



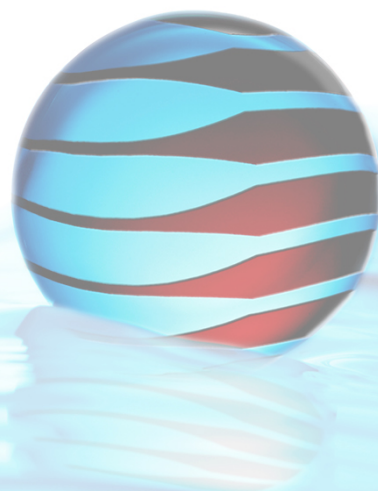
VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-SPORE 200[®] Plus

Peracetic Acid Hydrogen Peroxide Solution
Sterile Cleanroom Formula





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, sterilant sporicide, and deodorizer in the pharmaceutical, biotechnology, medical device, hospital, 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. **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** has been shown to be effective against all influenza A viruses and is an effective sporicide/sterilant against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) when used per the label directions. **DECON-SPORE 200 Plus** is compatible with numerous hard, non-porous, environmental, inanimate surfaces, and has been designed for daily use.

Sanitizer – Disinfectant – Virucide – Sterilant Sporicidal – Deodorizer

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 a lot specific Certificate of Analysis and Certificate of Sterility.

DECON-SPORE 200 Plus is available in three dilution ratios: as a concentrate, as a disinfectant dose, and as a sterilant/sporicidal dose in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200L drum. **DECON-SPORE 200 Plus** 1 gallon, 16 oz, and 200L containers come in our ready-to-use SimpleMix® System that allows for exact and fresh formulations each and every time without handling the concentrate. Each sterile container of **DECON-SPORE 200 Plus** is individually double bagged for easy transport into the core.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Raw components are air washed with 0.2 micron filtered air
- 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

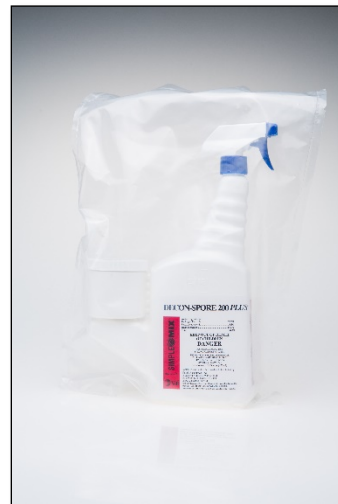
| DECON-SPORE 200 Plus – Peracetic Acid and Hydrogen Peroxide Solution | |
|--|------------------------------|
| Certificate of Analysis | Specifications |
| Appearance: | Clear, water white |
| IR: | Math Reference |
| Hydrogen Peroxide: | 25.60 - 29.40% |
| Peroxyacetic Acid: | 5.25 – 6.40% |
| Expiration Period: | 1 year from manufacture date |

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility
- Individually labeled with lot number and expiration
- EPA registered
- Specifically formulated as a sterile cleanroom formula
- Available in three configurations: concentrate, disinfectant dose, and sterilant/sporicidal dose
- Available in multiple container sizes either sterile or non-sterile
- Available in the convenient, ready-to-use, SimpleMix® System
- Concentrated broad-spectrum disinfectant-virucide
- Disinfects as it cleans in one operation
- Designed for the sterilization of manufacturing, filling, and packaging equipment in aseptic processes
- Effective in water up to 500ppm hardness in the presence of 5% serum contamination and dried soap film residue
- Expected to inactivate Pandemic 2009 H1N1 (formerly called swine flu)
- Effective against *Staphylococcus aureus* and *Salmonella enterica* in hard water (500 ppm as CaCO₃) when used as directed
- Effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) when used per the label directions
- Designed for daily use



Easy Tear Double Bag Packaging



DS200-06-16Z-01



DS200-03-1ZA

Uses

DECON-SPORE 200 Plus can be used to disinfect floors, walls, and other hard non-porous surfaces such as tables, chairs, countertops, shelves, racks, carts, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass. **DECON-SPORE 200 Plus** is made for use in veterinary facilities, animal care facilities, industrial facilities, and the pharmaceutical, hospital, medical device, and biotechnology industries. **Note:** When using as a sterilant it is recommended that you apply product to a smaller test area to determine compatibility before proceeding on surfaces other than stainless steel or aluminum. **DECON-SPORE 200 Plus** is not for use on food contact surfaces, medical devices, or medical equipment.

