

# DEC-SPORE<sup>®</sup> 200 Plus

## Peracetic Acid & Hydrogen Peroxide Solution

Sterile Pharmaceutical Clean Room Formula

DS-200-new-E

Revised 11 December, 2013

## Technical Data File



# O V E R V I E W

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## DEC-SPORE 200 Plus Sterile Clean Room Formula

### PRODUCT DESCRIPTION

Dec-Spore 200 Plus is a peroxyacetic acid and hydrogen peroxide solution, and an effective Sterilant, Virucide, Disinfectant, Sanitizer and booster for alkaline detergents. This product disinfects as it cleans in one operation and is available in two concentrations. Dec-Spore 200 Plus is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A viruses – tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic H1N1 (formerly called swine flu).

Dec-Spore 200 Plus is filled in ISO 5 (Grade A/B, former Class 100) and filtered at 0.2 microns into sterile components. It is available in several container sizes both sterile and non-sterile. Each lot is delivered with lot specific Certificate of Analysis and Certificate of Sterility. Dec-Spore 200 Plus products are completely traceable and have been completely validated for sterility and shelf life.

### The SimpleMix<sup>®</sup> System Technology Alternative:

Veltek Associates, Inc. has developed the 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. It assures the accurate measurement of a concentrate. The Patented (US Patent 6851580, 7066354) SimpleMix System Gallon and 16oz Systems provide a sealed multi-chamber container that when activated mixes the solution to the use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the USP WFI Quality Water. The 16 ounce side container houses the concentrate and the bottom reservoir houses the USP 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. **See SimpleMix Technical Data Report Available Upon Request.**

### ORDERING INFORMATION

Order#	Description	Quan/cs.
DS200-01A-E	DEC-SPORE 200 Plus 1-Gallon Non-Sterile	4
DS200-02A-E	DEC-SPORE 200 Plus 1-Gallon Sterile	4
DS200-03-1ZA-E	DEC-SPORE 200 Plus 0.8 oz Sterile (Unit Dose sporicidal w/ 16 oz. of water)	24
DS200-03-2ZA-E	DEC-SPORE 200 Plus 2 oz Sterile (Unit Dose disinfectant w/ 4 gal of water)	24
DS200-03-13ZA-E	DEC-SPORE 200 Plus 13 oz. Sterile (Unit Dose sporicidal w/ 2 gal of water)	12
DS200-04-1/2ZA-E	DEC-SPORE 200 Plus SimpleMix Gallon Disinfectant Dose Sterile	4
DS200-04A-E	DEC-SPORE 200 Plus SimpleMix Gallon Sporicidal Dose Sterile	4
DS200-05-1/2ZA-E	DEC-SPORE 200 Plus SimpleMix Gallon Disinfectant Dose Non-Sterile	4
DS200-05A-E	DEC-SPORE 200 Plus SimpleMix Gallon Sporicidal Dose Non-Sterile	4
DS200-06-16Z-01-E	DEC-SPORE 200 Plus SimpleMix Sporicidal Dose 16 oz Sterile	12
DS200-06-16Z-02-E	DEC-SPORE 200 Plus SimpleMix Disinfectant Dose 16 oz Sterile	12
DS200-07-16Z-01-E	DEC-SPORE 200 Plus SimpleMix Sporicidal Dose 16 oz Non-Sterile	12
DS200-07-16Z-02-E	DEC-SPORE 200 Plus SimpleMix Disinfectant Dose 16 oz Non-Sterile	12
DS200-10-200L-SD-CI-E	DEC-SPORE 200 Plus SimpleMix 200L Sporicidal Dose Cubiccontainer Sterile	1
DS200-11-200L-SD-CI-E	DEC-SPORE 200 Plus SimpleMix 200L Disinfectant Dose Cubiccontainer Sterile	1

