Veterinary Clinics and Kennels): For cleaning and disinfecting the following hard, nonporous surfaces: 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 pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces by spraying with product, allowing to remain wet for 1 (one) minute.
5. Spray handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure. Allow to remain wet for 1 (one) minute.
6. Ventilate buildings and other closed spaces.
7. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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For Use to Clean and Disinfect Life Science Laboratory Surfaces:

1. Pre-clean heavily soiled areas.
2. Apply product to hard, nonporous inanimate (environmental) surfaces. Ensure surfaces are thoroughly wet.
3. Allow the surface to remain wet for 1 (one) minute.
4. Wipe surfaces dry (or) (rinse) (and allow to air dry).

For Use as a Cleaner:

Apply product to hard, nonporous surfaces. Wipe surfaces dry (or) (allow to air dry).

To Clean/Remove Soap Scum:

Spray on soils and wipe clean (with a dry paper towel, dry disposable wiper, lint-free cloth, microfiber cloth, or sponge). (For best results, use a dry paper towel, dry disposable wiper, lint-free cloth, microfiber cloth, or sponge.) No rinsing necessary. Repeat for heavily soiled areas. For stubborn stains, heavily soiled areas or tougher jobs, allow product to penetrate soil (dirt,) (and) (or) (soap scum) before wiping. (For best results, use regularly to prevent (dirt,) (soil,) (and) (or) (soap scum) build-up.)

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage, disposal, or cleaning of equipment.

STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes skin burns and eye damage. Do not get in eyes, on skin, or on clothing. Wear chemical-splash goggles, chemical-resistant gloves and protective footwear when handling this product. In case of inadequate ventilation wear respiratory protection, such as a filtering face piece respirator. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Keep away from clothing and other combustible materials. Do not mix with any other product or chemical.

EPA Reg. No. 70627-72

EPA Est. No.

(Lot code letters indicate establishment number.)

(Manufactured)(Distributed)(by)(for):

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REFERENCE SHEET

Avert Sporicidal Disinfectant Cleaner

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
(Insert verbatim any set(s) of Directions for Use from above.)

(Insert verbatim any set(s) of Claims from above.)

See the container label for use directions and additional required information for First Aid, Precautionary Statements, and Storage and Disposal.

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