Veltek Associates, Inc.

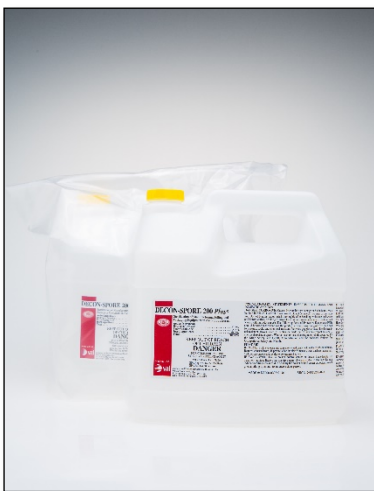
15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336

Rev: 15May2017, ML Rev: I-16

Ordering Information

| DECON-SPORE 200® Plus – Peracetic Acid and Hydrogen Peroxide Solution | | |
|--|--|---------------|
| 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, Sterile | 4 |
| DS200-04A | DECON-SPORE, 1 Gallon SimpleMix, Sporicidal Dose, Sterile | 4 |
| DS200-05-1/2ZA | DECON-SPORE, 1 Gallon SimpleMix, Disinfectant Dose, Non-Sterile | 4 |
| DS200-05A | DECON-SPORE, 1 Gallon SimpleMix, Sporicidal Dose, 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 |
| DS200-07-16Z-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 |



DS200-02A



DS200-07-16Z-01



DS200-03-2ZA



DS200-04-1/2ZA

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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, 16oz, and 200L 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. 200L SimpleMix systems are activated through a hose and valve system connecting the cubicontainer of concentrate to the VAI WFI Quality Water. 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.



1 Gallon SimpleMix, DS200-04A

DIRECTIONS FOR USE: Available on each container lid

AUTOMATED DILUTION SYSTEM: Remove cap from empty container. Fill empty container with a newly prepared use-solution. Replace cap. Place the use-dilution label on newly filled container.



Lid Directions

SIMPLEMIX® SYSTEM CONTAINER:***Trigger Spray Bottle Lid Label:***

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.



16 oz SimpleMix Container



1 gallon SimpleMix Container

Gallon Size Bottle Lid Label:

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.

200 Liter Drum Lid Label:

(note: To be used with a Veltek Associates, Inc. pump)

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.



200L Drum SimpleMix Container

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SIMPLEMIX® SYSTEM, 16 OZ CONTAINER OPERATION CONTINUED

SIMPLEMIX® 16 oz Aseptic Mixing System
For the Exact Formulation of 16 oz 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.



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SIMPLEMIX® SYSTEM, 1 GALLON CONTAINER OPERATION CONTINUED

SIMPLEMIX® 1 Gallon Aseptic Mixing System
For the Exact Formulation of 1 Gallon 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.

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SIMPLEMIX® SYSTEM, 200 L DRUM CONTAINER OPERATION CONTINUED

SIMPLEMIX® 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.



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



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



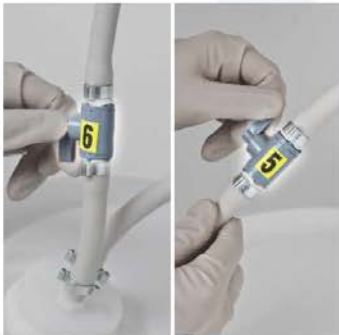
5) START pump to empty cubic container. 6) When cubic container is empty, turn pump OFF.



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.

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TOXICITY STUDY

DECON-SPORE 200® Plus Peracetic Acid and Hydrogen Peroxide

DECON-SPORE 200 Plus: Toxicity Data

By Dr. Robert Harrington Response to Fax dated January 5, 1998 from Veltek

This product contains both hydrogen peroxide and peroxyacetic acid in a water based matrix. Both of these materials have a relatively low vapor pressures and are infinitely soluble in water. At room temperatures both of these materials will tend to remain dissolved in water and not enter the vapor stage. Ventilation will further reduce the concentration of the hydrogen peroxide and peroxyacetic acid in the air. Inhalation of the vapors should not be a problem provided the room is adequately ventilated and there is not a significant mist generated by mechanical or other means.

