



VELTEK ASSOCIATES, INC.

DECON-SPORE 200 Plus

Fungicidal - Sporicidal - Disinfectant - Virucide · Kills *Clostridium difficile* Endospores

Product Description

DECON-SPORE 200® Plus is an EPA registered Peracetic Acid and Hydrogen Peroxide solution that is for use as a broad spectrum sanitizer, disinfectant, virucide, fungicide, sporicide, cleaner, and deodorizer in the hospital and healthcare industries. **DECON-SPORE 200 Plus** use solution cleans, disinfects, and deodorizes hard, non-porous hospital/medical surfaces in one step with no rinsing required. This product quickly removes dirt, grime, blood, and other organic matter commonly found in hospitals, in healthcare facilities, and on medical surfaces. When used as directed, EPA A.O.A.C. testing has demonstrated that **DECON-SPORE 200 Plus** kills *Clostridium difficile* spores in 3 minutes.



DECON-SPORE 200 Plus is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, former Class 100). Each lot of **DECON-SPORE 200 Plus** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-SPORE 200 Plus** is delivered each time with lot specific Certificate of Analysis and Certificate of Sterility.

DECON-SPORE 200 Plus is available as a 2.3% sporicidal dilution ratio (3 oz/gallon) in a 16 oz trigger spray and 1 gallon container. Both 16 oz and 1 gallon containers are sterile and come in our one-step, ready-to-use, SimpleMix® System. Each sterile container of **DECON-SPORE 200 Plus** is individually double bagged sterile in easy tear packaging.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

DECON-SPORE 200 Plus – Peracetic Acid and Hydrogen Peroxide Solution

Certificate of Analysis	Specifications
Appearance:	Clear, water white
IR:	Match Reference
Hydrogen Peroxide:	25.60 - 29.40%
Peroxyacetic Acid:	5.25 – 6.40%
Expiration Period:	1 year from manufacture date

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Features and Benefits

- EPA Registered; EPA Registration Number: 1677-129-68959
- Each sterile container is individually double bagged in easy tear packaging
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility
- Available in the convenient, one-step, ready-to-use, SimpleMix® System
- Cleans, disinfects, and deodorizes hard, non-porous hospital/medical surfaces in one step with no rinsing required
- One-step hospital use germicidal disinfectant cleaner and deodorant
- Quickly removes dirt, grime, blood, and other organic matter commonly found in hospitals, in healthcare facilities, and on medical surfaces
- Can be used to disinfect floors, walls and other hard, non-porous surfaces such as plastic, stainless steel, or glass
- Proven one-step disinfectant-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination
- One-step fungicide at 3 oz per gallon of water; treated surfaces must remain wet for 10 minutes
- Effective against Multidrug Resistant Organisms (MRDOs) †
- Designed for killing *C. diff* spores on pre-cleaned, hard non-porous surfaces in hospitals; kills in 3 minutes
- Only non-bleach *C. diff* spores concentrate available
- Tough on *C. diff* spores but easy on surfaces and designed for daily use

Uses

- Hospitals, healthcare facilities, and other medical surfaces
- Hard non-porous surfaces
- Floors, walls
- Tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers
- Tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass
- Not for use on food contact surfaces, medical devices, or medical equipment

The SimpleMix® System Technology Alternative

Veltek Associates, Inc. has developed the patented SimpleMix System Technology to eliminate measuring and additional containers. It provides for the transfer of the sterile concentrated disinfectant or sporicide and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System Gallon and 16 oz systems provide a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the VAI WFI Quality Water. The 16 ounce side container houses the concentrate and the bottom reservoir houses the VAI WFI Quality Water. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. The solution and water mix together. The system design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

Product Labeling and Directions for Use

SEE PRODUCT CASE LABEL FOR FULL FIRST AID INSTRUCTIONS, PRECAUTIONARY STATEMENTS, AND STORAGE AND DISPOSAL INSTRUCTIONS.

EMERGENCIES: In case of emergency, call 1-866-928-0789 (toll free) 24 hours a day from the USA, Canada, or Mexico.

