

VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-SPORE 200® Plus

Peracetic Acid Hydrogen Peroxide Solution Sterile Cleanroom Formula



16FEB2023 Copyright © 2023 Veltek Associates, Inc.



TABLE OF CONTENTS

PRODUCT OVERVIEW	3
Quality and Manufacturing	3
Product Uses	3
Features and Benefits	4
SIMPLEMIX®	5
The SimpleMix System Technology Alternative	5
SimpleMix Directions for Use	5
CHEMICAL SPECIFICATIONS	10
ORDERING INFORMATION	11
LABELING	12
VAI's Product Label Colors	12
Product Labeling	
Additional Instructions for Use	
Efficacy Claims	24
ADDITIONAL DOCUMENTATION	27



DECON-SPORE 200 Plus 16 oz SimpleMix Disinfectant DS200-06-16Z-02



PRODUCT OVERVIEW

VAI® manufactures an EPA Registered Peracetic Acid and Hydrogen Peroxide solution that is for use as a sanitizer, broad spectrum disinfectant, virucide, sporicide, sterilant, fungicide, cleaner, and deodorizer. **DECON-SPORE 200 Plus** is a proven "one-step" disinfectant – virucide that cleans as it disinfects in one operation and has been shown to be effective in water up to 500 ppm hardness in the presence of 5% serum contamination.*

DECON-SPORE 200 Plus is recommended for use in the pharmaceutical, biotechnology, medical device, hospital, healthcare, and lab animal research industries. **DECON-SPORE 200 Plus** has been developed for use in cleaning rotation cycles where hard surface disinfectants are essential to maintaining a clean environment.

Sanitizer – Disinfectant with Sporicidal Activity – Virucide* – Fungicide – Sterilant – Deodorizer – Cleaner – Kills *Clostridioides difficile* Endopsores*

DECON-SPORE 200 Plus is available in four dilution ratios: as a concentrate, as a disinfectant dose, as a sporicidal dose, and at a 3 oz/gallon dilution dose. **DECON-SPORE 200 Plus** 3 oz/gallon dilution (2.3%) dose is a one-step hospital use germicidal disinfectant, cleaner, and deodorant designed for general cleaning and disinfecting of hard, non-porous inanimate surfaces when used according to disinfectant directions.

DECON-SPORE 200 Plus is available in multiple container sizes including in our patented SimpleMix system that allows for fresh and safe dilutions every single time. For more information on our SimpleMix system, see "SIMPLEMIX®" on page 5.

* When used as directed

Quality and Manufacturing

- Filled in ISO 5 cleanroom (Grade A)
- 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

Product Uses

- Floors, walls, tables, chairs, countertops, sinks, shelves, racks, carts
- Filling equipment, packaging equipment
- Tiles, linoleum, vinyl, glazed porcelain, plastic, stainless steel, glass



Features and Benefits

- EPA Registered; EPA Registration Number: 1677-129-68959
- Each sterile container is individually bagged in easy tear packaging
- Each sterile container of SimpleMix is individually double bagged in easy tear packaging
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data tested to current USP compendium
- Available in four dilution ratios: as a concentrate, as a disinfectant dose, as a sporicidal dose, and at a 3 oz/gallon dilution dose
- All non-concentrate dilutions are available in the convenient, one-step, ready-to-use, SimpleMix® System made with USP Water for Injection (< 0.25 EU/mL)
- Concentrated broad-spectrum disinfectant-virucide with efficacy against Clostridiodes difficile
- Disinfects as it cleans in one operation when used according to disinfection directions
- Designed for the sterilization of manufacturing, filling, and packaging equipment in aseptic processes
- Proven one-step disinfectant-virucide which is effective in water up to 500 ppm hardness in the presence of 5% serum contamination
- Removes dirt, grime, blood and other organic matter commonly found in healthcare facilities
- At 3 oz./gal, this product is effective in 5 minutes against *Clostridioides difficile* (formerly known as *Clostridium difficile*), when used as directed



0.8 oz Concentrate Unit Dose Sporicidal DS200-03-1ZA



1 Gallon Concentrate DS200-02A



2 oz Concentrate Unit Dose Disinfectent DS200-03-2ZA



SIMPLEMIX®

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 concentrate 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 provides a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The small chamber holds the concentrate, and the bottom reservoir contains 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. 200L SimpleMix systems are activated through a hose and valve system connecting the cubicontainer of concentrate to the VAI WFI Quality Water. The SimpleMix System design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

SimpleMix Directions for Use

How to use the SimpleMix Trigger Spray

- 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 completely 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.