There is not a great of deal of toxicological studies on the inhalation of hydrogen peroxide or peroxyacetic acid. The best study available demonstrated that dogs exposed to hydrogen peroxide at air concentrations of 7 ppm for 6 hours a day for six months produced significant irritation to the lungs and bleaching of the hair. This exposure did not cause any serious adverse effects, but did cause considerable transient irritation. In a study conducted by Ecolab/VAI, rats were exposed to an artificially created atmosphere containing a product with similar levels of hydrogen peroxide and peroxyacetic acid for four hours at a concentration far greater than would ever be experienced in the real world. Animals displayed irregular breathing during the exposure, which is common when inhaling a substance that is irritating. All animals survived and did not have any long-term effects as a result of their exposure.

For workers, the American Conference of Governmental Industrial Hygienists (ACGIH) and the Occupational Safety and Health Administration (OSHA) have both set limits for exposure to hydrogen peroxide at 1 part per million (ppm) in the air for an eight hour work day. This limit was set to prevent the irritation of the nose and eyes rather than to protect from any adverse health effect or illness. The 1 ppm limit by OSHA establishes the maximum permissible exposure level under law. If there is reason to suspect workplace levels exceed 1 ppm, monitoring should be done to insure exposure stay below the legal limit. OSHA has not set a limit for exposure to peroxyacetic acid.

Since this is a two component system containing both hydrogen peroxide and peroxyacetic acid, consideration must be given to combining the exposures so that the exposure limit is 1 ppm for hydrogen peroxide and peroxyacetic acid combined. This is done because both chemicals produce the same effect by the same mechanism. Transient exposures above the 1 ppm limit are permitted as long as the overall time-weighted average is below the limit.

As a general rule for products such as hydrogen peroxide and peroxyacetic acid, if there is significant irritation to the eyes or the respiratory tract from the vapors, the concentration is too high and ventilation or other means should be employed to reduce them. Normally, the irritation produced tells a person that they need to vacate the area and escape the vapors. This irritation limits exposure to these materials.

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Summary of Acute Oral Toxicity in Rats Median Lethal Dosage Determination

Purpose

To determine the acute oral toxicity of **DECON-SPORE 200® Plus**

Testing Laboratory

Hill Top Biolabs, Inc.
Main and Mill Streets
Miamiville, Ohio 45147
(521) 831-3114

VAI Good Laboratory Practices No.

9200041

Hill Top Project No.

92-8864-21 (A)

Hill Top Test Protocol No.

Acute Oral Toxicity in Rats - Median Lethal Dosage Determination/
2-1-2/03-09-90/REV 6

Methods

The procedure satisfies the criteria established by the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act and the OECD Guidelines.

Young adult, male and female, Sprague Dawley derived rats weighing between 215 and 355 grams at the start of the study were used.

The test material was administered as a 25% w/v formulation in distilled water. Dilution was utilized in order to decrease the corrosive effects of the undiluted test material.

Results

The oral LD50 value with 95% Confidence Limits is 1.27 g/kg in male and female Sprague Dawley rats.

The test material is classified in EPA Toxicity Category III by oral administration.



Opening a **DECON-SPORE 200 Plus**
13 oz Container



13 oz Container, DS200-03-13ZA

Veltek Associates, Inc.

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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 | WHITE | | |
| DECON-AHOL WFI FORMULA 91% | WHITE | WHITE | | |
| DECON-AHOL FORMULA 99% | WHITE | WHITE | | |
| 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 | 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 | | |
| HYP0-CHLOR 0.25% | WHITE | WHITE | | |
| HYP0-CHLOR 0.52% | WHITE | WHITE | | |
| HYP0-CHLOR 5.25% | WHITE | WHITE | | |
| STERI-PEROX 3% | WHITE | WHITE | | |
| STERI-PEROX 6% | WHITE | WHITE | | |
| 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 | | |

PRODUCT LABELING

DECON-SPORE 200® Plus Peracetic Acid and Hydrogen Peroxide

(Any specific product label is available upon request.)



DECON-SPORE 200 Plus Family of Products

Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355-1234

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DECON-SPORE 200® Plus

Sterilization of Manufacturing, Filling and Packaging Equipment in Aseptic Processes.
Disinfection of Pharmaceutical Surfaces.