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

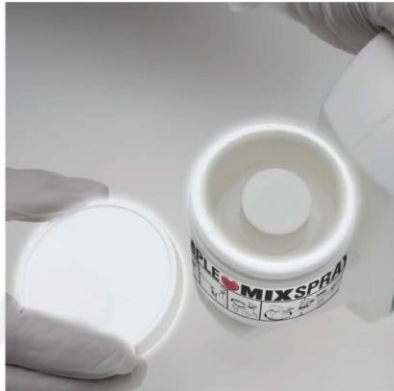
SIMPLEMIX USE DIRECTIONS

SIMPLEMIX[®] 16 oz/473 mL Aseptic Mixing System

For the Exact Formulation of 16 oz/473 mL Disinfectants and Sporicides

Ready-to-Use Mixing Instructions

- 1) To prepare use solution, open cap.
- 2) Peel off inner seal by grasping tab at far edge and pulling off.



- 3) Firmly push small, inner container all the way down.



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



SIMPLEMIX[®] 1 Gallon/3.79 L Aseptic Mixing System

For the Exact Formulation of 1 Gallon/3.79 L Size Disinfectants and Sporicides

Ready-to-Use Mixing Instructions

- 1) To prepare use solution, open cap.
- 2) Peel off inner seal by grasping tab at far edge and pulling off.



- 3) Firmly push small, inner container all the way down.



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Open small side spout and peel off inner seal, as above.



- 7) Pour solution from small side spout onto surfaces to be treated or alternate containers.



- 8) Follow directions for use on label.

SANITIZATION

SANITIZING NON-FOOD CONTACT SURFACES

Prior to sanitizing, remove gross soil particles and then wash with a detergent solution followed by a potable water rinse. Sanitize hard, non-porous, non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1 fl. oz. DECON-SPORE 200 Plus per 8 gal water. At this concentration the product is effective against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), *Escherichia coli* (ATCC 11229), *Listeria monocytogenes* (ATCC 7644), *Salmonella typhimurium* (ATCC 13311), *Pseudomonas aeruginosa* (ATCC 15442), and *Saccharomyces cerevisiae* (ATCC 834). It is also effective against organisms found in the brewing industry, *Pediococcus damnosus* (ATCC 25248) and *Lactobacillus malefermentans* (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. No rinse necessary.

DISINFECTION

DECON-SPORE 200 Plus disinfects as it cleans in one operation. **DECON-SPORE 200 Plus** can be used to disinfect floors, walls and other hard, non-porous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of Use: Housekeeping services; hospitals, academic facilities, veterinary facilities, animal care facilities, industrial facilities, dietary areas, office buildings, recreations facilities, retail and wholesale establishments. Not for use on food contact surfaces, medical devices or medical equipment.

COMBINATION GENERAL DISINFECTION AND CLEANING

DECON-SPORE 200 Plus is effective against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Salmonella enteritidis* (ATCC 13076), *Salmonella typhimurium* (ATCC 13311), *Proteus vulgaris* (ATCC 13315), *Streptococcus pyogenes* (ATCC 19615) and *Histoplasma capsulatum** at 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons of water) in hard (500 ppm as CaCO₃), 5% blood serum and dried soap film residue on hard, non-porous surfaces. For heavily soiled areas a pre-cleaning step is required. Prepare a disinfecting and cleaning solution by diluting 4 fl. oz.

DECON-SPORE 200 Plus in 8 gallons of water (0.4% v/v). Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, and then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

*Not tested in the presence of soap film residue.

VIRUCIDAL

At 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons of water) **DECON-SPORE 200 Plus** is effective against Influenza B/Taiwan/2/62 Virus, Influenza A Virus (H3N2) and Influenza A Virus (H1N1) when used at (20°C) (68°F) with a 10 minute contact time in the presence of 500 ppm hard water and organic soil. Apply as directed under disinfection.

(**DECON-SPORE 200 Plus** is effective against Respiratory Syncytial Virus (Strain Long) [RSV], Vaccinia Virus (Strain WR) [Pox Virus], Norovirus (Feline Calicivirus tested surrogate), Rhinovirus (Type 37, Strain 151-1), Rotavirus (Strain WA), and Adenovirus Type 5 at a dilution of 3 fl. oz./ gallon of water and a contact time of 3 minutes. At 3 fl. oz./ gallon of water **DECON-SPORE 200 Plus** is effective against Poliovirus (Type 1, Chat strain) with a contact time of 10 minutes. (Apply as directed under disinfection.))

