



VELTEK ASSOCIATES, INC.

# TECHNICAL DATA FILES



## DECON-PHENE<sup>®</sup> *Plus* High pH Phenolic

*Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.*

15MAR2024

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## **Product Overview**

**DECON-PHENE Plus**® is a high pH phenolic, broad spectrum, disinfectant for use in cleanrooms and controlled areas. **DECON-PHENE Plus** disinfects controlled areas such as those in compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. **DECON-PHENE Plus** is compatible with most non-porous hard surface materials and can be used on surfaces in aseptic filling and gowning rooms, in general manufacturing areas, and in laboratories. The efficacy of **DECON-PHENE Plus** has been confirmed using the A.O.A.C Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:128 use dilution with a 10 minute contact time.

### **Disinfectant – Detergent – Bactericidal – Deodorizer**

**DECON-PHENE Plus** is filled in ISO 7 cleanroom (Grade B), filtered at 0.2 microns, and subsequently terminally sterilized to 10<sup>-6</sup> sterility assurance level. Each lot of **DECON-PHENE Plus** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-PHENE Plus** is delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

**DECON-PHENE Plus** is available in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200 L drum. **DECON-PHENE Plus** 1 gallon, 16 oz, and 200 L containers come in our one-step, 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-PHENE Plus** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

## **Quality and Manufacturing**

- Filled in an ISO 7 cleanroom (Grade B)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10<sup>-6</sup> SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

## Features and Benefits

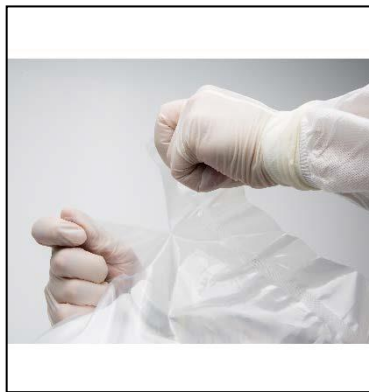
- US EPA Registered; EPA Registration Number: 68959-13
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical, irradiation, and sterility data, tested to USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Multiple convenient container sizes – Unit Dose, 16 oz, 1 Gallon, and 200 L either sterile or non-sterile
- Broad spectrum efficacy confirmed by using A.O.A.C protocol testing at a use dilution of 1:128
- Effective against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) in 10 minutes
- Effective in hard water (200 ppm)
- One-step cleaner, deodorizer and disinfectant
- Multi-purpose detergent
- Hospital grade disinfectant
- This product eliminates odors by killing odor-causing bacteria

## Product Uses

- Cleanrooms and controlled areas such as those in compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on
- Aseptic filling and gowning rooms, general manufacturing areas and laboratories
- Hard non-porous, inanimate surfaces
- Machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves
- Plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces.

## ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags



## 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 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, 16 oz, and 200 L 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. 200 L SimpleMix systems are activated through a hose and valve system connecting the cubicon 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.

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**Veltek Associates, Inc.**

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8336 [www.sterile.com](http://www.sterile.com)

Rev: 15MAR2024 ML Rev: D-19

## SimpleMix® Directions for Use

**Prepare use solution by following SimpleMix® System Container Instructions.**

### **16 oz Trigger Spray Bottle:**

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.

### **1 Gallon Size Bottle:**

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:**

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

Connect cubic container to the 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.

*See pictorial directions below.*

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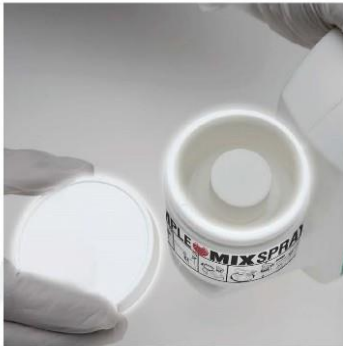
Tel: 610-644-8335 Fax: 610-644-8336 [www.sterile.com](http://www.sterile.com)