ACID LIQUID SANITIZER

DISINFECTANT

Veterinary Facilities, Animal Care Facilities, Industrial Facilities

STERILANT SPORICIDAL

DISINFECTANT, SANITIZER, AND VIRUCIDE FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

| Active Ingredients: | Percentage: |
|---------------------------------|--------------|
| Hydrogen Peroxide | 27.5% |
| Peroxyacetic Acid | 5.8% |
| Inert Ingredients: | <u>66.7%</u> |
| Total | 100.0% |

**KEEP OUT OF REACH OF CHILDREN
DANGER
PELIGRO**

FOR COMMERCIAL USE

STRONG OXIDIZING AGENT

See label for complete information.

Refer to SDS for additional product hazard information.

Container and Product Sterilized and Distributed By:

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335

Fax: 610-644-8336

EPA Reg No: 1677-129-68959

EPA Est. No: 68959-PA-1

For chemical or environmental emergencies, call CARECHEM 24 at 866-928-0789

Made in United States of America

Veltek Associates, Inc.

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DECON-SPORE 200® Plus

DECON-SPORE 200 Plus is for use as a broad-spectrum, hard surface disinfectant in industrial facilities and hospitals that disinfects as it cleans in one operation. **DECON-SPORE 200 Plus** is a “one step” disinfectant – virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination. **DECON-SPORE 200 Plus** has been shown to be effective against and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). This product is effective against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) in hard water (500 ppm as CaCO₃) when used as directed.

DECON-SPORE 200 Plus is specifically designed to disinfect, deodorize, and clean inanimate, hard, non-porous surfaces in animal laboratories. **DECON-SPORE 200 Plus** is for use as a broad-spectrum, hard surface disinfectant in and veterinary facilities and animal care facilities. **DECON-SPORE 200 Plus** is effective as a disinfectant against viruses pathogenic to poultry: Influenza A (H10N7), Newcastle Disease virus, Infectious bronchitis virus, Avian Reovirus, Infectious bovine rhinotracheitis (IBR), Parainfluenza 3 Virus, and the foot & mouth disease virus (Aphthovirus).

DECON-SPORE 200 Plus is for use as a sterilant sporicidal disinfectant in the pharmaceutical and cosmetic industries. This product is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) when used per the label directions. This product in this use solution is compatible with stainless steel and aluminum surfaces.

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. Wash thoroughly after handling with soap and water and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse. The following Personal Protective Equipment (PPE) must be used when handling the product: coveralls over long-sleeved shirt and long pants, socks and chemical-resistant footwear, goggles or face shield, chemical-resistant gloves (such as rubber or made out of any waterproof material), chemical-resistant apron. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

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 further 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 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 and unconscious person.

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

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

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NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. (Refer to the product container label for Precautionary Statements, First Aid Instructions and Storage & Disposal information)

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.

(For 5 gal containers and larger)

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

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 instruction, 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:

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ 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.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or 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.

DIRECTIONS FOR USE

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

SANITIZATION

SANITIZING NON-FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles and then wash with a detergent solution followed by a potable water rinse. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1 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 1229), *Listeria monocytogenes* (ATCC 7644), *Salmonella typhimurium*

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(ATCC 1311), *Pseudomonas aeruginosa* (ATCC 15442), and *Saccharomyces cerevisiae* (ATCC 834). 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 nonporous surfaces such as tables, chairs, countertops, sinks, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

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 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 and drinking water must be rinsed with potable water before reuse.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

Areas of Use: Veterinary facilities, animal care facilities, industrial facilities. 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*¹ at 0.4% to 1.0% (2 oz./4 gallons to 5 oz./4 gallons of water) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue on hard nonporous surfaces. For heavily soiled areas a pre-cleaning step is required. Prepare a disinfecting and cleaning solution by diluting 4 ounces **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.

VIRUCIDAL

At 0.4% - 1.0% (2 oz./4 gallons to 5 oz./4 gallons of water) **DECON-SPORE 200 Plus** is effective against Influenza B/Taiwan/2/62, Influenza A (H3N2) and Influenza A (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.

DISINFECTION OF PHARMACEUTICAL 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% to 1.0% (2 oz./4 gallons to 5 ounces/4 gallons of water) in hard water (500 ppm as

¹ Not tested in the presence of soap film residue.