HOSPITALS/HEALTHCARE FACILITIES

This product use solution cleans, disinfects and deodorizes hard, non-porous hospital/medical surfaces in one step with no rinsing required.

This product use solution is a one-step hospital use, germicidal, disinfectant, cleaner and deodorant designed for general cleaning and disinfecting and deodorizing of hard, non-porous inanimate surfaces. Quickly removes dirt, grime, blood and

other organic matter commonly found in hospitals, healthcare facilities, and on medical surfaces. It also eliminates odors, leaving surfaces smelling clean and fresh. Use where odors are a problem.

This product use solution is a broad spectrum, germicidal, sporicidal, disinfectant cleaner and deodorizer designed for general cleaning and disinfecting and deodorizing of hard, non-porous surfaces and is efficacious against *Clostridium difficile* (*C. difficile*) (*C. diff*) endospores. Quickly removes dirt, grime, blood and other organic matter commonly found in hospital, in healthcare facilities, and on medical surfaces.

This product can be used where housekeeping is of prime importance in controlling the hazard of cross-contamination between treated hard, non-porous surfaces.

SPORICIDAL

Clostridium difficile

This product kills and/or inactivates spores of *Clostridium difficile* on hard, non-porous surfaces. Fecal matter/waste must be thoroughly pre-cleaned from surfaces/objects. This cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. This product is effective against *Clostridium difficile* endospores when diluted at 3 fl. oz product per gallon in 400 ppm hard water and applied to hard, non-porous surfaces with a clean cloth, mop, and/or sponge so as to wet all surfaces thoroughly. Leave surface wet for 3 minutes, and then remove solution with a clean wet mop, cloth or wet vacuum pickup.

SPECIAL INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST *Clostridium difficile* SPORES

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

Contact time: Leave surface wet for 3 minutes with 3 fl. oz. per gallon use solution.

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 disinfectant product. This cleaning may be accomplished with any cleaning solution, including this 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.

Organism	ATCC Number
3 minute contact time	
<i>Clostridium difficile</i> *	ATCC 700792

*Not tested in presence of soil load in accordance with US EPA Guidance for the Efficacy Evaluation of Products with Sporicidal Claims against *Clostridium difficile*

FUNGICIDAL

This product kills *Trichophyton interdigitale* (formerly *Trichophyton mentagrophytes*) (the athlete's food fungus) in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

This product is a one-step fungicide at 3 fl. oz. per gallon of water. Treated surfaces must remain wet for 10 minutes.

DISINFECTION OF PHARMACEUTICAL AND COSMETIC SURFACES

DECON-SPORE 200 Plus is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities. This product is effective against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) at 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons of water) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue. For heavily soiled areas a pre-

cleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

Efficacy Chart

DECON-SPORE 200 Plus – Peracetic Acid and Hydrogen Peroxide Solution		
Organism	ATCC	Contact Time
Sanitizing Non-Food Contact Surfaces; Dilution: 1 fl. oz. / 8 gal. of water		
<i>Enterobacter aerogenes</i>	ATCC 13048	5 min
<i>Escherichia coli</i>	ATCC 11229	5 min
<i>Lactobacillus malefermentans</i>	ATCC 11307	5 min
<i>Listeria monocytogenes</i>	ATCC 7644	5 min
<i>Pediococcus damnosus</i>	ATCC 25248	5 min
<i>Pseudomonas aeruginosa</i>	ATCC 15442	5 min
<i>Saccharomyces cerevisiae</i>	ATCC 834	5 min
<i>Salmonella typhimurium</i>	ATCC 13311	5 min
<i>Staphylococcus aureus</i>	ATCC 6538	5 min
General Cleaning & Disinfecting; Dilution: 2 fl. oz. / 4 gal. to 5 fl. oz. / 4 gal. of water		
<i>Histoplasma capsulatum</i>	-	10 min
<i>Proteus vulgaris</i>	ATCC 13315	10 min
<i>Salmonella enterica</i>	ATCC 10708	10 min
<i>Salmonella enteritidis</i>	ATCC 13076	10 min
<i>Salmonella typhimurium</i>	ATCC 13311	10 min
<i>Staphylococcus aureus</i>	ATCC 6538	10 min
<i>Streptococcus pyogenes</i>	ATCC 19615	10 min
Hospital Disinfection; Dilution: 2 fl. oz. / 4 gal. to 5 fl. oz. / 4 gal. of water		
† <i>Acinetobacter baumannii</i> – MDR	ATCC BAA 1605	3 min
† <i>Enterococcus faecalis</i> – VRE	ATCC 51299	3 min
† <i>Escherichia coli</i>	ATCC BAA 196	3 min
† <i>Klebsiella pneumoniae</i> – KPC	ATCC BAA 1705	3 min
† <i>Staphylococcus aureus</i> – CA-MRSA	ATCC BAA 1556	3 min
† <i>Staphylococcus aureus</i> – CA-MRSA	ATCC BAA 1683	3 min
† <i>Staphylococcus aureus</i> – MRSA	ATCC BAA 33592	3 min
† <i>Staphylococcus aureus</i> – VISA	ATCC 700788	3 min
† <i>Staphylococcus epidermidis</i> – MRSE	ATCC 51625	3 min