### Available Technical Data Supplements (Upon Request):

- Validation Report
- Specific Test Reports (Consult VAI)
- MSDS

**Veltek Associates, Inc.**

15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com

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## SPECIFICATIONS

<u>Specification</u>	<u>DEC-SPORE 200 Plus</u>
Appearance:	Clear, water white
IR:	Match Reference
Hydrogen Peroxide:	25.60-29.40%
Peroxyacetic Acid:	5.25-6.40%
Chemical stability:	Stable under normal temperature conditions
Aseptic Fill:	.2 micron filtration
Sporicidal Dose:	
pH:	2.5 (1%)
Specific gravity:	1.12
Flash point:	181.4 °F
Disinfectant Dose:	
pH:	2.5-3
Specific gravity:	1.004
Flash point:	Not flammable

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### VELTEK DEC PRODUCT LABEL COLORS

PRODUCT NAME	BOTTLE/CAN COLOR	LABEL BACKGROUND COLOR	BAR & USER INFO COLOR	TEXT COLOR
DEC-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI 60%	WHITE	LIGHT BLUE		
DEC-AHOL WFI 91%	WHITE	LIGHT BLUE		
DEC-AHOL WFI 99%	WHITE	LIGHT BLUE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DEC-HAND STERILE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-HAND NON-STERILE	CLEAR	LIGHT BLUE		
DEC-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	PRINTED BOTTLE		
DEC-CYCLE	WHITE	LIGHT BLUE		
DEC-CLEAN	WHITE	LIGHT BLUE		
DEC-QUAT 100	WHITE	LIGHT BLUE		
DEC-QUAT 200C	WHITE	LIGHT BLUE		
DEC-QUAT 200V	WHITE	LIGHT BLUE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	MEDIUM BLUE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DEC-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DEC-GLASS	WHITE	LIGHT BLUE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

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# **DEC-SPORE 200 Plus**

**Sterile Pharmaceutical Clean Room Formula**

**PERACETIC ACID & HYDROGEN PEROXIDE**

## **PRODUCT LABELING**

**All Product Labels Are Available Upon Request.**

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*Presented from the Master Label dated 10 April 2013.*

# DEC-SPORE 200 Plus

SANITIZER

DISINFECTANT

Veterinary Facilities, Animal Care Facilities, Industrial Facilities

STERILANT

DISINFECTION FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY  
FOR ORGANIC PRODUCTION

**Active Ingredients:**

Hydrogen Peroxide ..... 27.5%  
Peroxyacetic Acid..... 5.8%

**Inert Ingredients:**..... 66.7%

**Total**..... 100.0%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**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, or using tobacco. Remove contaminated clothing and wash clothing before reuse. The following Personal Protective Equipment (PPE) should 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 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.

**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.

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**

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

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## CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to do so. 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.

After product has been diluted according to label directions PPE is not required.

**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.

**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.

## DIRECTIONS FOR USE

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

## SANITIZATION

**DEC-SPORE 200 Plus** acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO<sub>3</sub>.

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 should be prepared at least daily or more often if the solution becomes diluted or soiled.

## SANITIZING NON-FOOD CONTACT SURFACES

Preclean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs and drip pans with 1 oz **DEC-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). Also effective against organisms found in the brewing industry, *Pedococcus damnosus* (ATCC 25248) and *Lactobacillus malefermentans* (ATCC 11305). All surfaces should 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.

## DIRECTIONS FOR FOGGING

To sanitize hard surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces: Prior to fogging, food products and packaging materials must be removed from the room and carefully protected. Fog desired areas using one quart of a 0.3% - 3.0% **DEC-SPORE 200 Plus** solution (3 ounces to 60 ounces per 8 gallons of water) per 1000 cu ft of room volume. Vacate the area of all personnel during fogging and until the hydrogen peroxide air concentration is below 0.5ppm. Allow surfaces to drain thoroughly before operations are resumed. Solutions above 0.5% may be corrosive and are not to be used on all surfaces. Test solutions on surfaces prior to

**Veltek Associates, Inc.**

15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com

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use. All hard non-porous food contact surfaces treated with the disinfectant and fog must be rinsed thoroughly with a potable water rinse.

### SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For sanitization against the beverage spoilage organisms *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305) and *Saccharomyces cerevisiae* (ATCC 834), apply 0.5 – 4.0% (5 ounces to 40 ounces to 8 gallons of water) of **DEC-SPORE 200 Plus** to surfaces at a temperature of 25<sup>0</sup> to 45<sup>0</sup>C and allow to remain wet for at least 5 minutes. Allow surfaces to drain thoroughly before operations are resumed.