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.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNs, KENNELs, HUTCHES)

Remove animals and feed from facilities. Remove litter, waste matter and gross soils. Empty all troughs, rack 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% to 1.0% (2 oz./4 gallons to 5 oz./4 gallons of water) solution of **DECON-SPORE 200 Plus** with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

VIRUCIDAL ACTIVITY – Poultry and Livestock Pathogens

DECON-SPORE 200 Plus is effective as a disinfectant against viruses pathogenic to poultry: Influenza A (H10N7), Newcastle Disease virus, Infectious bronchitis virus, Avian Reovirus, Infectious bovine rhinotracheitis (IBR), Parainfluenza 3 Virus, and the foot & mouth disease virus (Aphthovirus).

STERILIZATION

STERILIZATION OF MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT IN ASEPTIC PROCESSES

Prior to use of this product, remove gross 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

| <u>Concentration</u> | <u>Temperature</u> | <u>Time</u> |
|----------------------|--------------------|-------------|
| 5% | 68°F (20°C) | 6 hours |
| 5% | 122°F (50°C) | 20 minutes |
| 5% | 176°F (80°C) | 5 minutes |

Thoroughly rinse food contact surfaces with either a sterile water or potable water rinse. For food contact surfaces, follow with a sanitizing solution of **DECON-SPORE 200 Plus**. Allow surfaces to drain thoroughly prior to any food product contact. This product is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogens* (ATCC 3584) when used per the label directions.

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.

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EFFICACY TEST SUMMARY

DECON-SPORE 200® Plus Peracetic Acid and Hydrogen Peroxide

STUDY TITLE (Previous Product Studies²)

Test Substance Identification

DECON-SPORE 200 Plus

Veltek Associates, Inc.

EPA Reg #: 1677-129-68959

EPA Est. #: 68959-PA-1

| | |
|---------------------------------|--------------------|
| Active Ingredients: | Percentage: |
| Hydrogen Peroxide | 27.5% |
| Peroxyacetic Acid | 5.8% |
| Inert Ingredients: | 66.7% |
| Total | 100.0% |

Non-Food Contact Sanitizing Efficacy

Test Concentration

1 oz./8 gal. (0.10% solution)

Diluent

500 ppm synthetic hard water

Exposure Time

5 minutes

Test Method

Non-Food Contact Surface Sanitizer Method, DIS/TSS-10 07 January 1982

| DECON-SPORE 200® Plus – Non-Food Contact Surface Sanitizing Results | | | | |
|---|-------|-----------|----------|----------------------------|
| Test System | ATCC# | Test Date | Batch # | Result (Percent Reduction) |
| <i>Staphylococcus aureus</i> | 6538 | 1/6/93 | 8428-12 | >99.9 |
| | | | 8428-14 | >99.9 |
| | | | 8428-15 | >99.9 |
| <i>Escherichia coli</i> | 11229 | 1/6/93 | 8428-12 | >99.9 |
| | | | 8428-14 | >99.9 |
| | | | 8428-15 | >99.9 |
| <i>Listeria monocytogenes</i> | 7644 | 10/12/92 | SI050522 | >99.9 |
| | | | SI061022 | >99.9 |

² Note: Current label claims have been revised to reflect more current testing lists that may not include all organisms tested previously. These results are presented for illustration of the development history of this product.



| | | | | |
|---|-------|--|----------|-------|
| <i>Salmonella typhimurium</i> | 13311 | 10/12/92 | SI050522 | >99.9 |
| | | | SI061022 | >99.9 |
| <i>Pseudomonas aeruginosa</i> | 15442 | 10/12/92 | SI050522 | >99.9 |
| | | | SI061022 | >99.9 |
| <i>Saccharomyces cerevisiae</i> | 834 | 10/12/92 | SI050522 | >99.9 |
| | | | SI061022 | >99.9 |
| <i>Lactobacillus malefermentans</i> (f.k.a. <i>Lactobacillus buchneri</i>) | 11305 | 6/16/93 | 8428-14 | >99.9 |
| | | | 8428-15 | >99.9 |
| <i>Pediococcus damnosus</i> | 25248 | 6/16/93 | 8428-14 | >99.9 |
| | | | 8428-15 | >99.9 |
| <i>Enterobacter aerogenes</i> | 13048 | Specific testing data and lot number not available | | |

The EPA test requirement for an effective non-food contact surface sanitizer is that a >99.9 percent reduction must be achieved within a 5 minutes exposure time.