Virucidal; Dilution: 2 fl. oz. / 4 gal. to 5 fl. oz. / 4 gal. of water		
*Adenovirus Type 5	-	3 min
*Influenza A Virus (H1N1)	-	10 min
*Influenza A Virus (H3N2)	-	10 min
*Influenza B/Taiwan/2/62 Virus	-	10 min
*Norovirus (Feline Calicivirus tested surrogate)	-	3 min
*Poliovirus (Type 1, Chat strain)	-	10 min
*Respiratory Syncytial Virus (Strain Long) [RSV]	-	3 min
*Rhinovirus (Type 37, Strain 151-1)	-	3 min
*Rotavirus (Strain WA)	-	3 min
*Vaccinia Virus (Strain WR) [Pox Virus]	-	3 min
Sporicidal; Dilution: 3 fl. oz / 1 gal. of water		
<i>Clostridium difficile</i> **	ATCC 700792	3 min
Fungicidal; Dilution: 3 fl. oz / 1 gal. of water		
<i>Trichophyton interdigitale</i>	-	10 min

† Multi-Drug Resistant Organisms [MDROs]

**Not tested in presence of soil load in accordance with US EPA Guidance for the Efficacy Evaluation of Products with Sporicidal Claims against *Clostridium difficile*

Ordering Information

DECON-SPORE 200 Plus – Peracetic Acid and Hydrogen Peroxide Solution		
Part Number	Description	Qty/cs
DS200-06-16Z-03	DECON-SPORE 200 Plus, 16 oz SimpleMix, Attached Trigger, 3 oz/gal Dilution, Sterile	12
DS200-04-2/5ZA	DECON-SPORE 200 Plus, 1 Gallon SimpleMix, 3 oz/gal Dilution, Sterile	4



DS200-04-2/5ZA



DS200-06-16Z-03

Additional Documentation

The following documentation is available upon request

- Specific product testing reports
- Product case and container labels
- Safety Data Sheet
 - **Concentrate SDS # DS200-0397-01-01**
 - **2.3% (3 oz/gal) Use Dilution SDS # VEL-145**
- Sample lot specific certificates including Certificate of Analysis and Certificate of Sterility



Veltek Associates, Inc. covers every aspect of [cleaning](#) and [decontaminating](#) necessary for full compliance to USP including consultation from industry experts on setting up and maintaining aseptic processes during the compounding of sterile products. VAI has a complete line of sterile cleaning agents and disinfectants with easy to use sterilizable cleaning systems. The [Core2Clean® Plus](#) System addresses the cleaning and disinfection of environmental surface areas. The [SimpleMix®](#) System provides easy-to-use disinfectants in a pre-measured container system. In addition, VAI offers complete line of sterile, individually packaged, [saturated wipes](#).

To further address the requirements, VAI provides a unique [innovative gowning system](#) to address aseptic gowning requirements. Furthermore, the easy to use [SMA air samplers](#) are an accepted industry standard that simplifies microbial air testing in aseptic compounding areas. As the compounding pharmacy industry moves forward to require greater control of environmental production areas, be assured VAI is one step ahead with innovation and support.

Please visit our website www.sterile.com or call 1-888-4-STERILE for more information regarding our products and services for USP <797> compliance. Patents: www.sterile.com/patents.