### ANTIMICROBIAL TREATMENT OF REVERSE OSMOSIS WATER MEMBRANES

To reduce the number of the beverage spoilage organisms *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305) and *Saccharomyces cerevisiae* (ATCC 834). Clean the RO system with a detergent solution followed by a potable water rinse. Apply **DEC-SPORE 200 Plus** as a 0.1-0.2% (1 to 2.1 fluid ounces per 8 gallons of water) use solution at 75°F for a minimum contact time of 5 minutes. After treatment with **DEC-SPORE 200 Plus** use solution, rinse membranes thoroughly with a disinfected water rinse free of pathogenic bacteria. Do not treat membranes more than once per week. Consult membrane manufacturer for membrane compatibility guidelines. Conduct membrane treatment while the membrane system is off-line.

### BOOSTER FOR ALKALINE DETERGENTS TO CLEAN FOOD PROCESSING EQUIPMENT

**DEC-SPORE 200 Plus** is an effective oxygen bleach cleaning booster for use with alkaline detergents. For cleaning application as a detergent booster, use 0.5 – 2.5% v/v total product (0.64 – 3.2 ounces per gallon of detergent use solution) to aid in the removal of organic soil. All hard non-porous food contact surfaces treated with this boosted detergent must be rinsed thoroughly with a potable water rinse followed by sanitizing with an approved food contact surface sanitizer.

## DISINFECTION

**DEC-SPORE 200 Plus** disinfects as it cleans in one operation. **DEC-SPORE 200 Plus** can be used to disinfect floors, walls and other hard nonporous 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, 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, medical devices or medical equipment.

### COMBINATION GENERAL DISINFECTION AND CLEANING

**DEC-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*<sup>1</sup> at 0.4% 0 1.0% (2 ounces/4 gallons to 5 ounces/4 gallons of water) in hard water (500 ppm as CaCO<sub>3</sub>), 5% blood serum and dried soap film residue on hard nonporous surfaces. For heavily soiled areas a precleaning step is required. Prepare a disinfecting and cleaning solution by diluting 4 ounces **DEC-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.

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<sup>1</sup> Not tested in the presence of soap film residue.

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### VIRUCIDAL

At 0.4% - 1.0% (2 ounces/4 gallons – 5 ounces/4 gallons of water) **DEC-SPORE 200 Plus** is effective against Influenza B/Taiwan/2/62, Influenza A (H3N2) and Influenza A (H1N1) when used at 20°C 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

**DEC-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 ounces/4 gallons – 5 ounces/4 gallons of water) in hard water (500 ppm as CaCO<sub>3</sub>), 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.

**DEC-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, **DEC-SPORE 200 Plus** is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding and watering equipment. In addition **DEC-SPORE 200 Plus** will deodorize those areas that are generally hard to keep fresh smelling such as garage 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.

### DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES

Remove animals and feed from facilities. Remove litter, waste matter and gross 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 ounces/4 gallons – 5 ounces/4 gallons of water) solution of **DEC-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.

### 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 **DEC-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 should 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:

<u>DEC-SPORE 200 Plus Active 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 **DEC-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 sporogenes* (ATCC 3584) when used per the label directions.

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**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 surfaces, 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 should 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 DISPOSAL:**

(≤ 55 gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying.

(2.5 gallon bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling, if available.

**FOR COMMERCIAL USE STRONG OXIDIZING AGENT**

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# **DEC-SPORE 200 Plus**

## **Sterile Pharmaceutical Clean Room Formula**

### **PERACETIC ACID & HYDROGEN PEROXIDE**

**STUDY TITLE (Previous Product Studies<sup>2</sup>)**

**DEC-SPORE 200 Plus Efficacy Data Summary**

**EPA REGISTRATION NO. 1677-129-68959**

**EPA ESTABLISHMENT NO. 68959-PA-1**

**EPA DATA REQUIREMENT**

**Guideline 91-2**

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<sup>2</sup> 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.

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## I. TEST SUBSTANCE IDENTIFICATION:

### DEC-SPORE 200 Plus

Veltek Associates, Inc.