For pictorial directions, see page 7.

How to use the SimpleMix Gallon Size

- 1. To prepare use solution, open cap.
- 2. Peel off inner seal by grasping far edge and pulling off.
- 3. Firmly push small, inner container completely 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.

For pictorial directions, see page 8.



How to use the SimpleMix 200 Liter Drum

- 1. Close all valves.
- 2. Uncoil hoses.
- 3. Connect center hose to pump between X and Y.
- 4. Open valve 1, then valve 2, then valve 4.
- 5. START pump to empty cubic container.
- 6. When cubic container is empty, turn pump OFF.
- 7. Close valve 1 and valve 2.
- 8. Open valve 6 and valve 5.
- 9. Re-start pump and mix 15 minutes
- 10. STOP pump.
- 11. Close valve 4.
- 12. To dispense Open valves 3 and 7. Run pump only when dispensing.
- 13. Follow directions for use on label.

For pictorial directions, see page 9.



SimpleMix Trigger 16 oz Sporicidal DS200-06-16Z-01



SimpleMix Gallon

1 Gallon Disinfectent

DS200-04-1/2ZA



SimpleMix Drum
200L Sporicidal
DS200-10-200L-SD-CI



SimpleMix Trigger Spray

SIMPLE 16 oz/473 mL Aseptic Mixing System

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

Ready-to-Use Mixing Instructions

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



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



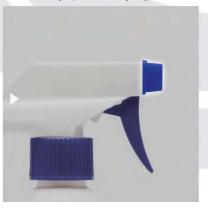
4) Replace cap and tighten.



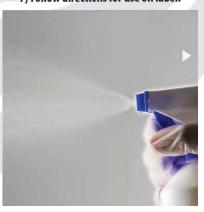
5) Slowly swirl for 15 seconds.



6) Move spray nozzle to open position.



7) Follow directions for use on label.





SimpleMix Gallon

SIMPLE 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.





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



8) Follow directions for use on label.



SimpleMix Drum

SIMPLE 200 L Aseptic Mixing System

For Large Scale Aseptic Manufacturing Environments

Ready-to-Use Mixing Instructions

Remove drum from double-bag packaging.



Remove cubic container from top of drum. 1) Close all valves. 2) Uncoil hoses.



5) START pump to empty cubic container.6) When cubic container is empty, turn

3) Connect center hose to pump between X and Y.



4) Open valve 1, then valve 2, then valve 4.



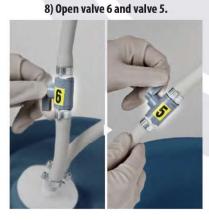
pump OFF.



9) Re-start pump and mix 15 minutes. 10) Stop pump.



11) Close valve 4. 12) To dispense- Open valves 3 and 7. Run pump only when dispensing.







13) Follow directions for use on label.



CHEMICAL SPECIFICATIONS

DECON-SPORE 200 Plus – Peracetic Acid and Hydrogen Peroxide Solution		
Appearance	Clear, water white	
IR	Match reference	
Hydrogen Peroxide	25.60 - 29.40%	
Peroxyacetic Acid	5.25 - 6.40%	
Physical state	Liquid	
Appearance	Clear	
Color	Colorless	
Odor	Pungent	
Expiration Period	1 year from manufacture date	