Conclusion

DECON-SPORE 200® Plus demonstrated non-food contact sanitizing efficacy diluted at 1 oz./8 gal. against *Staphylococcus aureus*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Saccharomyces cerevisiae*, *Lactobacillus malefermentans*, *Pediococcus damnosus*, and *Enterobacter aerogenes* after a 5 minute contact time.

Disinfectant Efficacy

Test Concentration

4 oz/8 gal. (0.4%)

Artificial Soil Load

5% fetal bovine serum and dried soap film residue

Test Exposure Time

10 minutes

Test Procedure

Use Dilution method, A.O.A.C Official Methods of Analysis

Conclusion

DECON-SPORE 200 Plus demonstrated one step cleaner-hospital disinfectant efficacy diluted at 0.4% in 500 ppm sterile synthetic hard water as CaCO₃ against *Staphylococcus aureus* (ATCC 6538), *Histoplasma capsulatum**, *Salmonella enterica* (ATCC 10708), *Salmonella enteritidis* (ATCC 13076), *Salmonella typhimurium* (ATCC 13311), *Streptococcus pyogenes* (ATCC 19615), and *Proteus vulgaris* (ATCC 13315).

*not tested in the presence of soap film residue

Virucidal Efficacy

Test Procedure

Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces. ASTM Method E-1053-91.

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| DECON-SPORE 200® Plus – Virucidal Efficacy Results | | | |
|---|--|------------------|---------------|
| Test System | ATCC# | Test Date | Batch# |
| Influenza A (H1N1) | VR-897 | 03/05/92 | SIO11622 |
| | | | SIO11522 |
| Influenza A (H3N2) | VR-810 | 03/12/92 | SIO11622 |
| | | | SIO11522 |
| Influenza A (HI0N7) | VR-1334 | 01/11/92 | 8229-15-A |
| | | | 8229-15-B |
| Avian Reovirus | VR-2040 | 03/06/92 | 8229-15-A |
| | | | 8229-15-B |
| Parainfluenza 3 | VR-281 | 03/31/92 | 8229-15-A |
| | | | 8229-15-B |
| Infectious Bovine Rhinotracheitis | VR-188 | 2/25/92 | 8229-15-A |
| | | | 8229-15-B |
| Newcastle Disease Virus | VR-109 | 01/30/92 | 8229-15-A |
| | | | 8229-15-B |
| Infectious Bronchitis Virus | VR-22 | 03/19/92 | 8229-15-A |
| | | | 8229-15-B |
| Influenza B/Taiwan/2/26 | Specific testing data and lot number not available | | |
| Foot & mouth disease virus (Apthovirus) | Specific testing data and lot number not available | | |

Results are intended as a summary of label claim and therefore are representative of only the test system, batch number and test date and do not include raw data. EPA test requirements for an effective virucidal disinfectant are:

1. The test system (virus) titer must be $\geq 10^4$.
2. A ≥ 3 -log difference must be observed between the cytotoxicity titer (of the test substance) and virus titer
3. The test substance must demonstrate complete inactivation of test system (virus) at all dilutions.

These requirements have been met for all the listed above.

Conclusion

DECON-SPORE 200 Plus diluted 0.4% (4 oz/8 gal.) in 500 ppm synthetic hard water, is an effective disinfectant against the listed viruses when evaluated in the presence of an organic soil load (represented by at least 5% blood serum) and soap film residue (represented by 0.005% sodium stearate) with a 10 minute exposure time.

Sterilant/Sporicidal Efficacy

Conclusion

This product is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) when used per the label directions.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
 - **DECON-SPORE 200 Plus** Concentrate – SDS# VEL-120
 - **DECON-SPORE 200 Plus** Disinfectant – SDS# VEL-029
 - **DECON-SPORE 200 Plus** Sporicide (5% Dilution) – SDS# DS200-0397-01-01
- Product Validation
- In-use Validation
- Sample lot specific documentation packages including Certificates of Sterility and Certificates of Analysis



SCMD

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 (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. To learn more about our division capabilities please visit

www.sterile.com.

[Patents: www.sterile.com/patents](http://www.sterile.com/patents)

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