EPA Reg #: 1677-129-68959

EPA Est. #: 68959-PA-1

Active Ingredients	Percentage
Hydrogen peroxide:	27.50
Peroxyacetic acid:	5.80
Inert Ingredients:	66.70
TOTAL	100.0%

## II. FOOD CONTACT SURFACE SANITIZING EFFICACY:

### Test Concentration:

1 oz./4 gal. (0.20% solution)

### Diluent:

500 ppm synthetic hard water

### Exposure Time:

30 seconds

### Test Method:

*Germicidal and Detergent Sanitizing Action of Disinfectants*, created from AOAC 960.09, 15<sup>th</sup> edition.

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## Food Contact Surface Sanitizing Results:

TEST SYSTEM	ATCC#	TEST DATE	BATCH #	RESULT (Percent Reduction)
<i>Staphylococcus aureus</i>	6538	6/25/87	7008-34-1	>99.999
			7008--4-2	>99.999
			7008-34-3	>99.999
<i>Escherichia coli</i>	11229	6/25/87	7008-34-1	>99.999
			7008-34-2	>99.999
			7008-34-3	>99.999
<i>Vibrio cholerae</i>	25873	3/11/92	SI011522	>99.999
			SI011622	>99.999
<i>Listeria monocytogenes</i>	Scott A	10/12/92	SI050522	>99.999
			SI061022	>99.999
<i>Salmonella typhimurium</i>	Milk Isolate	10/12/92	SI050522	>99.999
			SI061022	>99.999
<i>Pseudomonas aeruginosa</i>	15442	10/12/92	SI050522	>99.999
			SI061022	>99.999
<i>Saccharomyces cerevisiae</i>	834	10/12/92	SI050522	>99.999
			SI061022	
<i>Lactobacillus buchneri</i>	11305	6/16/93	8428-20	>99.999
			8428-21	>99.999
<i>Pediococcus damnosus</i>	25248	6/16/93	8428-20	>99.999
			8428-21	>99.999

The EPA test requirement for an effective food contact surface sanitizer is that a >99.999 percent reduction must be achieved within a 30 second exposure time.

### CONCLUSION

DEC-SPORE 200 Plus demonstrated food contact sanitizing efficacy diluted at 0.2% in 500 ppm sterile synthetic hard water as CaCO<sub>3</sub> against *Staphylococcus aureus*, *Escherichia coli*, *Vibrio cholerae*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Saccharomyces cerevisiae*, *Lactobacillus buchneri*, *Pediococcus damnosus* after a 30 second contact time at 25°C.

**Veltek Associates, Inc.**

15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com

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## III. FOOD CONTACT SANITIZING EFFICACY AT 120°F

(Same parameters noted above)

### Food Contact Surface Sanitizing Results at 120°F

TEST SYSTEM	ATCC#	TEST DATE	BATCH #	RESULT (Percent Reduction)
<i>Staphylococcus aureus</i>	6538	3/3/94	9226.1-1	>99.999
			9226.1-2	>99.999
			SI073032	>99.999
<i>Escherichia coli</i>	11229	3/3/94	9226.1-1	>99.999
			9226.1-2	>99.999
			SI073032	>99.999

The EPA test requirement for an effective food contact surface sanitizer is that a >99.999 percent reduction must be achieved within a 30 second exposure time.

### **CONCLUSION**

DEC-SPORE 200 Plus demonstrated food contact sanitizing efficacy diluted at 0.2% in 500 ppm sterile synthetic hard water as CaC<sub>03</sub> against *Staphylococcus aureus* and *Escherichia coli* in the after a 30 second contact time at 120°F.

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## IV. 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*

### **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>Vibrio cholerae</i>	25873	10/12/92	SI011522	>99.9
			SI011622	>99.9
<i>Listeria monocytogenes</i>	Scott A	10/12/92	SI050522	>99.9
			SI061022	>99.9
<i>Salmonella typhimurium</i>	Milk Isolate	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 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

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**

DEC-SPORE 200 Plus demonstrated non-food contact sanitizing efficacy diluted at 1 oz./8 gal. in 500 ppm sterile synthetic hard water as CaCO<sub>3</sub> against *Staphylococcus aureus*, *Escherichia coli*, *Vibrio cholerae*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Saccharomyces cerevisiae*, *Lactobacillus buchneri*, *Pediococcus damnosus* after a 30 second contact time at 25°C.