Sources: Certificate of Analysis, Certificate of Sterility, SDS



SimpleMix Trigger 16 oz Sporicidal DS200-06-16Z-01



SimpleMix Trigger 16 oz Disinfectant DS200-06-16Z-02



SimpleMix Trigger

16 oz / 3 oz per gallon Dilution

DS200-06-16Z-03



ORDERING INFORMATION

Part number	Description	Qty/cs
DS200-01A	DECON-SPORE, 1 Gallon Concentrate, Non-Sterile	4
DS200-02A	DECON-SPORE, 1 Gallon Concentrate, Sterile	4
DS200-03-1ZA	DECON-SPORE, 0.8 oz Concentrate, Unit Dose, Sterile (sporicidal w/ 16 oz of water)	24
DS200-03-2ZA	DECON-SPORE, 2 oz Concentrate, Unit Dose, Sterile (disinfectant w/ 4 gal of water)	24
DS200-03-13ZA	DECON-SPORE, 13 oz Concentrate, Unit Dose, Sterile (sporicidal w/ 2 gal of water)	12
DS200-04-1/2ZA	DECON-SPORE, 1 Gallon SimpleMix, Disinfectant Dose, 1:256, Sterile	4
DS200-04-2/5ZA	DECON-SPORE, 1 Gallon SimpleMix, 3 oz/gal Dilution, Sterile	4
DS200-04A	DECON-SPORE, 1 Gallon SimpleMix, Sporicidal Dose, 1:20, Sterile	4
DS200-05-1/2ZA	DECON-SPORE, 1 Gallon SimpleMix, Disinfectant Dose, 1:256, Non-Sterile	4
DS200-05A	DECON-SPORE, 1 Gallon SimpleMix, Sporicidal Dose, 1:20, Non-Sterile	4
DS200-06-16Z-01	DECON-SPORE, 16 oz SimpleMix, Attached Trigger, Sporicidal Dose, Sterile	12
DS200-06-16Z-02	DECON-SPORE, 16 oz SimpleMix, Attached Trigger, Disinfectant Dose, Sterile	12
DS200-06-16Z-03	DECON-SPORE, 16 oz SimpleMix, Attached Trigger, 3 oz/gal Dilution, Sterile	12
DS200-07-16Z-01	DECON-SPORE, 16 oz SimpleMix, Attached Trigger Sporicidal Dose, Non-Sterile	12
DS200-07-16Z-02	DECON-SPORE, 16 oz SimpleMix, Attached Trigger, Disinfectant Dose, Non-Sterile	12
DS200-10-200L-SD-CI	DECON-SPORE, 200L SimpleMix Drum, Sporicidal Dose, Sterile	1
DS200-11-200L-SD-CI	DECON-SPORE, 200L SimpleMix Drum, Disinfectant Dose, Sterile	1



LABELING

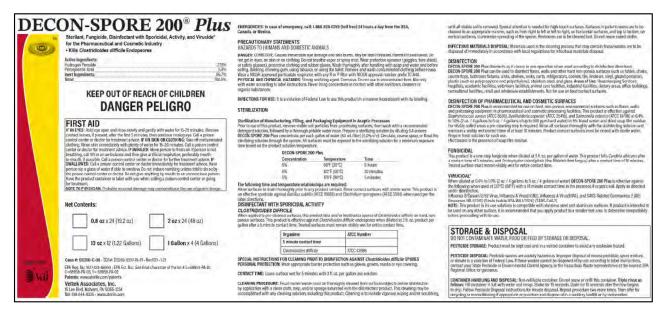
VAI's Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 91%	WHITE	COOL GREY		
DECON-AHOL FORMULA 99%	WHITE	COOL GREY		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL STERI	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE	H	
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE	1	
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE	1 - 2	

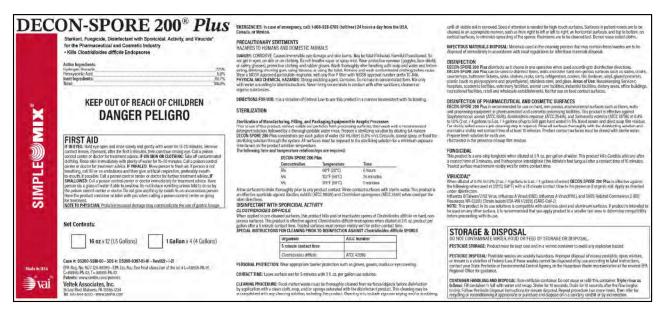


Product Labeling

DECON-SPORE 200 Plus Peracetic Acid Hydrogen Peroxide Solution



Case Label DS200-C-00 Rev1121



Case Label DS200-SSM-00_Rev1121

Any specific product label is available upon request.



DECON-SPORE 200 Plus

Sterilant, Fungicide, Disinfectant with Sporicidal Activity, and Virucide* for the Pharmaceutical and Cosmetic Industry • Kills *Clostridioides difficile* Endopsores

ACTIVE INGREDIENTS:

Hydrogen Peroxide	27.5%
Peroxyacetic Acid	5.8%
Inert Ingredients	66.7%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

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. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a 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. Have the product container or label with you when calling a poison control center or going for treatment.

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

Case #: DS200-C-00 • SDS #: DS200-0397-01-01 • Rev1121 • I-21

EPA Reg. No. 1677-129-68959 • EPA Est. No.: See final character of the lot # L=68959-PA-01, C=68959-PA-03, T= 68959-PA-02

Patents: www.sterile.com/patents.

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335 • www.sterile.com



Product Labeling (Continued)

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear a NIOSH approved particulate respirator, with any R or P filter with NIOSH approval number prefix TC-84A.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

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

STERILIZATION

Sterilization of Manufacturing, Filling, and Packaging Equipment in Aseptic Processes

Prior to use of this product, remove visible soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a sterilizing solution by diluting 6.4 ounces DECON- SPORE 200 Plus concentrate per each gallon of water (50 mL/liter) (5.0% v/v). Circulate, coarse spray, or flood the sterilizing solution through the system. All surfaces must be exposed to the sterilizing solution for a minimum exposure time based on the product solution temperature.

The following time and temperature relationships are required:

DECON-SPORE 200 Plus

Concentration	Temperature	Time
5%	68°F (20°C)	6 hours
5%	122°F (50°C)	20 minutes
5%	176°F (80°C)	5 minutes

Allow surfaces to drain thoroughly prior to any product contact. Rinse contact surfaces with sterile water. This product is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) when used per the label directions.



Product Labeling (Continued)

DISINFECTANT WITH SPORICIDAL ACTIVITY

CLOSTRIDIOIDES DIFFICILE

When applied to pre-cleaned surfaces, this product kills and/or inactivates spores of *Clostridioides difficile* on hard, non- porous surfaces. This product is effective against *Clostridioides difficile* endospores when diluted at 3 fl. oz. product per gallon after a 5 minute contact time. Treated surfaces must remain visibly wet for entire contact time.

Organism	ATCC Number
5 minute contact time	
Clostridioides difficile	ATCC 43598

SPECIAL INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST Clostridioides difficile SPORES

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

CONTACT TIME: Leave surface wet for 5 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.

DISINFECTION

DECON-SPORE 200 Plus disinfects as it cleans in one operation when used according to disinfection directions. 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, and glass. Areas of Use: Housekeeping Services; hospitals, academic facilities, veterinary facilities, animal care facilities, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments. Not for use on food contact surfaces.



Product Labeling (Continued)

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), *Burkholderia cepacia*† (ATCC 25416), and *Salmonella enterica* (ATCC 10708) at 0.4% to 1.0% (2 oz. / 4 gallons to 5 oz. / 4 gallons of up to 500 ppm hard water) in 5% blood serum and dried soap film residue. For visibly soiled areas a pre- cleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a visibly wet contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water. Prepare fresh solution for each use. †Not tested in the presence of soap film residue.

FUNGICIDAL

This product is a one-step fungicide when diluted at 3 fl. oz. per gallon of water. This product kills *Candida albicans* after a contact time of 3 minutes, and *Trichophyton interdigitale* (the Athlete's foot fungus) after a contact time of 10 minutes. Treated surface must remain visibly wet for entire contact time.

VIRUCIDAL*

When diluted at 0.4% to 1.0% (2 oz. / 4 gallons to 5 oz. / 4 gallons of water) DECON-SPORE 200 Plus is effective against the following when used at (20°C) (68°F) with a 10 minute contact time in the presence of organic soil. Apply as directed under disinfection. Influenza B/Taiwan/2/62 Virus, Influenza A Virus (H3N2), Influenza A Virus (H1N1), and SARS-Related Coronavirus 2 (BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020) (SARS-CoV-2)

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Product must be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely 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 AND DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ½ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.