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## V. NON-FOOD CONTACT SANITIZING EFFICACY WITH LIQUID K:

(Same parameters noted above)

TEST SYSTEM	ATCC#	TEST DATE	BATCH #	RESULT (Percent Reduction)
<i>Staphylococcus aureus</i>	6538	11/22/95	B-1431	>99.9
			B-1492	>99.9
			B-1496	>99.9
<i>Enterobacter aerogenes</i>	13048	1/6/93	B-1431	>99.9
			B-1492	>99.9
			B-1496	>99.9
<i>Listeria monocytogenes</i>	Scott A	11/22/95	B-1431	>99.9
			B-1492	>99.9

## CONCLUSION

DEC-SPORE 200 Plus with Liquid K demonstrated non-food contact sanitizing efficacy diluted at 1 oz./4 gal. in 500 ppm sterile synthetic hard water as CaCO<sub>3</sub> against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, 5 minute contact time at ambient temperature.

## VI. DISINFECTANT EFFICACY:

### Test Concentration

4 oz/8 gal. (0.4%)

### Artificial Soil Load

5% fetal bovine serum and 0.005% sodium stearate

### Test Exposure Time

10 minutes

### Test Procedure

Use Dilution method, A.O.A.C Official Methods of Analysis, 14<sup>th</sup> Edition, 1984

\* Results are representative of # negative growth tubes/# tubes tested.

## CONCLUSION

DEC-SPORE 200 Plus demonstrated one step cleaner-hospital disinfectant efficacy diluted at 0.4% in 500 ppm sterile synthetic hard water as CaCO<sub>3</sub> against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Histoplasma capsulatum*, *Aspergillus fumigatus* and *Mycobacterium bovis* in the presence of an organic soil load of 5% fetal bovine serum and 0.005% sodium stearate with a 10 minutes contact time at 20° C.

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## VII. VIRUCIDAL EFFICACY:

### Test Procedure:

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

### Results\*

TEST SYSTEM	ATCC#	TEST DATE	BATCH #
<i>Influenza A (H1N1)</i>	VR-897	03/05/92	SIO11622
			SIO11522
<i>Influenza A (H3N2)</i>	VR-810	03/12/92	SIO11622
			SIO11522
<i>Influenza A (H10N7)</i>	VR-1334	01/11/92	8229-15-A
			8229-15-B
<i>Reovirus CO<sub>8</sub></i>	VR-2040	03/06/92	8229-15-A
			8229-15-B
<i>Parainfluenza 3 (Bovine, SF-4)</i>	VR-281	03/31/92	8229-15-A
			8229-15-B
<i>Infectious Bovine Rhinotracheitis</i>	VR-188	2/25/92	8229-15-A
			8229-15-B
<i>Newcastle Disease Virus</i>	VR-109	01/30/92	8229-15-A
			8229-15-B
<i>Infectious Bronchitis</i>	VR-22	03/19/92	8229-15-A
			8229-15-B

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  $\geq 3$ -log difference must be observed between the cytotoxicity titer (of the test substance) and virus titer
- 1) 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

DEC-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.

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**DEC-SPORE 200 Plus**  
**Sterile Pharmaceutical Clean Room Formula**

**PERACETIC ACID & HYDROGEN PEROXIDE**

**TOXICITY STUDY**

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## DEC-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 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.

### SUMMARY OF ACUTE ORAL TOXICITY IN RATS MEDIAN LETHAL DOSAGE DETERMINATION

**Purpose:** To determine the acute oral toxicity of DEC-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

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**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.

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# **DEC-SPORE 200 Plus**

**Sterile Pharmaceutical Clean Room Formula**

**PERACETIC ACID & HYDROGEN PEROXIDE**

## **Lot Specific Sterile Documentation**

**(received with each shipment)**

**Certificate of Analysis**

**Certificate of Sterility (Current USP Compendium for Sterility Test)**

**(Please contact VAI for a sample of this documentation)**

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