Additional Instructions for Use

SANITIZATION	19
Sanitizing Food Contact Surfaces	19
Sanitizing Non-Food Contact Surfaces	19
DISINFECTION	20
Combination General Disinfection And Cleaning	20
Virucidal*	21
Hospitals/ Healthcare Facilities	22
DISINFECTION AGAINST POULTRY & LIVESTOCK VIRUSES	22
Disinfection And Deodorizing Of Animal Housing Facilities (Barns, Kennels, Hutches)	22
Virucidal* Activity	23
EFFICACY CLAIMS	24
Sanitizing Claims-Food Contact Surfaces Organisms at 1.0-1.4 fl. oz/4 Gallons Water	24
Sanitizing Claims-Non-Food Contact Surfaces Organisms at 1.0-2.5 fl. oz/8 Gallons Water .	24
Disinfecting Claims-Organisms at 3 fl. oz/1 Gallon Water	25
Disinfecting Claims-Organisms at 2 fl. oz/4 Gallons Water	26
Sterilization Claims-Organisms at 6.4 fl oz/1 Gallon Water	26



DECON-SPORE 200 Plus Product Family



SANITIZATION

DECON-SPORE 200 Plus is recommended for use on hard, non-porous, pre-cleaned surfaces such as equipment, associated equipment, in cosmetics manufacturing and pharmaceutical manufacturing facilities. DECON-SPORE 200 Plus is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

NOTE: For Mechanical Operations prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning. For Manual Operations fresh sanitizing solutions must be prepared at least daily or more often if the solution becomes diluted or soiled.

Sanitizing Food Contact Surfaces

Prior to sanitizing, remove visible particles, and then wash with a detergent solution, followed by a potable water rinse. Sanitize hard, non-porous surfaces with a concentration of 1.0 - 1.4 fl. oz. DECON-SPORE 200 Plus concentrate per 4 gallons of water [up to 500 ppm hard water]. (0.20 - 0.28% v/v concentration). At this dilution DECON-SPORE 200 Plus is effective against the following organisms:

- *Staphylococcus aureus* (ATCC 6538)
- Escherichia coli (ATCC 11229)
- Escherichia coli O157:H7 (ATCC 43895) •
- *Listeria monocytogenes* (ATCC 7644)
- *Salmonella typhimurium* (ATCC 13311)
- Pseduomonas aeruginosa (ATCC 15442)
- *Vibrio cholerae* (ATCC 25873)
- Saccharomyces cerevisiae (ATCC 834)
- Pediococcus damnosus (ATCC 25248)
- *Lactobacillus malefermentans* (ATCC 11307)

Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces must be exposed to the sanitizing solution for a period of 1 minute unless a longer time is specified by the governing sanitary code. Drain thoroughly and allow to air dry. No rinse necessary.

Sanitizing Non-Food Contact Surfaces

Prior to sanitizing, remove visible 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 equipment, blenders, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, associated equipment, floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1.0-2.5 fl. oz. DECON-SPORE 200 Plus per 8 gal water [up to 500 ppm hard water] (0.1-0.3% v/v). At this concentration the product is effective against the following organisms:

- Staphylococcus aureus (ATCC 6538)
- *Klebsiella aerogenes* (formerly known as *Enterobacter aerogenes*) (ATCC 13048)
- Escherichia coli (ATCC 11229)
- *Listeria monocytogenes* (ATCC 7644)
- Salmonella typhimurium (ATCC 13311)
- Pseduomonas aeruginosa (ATCC 15442)
- Burkholderia cepacia (ATCC 25416)
- Saccharomyces cerevisiae (ATCC 834)
- *Pediococcus damnosus* (ATCC 25248)
- *Lactobacillus malefermentans* (ATCC 11307)

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

Combination General Disinfection And Cleaning

A pre-cleaning step is required for visibly soiled areas. Dilute according to disinfection directions below, then 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 visibly wet for required contact time, 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.

When diluted at 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons) in water [up to 500 ppm hard water] in the presence of 5% blood serum and dried soap film residue with a 10 minute contact time, DECON-SPORE 200 Plus is effective against:

- Burkholderia cepacia† (ATCC 25416)
- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- *Salmonella enteritidis* (ATCC 13076)
- *Salmonella typhimurium* (ATCC 13311)
- *Proteus vulgaris* (ATCC 13315)
- Streptococcus pyogenes (ATCC 19615)
- Histoplasma capsulatum†

†Not tested in the presence of soap film residue.

When diluted at 3 fl. oz. / gallon in water [up to 400 ppm hard water] in the presence of 5% blood serum with a 3 minute contact time, DECON-SPORE 200 Plus is effective against:

- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- Escherichia coli (ATCC 11229)
- *Klebsiella pneumoniae* (ATCC 4352)
- Acinetobacter baumannii (ATCC 19606)
- Streptococcus pyogenes (ATCC 19615)
- Streptococcus pneumoniae (ATCC 6303)
- *Bordetella pertussis* (ATCC 12743)
- Proteus mirabilis (ATCC 7002)

When diluted at 3 fl. oz. / gallon in water [up to 400 ppm hard water] in the presence of 5% blood serum with a 10 minute contact time, DECON-SPORE 200 Plus is effective against:

• *Mycobacterium bovis* (TB) (Tuberculosis)



DISINFECTION (Continued)

Virucidal*

When diluted at 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons of water [up to 500 ppm hard water]) DECON-SPORE 200 Plus is effective against the following when used at (20 °C) (68 °F) with a 10 minute contact time in the presence of organic soil. Apply as directed under disinfection.

- *Influenza B/Taiwan/2/62 Virus
- *Influenza A Virus (H3N2)
- *SARS-Related Coronavirus 2 (BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020)[SARS-CoV-2]
- *Influenza A Virus (H1N1)
- *Influenza A Virus (H10N7)

When diluted at 3 fl. oz./gallon in water] [up to 400 ppm hard water] with a contact time of 3 minutes, 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)
- *Adenovirus Type 5
- *HIV virus (Type 1) (AIDS virus)
- *Human Coronavirus (ATCC VR-740)
- *Herpes Simplex Virus Type 1 (ATCC VR-733)
- *Herpes Simplex Virus Type 2 (ATCC VR-734)
- *Influenza A Virus (Hong Kong strain)
- *SARS-Related Coronavirus 2 (BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020)[SARS-CoV-2]

When diluted at 3 fl. oz. / gallon in water [up to 400 ppm hard water] with a contact time of 5 minutes, DECON-SPORE 200 Plus is effective against:

- *Hepatitis B Virus
- *Hepatitis C Virus

When diluted at 3 fl. oz. / gallon in water [up to 400 ppm hard water] with a contact time of 10 minutes, DECON-SPORE 200 Plus is effective against:

• *Poliovirus (Type 1, Chat strain)



DISINFECTION (Continued)

Hospitals/ Healthcare Facilities

When diluted at 3 fl. oz./ gallon in water [up to 400 ppm hard water] with a contact time of 3 minutes, DECON-SPORE 200 Plus is effective against the following antibiotic resistant organisms:

- Acinetobacter baumannii Multi-Drug Resistant¥ (MDR) (ATCC BAA-1605)
- Enterococcus faecalis Vancomycin Resistant (VRE) (ATCC 51299)
- Escherichia coli Extended Spectrum Beta Lactamase producing (ESBL) (ATCC BAA-196)
- *Klebsiella pneumoniae* Carbapenemase producer (KPC) (ATCC BAA-1705)
- Staphylococcus aureus Community Associated Methicillin Resistant (CA-MRSA) (Genotype USA300) (ATCC BAA-1556)
- Staphylococcus aureus Community Associated Methicillin Resistant CA-MRSA (Genotype USA400) (ATCC BAA-1683)
- Staphylococcus aureus Methicillin Resistant (MRSA) (ATCC BAA-33592)
- Staphylococcus aureus Intermediate Vancomycin Resistant (VISA) (ATCC 700788)
- Staphylococcus epidermidis Methicillin Resistant (MRSE) (ATCC 51625)

¥gentamicin, imipenem, ceftazidime

DISINFECTION AGAINST POULTRY & LIVESTOCK VIRUSES

DECON-SPORE 200 Plus is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, DECON-SPORE 200 Plus is specifically designed to disinfect, deodorize and clean inanimate, hard, non-porous surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding and watering equipment. In addition DECON-SPORE 200 Plus 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. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse. For visibly soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

Disinfection And Deodorizing Of Animal Housing Facilities (Barns, Kennels, Hutches)

Remove animals and feed from facilities. Remove litter, waste matter and visible soils. Empty all troughs, racks and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply a 0.4% - 1.0% (2 fl. oz. / 4 gallons to 5 fl. oz. / 4 gallons of water [up to 500 ppm hard water]) solution of DECON-SPORE 200 Plus with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain visibly wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.



DISINFECTION AGAINST POULTRY & LIVESTOCK VIRUSES (Continued)

Virucidal* Activity

DECON-SPORE 200 Plus is effective as a disinfectant against poultry and livestock viruses on hard, non- porous surfaces of agricultural facilities and equipment, dairy processing facilities, military facilities and equipment, airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment (including processing facilities), shipping facilities and equipment, and similar sites where animals, animal by- products or soil contaminants suspected of harboring the following poultry and livestock pathogens:

- *Influenza A Virus (H10N7)
- *Avian Influenza A Virus (H5N1)
- *Newcastle Disease Virus,
- *Infectious Bronchitis Virus
- *Avian Reovirus
- *Infectious Bovine Rhinotracheitis Virus (IBR)
- *Parainfluenza 3 Virus
- *Foot & Mouth Disease Virus (Aphthovirus)

Within these facilities, hard, non-porous surfaces of treated objects include, but are not limited to, vehicles, farm equipment (including tractors, plough shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (bins and containers).

Apply a 0.4% (2 fl. oz. / 4 gallons of water [up to 500 ppm hard water]) solution of DECON-SPORE 200 Plus with a mop, cloth, brush or coarse spray to disinfect walls, ceilings, floors, decks, container surfaces, vehicles, water proof footwear (such as rubber boots), livestock equipment, utensils, hoses, and instruments. Wet all surfaces and allow to remain visibly wet for 10 minutes. Allow surfaces to air dry and rinse with potable water before reuse.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.



Efficacy Claims

Sanitizing Claims-Food Contact Surfaces Organisms at 1.0-1.4 fl. oz/4 Gallons Water

Organism	ATCC	Contact Time	
Food Contact Surfaces			
Escherichia coli	ATCC 11229	1 min	
Escherichia coli O157:H7	ATCC 43895	1 min	
Lactobacillus malefermentans	ATCC 11307	1 min	
Listeria monocytogenes	ATCC 7644	1 min	
Pediococcus damnosus	ATCC 25248	1 min	
Pseduomonas aeruginosa	ATCC 15442	1 min	
Saccharomyces cerevisiae	ATCC 834	1 min	
Salmonella typhimurium	ATCC 13311	1 min	
Staphylococcus aureus	ATCC 6538	1 min	
Vibrio cholerae	ATCC 25873	1 min	

Sanitizing Claims-Non-Food Contact Surfaces Organisms at 1.0-2.5 fl. oz/8 Gallons Water

Organism	ATCC	Contact Time
Non-Food Contact	Surfaces	
Burkholderia cepacia	ATCC 25416	5 min
Klebsiella aerogenes (formerly known as Enterobacter aerogenes)	ATCC 13048	5 min
Escherichia coli	ATCC 11229	5 min
Lactobacillus malefermentans	ATCC 11307	5 min
Listeria monocytogenes	ATCC 7644	5 min
Pediococcus damnosus	ATCC 25248	5 min
Pseduomonas aeruginosa	ATCC 15442	5 min
Saccharomyces cerevisiae	ATCC 834	5 min
Salmonella typhimurium	ATCC 13311	5 min
Staphylococcus aureus	ATCC 6538	5 min



Disinfecting Claims-Organisms at 3 fl. oz/1 Gallon Water Dilution

Organism	ATCC	Contact Time
General Cleaning & D	isinfection	
Acinetobacter baumannii	ATCC 19606	3 min
Escherichia coli	ATCC 11229	3 min
Klebsiella pneumoniae	ATCC 4352	3 min
Mycobacterium bovis (TB)	-	10 min
Proteus mirabilis	ATCC 7002	3 min
Pseudomonas aeruginosa	ATCC 15442	3 min
Salmonella enterica	ATCC 10708	3 min
Staphylococcus aureus	ATCC 6538	3 min
Streptococcus pneumoniae	ATCC 6303	3 min
Hospital Disinfection – Anti		
† Acinetobacter baumannii – MDR	ATCC BAA-1605	3 min
† Enterococcus faecalis – VRE	ATCC 51299	3 min
† Escherichia coli – ESBL	ATCC BAA-196	3 min
† Klebsiella pneumoniae – KPC	ATCC BAA-1705	3 min
† Staphylococcus aureus – CA-MRSA	ATCC BAA-1556	3 min
† Staphylococcus aureus – CA-MRSA	ATCC BAA-1683	3 min
† Staphylococcus aureus – MRSA	ATCC BAA-33592	3 min
† Staphylococcus aureus – VISA	ATCC 700788	3 min
† Staphylococcus epidermidis – MRSE	ATCC 51625	3 min
Virucidal*	1110001020	3 mm
*Adenovirus (Type 5)	-	3 min
*HIV Type 1 (AIDS Virus)	-	3 min
*Hepatitis B Virus	-	5 min
*Hepatitis C Virus	-	5 min
*Herpes Simplex Type 1 virus	ATCC VR-733	3 min
*Herpes Simplex Type 2 virus	ATCC VR-734	3 min
*Human Coronavirus	ATCC VR-740	3 min
*Influenza A Virus (Hong Kong strain)	-	3 min
*Norovirus (FCV surrogate tested)	ATCC VR-782	3 min
*Poliovirus (Strain Chat)	ATCC VR-1562	10 min
*Respiratory Syncytial Virus (Strain Long)	ATCC VR-26	3 min
*Rhinovirus (Type 37)	ATCC VR-1147	3 min
*Rotavirus (Strain WA)	-	3 min
*Vaccina Virus (Strain WR)	ATCC VR-119	3 min
*SARS-Related Coronavirus 2 (BEI Resources NR-	-	3 min
52281) (Strain Isolate USA-WA 1/2020) [SARS-CoV-2]		
Disinfectant with Sporice	idal Activity	
Clostridioides difficile (Clostridium difficile)	ATCC 43598	5 min
Fungicidal		
Trichophyton interdigitale	-	10 min
Candida albicans	ATCC 10231	3 min



Disinfecting Claims-Organisms at 2 fl. oz/4 Gallons Water Dilution

Organism	ATCC	Contact Time	
General Cleaning and Disinfection			
Burkholderia cepacia†	ATCC 25416	10 min	
Histoplasma capsulatum†	-	10 min	
Proteus vulgaris	ATCC 13315	10 min	
Pseudomonas aeruginosa	ATCC 15442	10 min	
Salmonella enterica	ATCC 10708	10 min	
Salmonella enteritidis	ATCC 13076	10 min	
Salmonella typhimurium	ATCC 13311	10 min	
Staphylococcus aureus	ATCC 6538	10 min	
Streptococcus pyogenes	ATCC 19615	10 min	
Virucidal	*		
*Avian Influenza A Virus (H5N1)	-	10 min	
*Avian Reovirus	-	10 min	
*Foot & Mouth Disease Virus	-	10 min	
*Infectious Bronchitis Virus	-	10 min	
*Infectious Bovine Rhinotracheitis Virus	-	10 min	
*Influenza A Virus (H1N1)	-	10 min	
*Influenza A Virus (H3N2)	-	10 min	
*Influenza A Virus (H10N7)	-	10 min	
*Influenza B/Taiwan/2/62 Virus	-	10 min	
*Newcastle Disease Virus	-	10 min	
*Parainfluenza 3 Virus	-	10 min	
*SARS-Related Coronavirus 2 (BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020) [SARS-CoV-2]	-	10 min	

[†]Not tested in the presence of soap film residue.

Sterilization Claims-Organisms at 6.4 fl oz/1 Gallon Water Dilution

Organism	ATCC	Contact Time
Sporicidal (80 °C)		
Bacillus subtilis	ATCC 19659	5 min
Clostridium sporogenes	ATCC 3584	5 min
Sporicidal (50 °C)		
Bacillus subtilis	ATCC 19659	20 min
Clostridium sporogenes	ATCC 3584	20 min
Sporicidal (20 °C)		
Bacillus subtilis	ATCC 19659	6 hours
Clostridium sporogenes	ATCC 3584	6 hours



ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample Lot Specific Documentation Product Release Certificate containing analytical and sterility data tested to current USP compendium



VAI®'s SCMD Product Family

VAI's Sterile Chemical Manufacturing Division (SCMD) manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 or 7 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility.

For more information call 610-644-8335, email <u>sales@sterile.com</u> or visit our website at <u>www.sterile.com</u>. Patents: <u>www.sterile.com/patents</u>