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## SimpleMix Trigger Spray

**SIMPLEMIX® 16 oz/473 mL Aseptic Mixing System**  
 For the Exact Formulation of 16 oz/473 mL Disinfectants and Sporicides  
**Ready-to-Use Mixing Instructions**

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



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



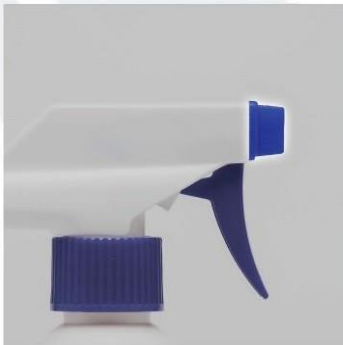
- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



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## SimpleMix Gallon

### **SIMPLEMIX**® 1 Gallon/3.79 L Aseptic Mixing System For the Exact Formulation of 1 Gallon/3.79 L Size Disinfectants and Sporicides **Ready-to-Use Mixing Instructions**

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



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



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



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



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



- 8) Follow directions for use on label.

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## SimpleMix Drum


### 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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## Chemical Specifications

<b>DECON-PHENE Plus® – High pH Phenolic</b>	
<b>Certificate of Analysis</b>	<b>Specification</b>
Appearance	Clear, Straw/Amber, Color varies and darkens with age
Odor	Slight Camphor
Specific Gravity	1.083 – 1.116
Ortho-benzyl-para-clorophenol	10.36% – 11.78%
Ortho-phenylphenol	10.50% – 11.94%
pH (Concentrate)	11.0 – 13.0
Expiration Period	2 years

## Ordering Information

<b>DECON-PHENE Plus® – High pH Phenolic</b>		
<b>Part number</b>	<b>Description</b>	<b>Qty/cs</b>
DPP-01	DECON-PHENE Plus, 1 Gallon Concentrate, Non-Sterile	4
DPP-02	DECON-PHENE Plus, 1 Gallon Concentrate, Sterile	4
DPP-03-2Z	DECON-PHENE Plus, 2 oz Concentrate, Unit Dose, Sterile	24
DPP-03-4Z	DECON-PHENE Plus, 4 oz Concentrate, Unit Dose, Sterile	24
DPP-04-1Z	DECON-PHENE Plus, 1 Gallon SimpleMix, Use Dilution 1:128, Sterile	4
DPP-04-2Z	DECON-PHENE Plus, 1 Gallon SimpleMix, Use Dilution 1:64, Sterile	4
DPP-05-1Z	DECON-PHENE Plus, 1 Gallon SimpleMix, Use Dilution 1:128, Non-Sterile	4
DPP-05-2Z	DECON-PHENE Plus, 1 Gallon SimpleMix, Use Dilution 1:64, Non-Sterile	4
DPP-06-16Z-01	DECON-PHENE Plus, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:128, Sterile	12
DPP-06-16Z-02	DECON-PHENE Plus, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:64, Sterile	12
DPP-07-16Z-01	DECON-PHENE Plus, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:128, Non-Sterile	12
DPP-07-16Z-02	DECON-PHENE Plus, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:64, Non-Sterile	12
DPP-10-200L-CI-01	DECON-PHENE Plus, 200 L, SimpleMix Drum, Sterile	1

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**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	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		

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Product Labeling

# DECON-PHENE® Plus

## High pH Phenolic

(Any specific product label is available upon request.)

**EMERGENCIES:** In the case of emergency call: 1-866-929-0799 (toll free) 24 hours a day from the USA, Canada, or Mexico.

**For Use in Cleanrooms and Controlled Areas**  
**Broad Spectrum Disinfectant - Hospital Disinfectant**  
**Asceptically Filtered at 0.2 µm - Sterile Pharmaceutical Cleanroom Formula**  
**Formulated for Use in Aseptic and Controlled Environments (Cleanrooms)**

**Active Ingredients:**

Ortho-Phenylphenol.....	(CAS# 90-43-7).....	11.85%
Ortho-tolyl-para-Chlorophenol.....	(CAS# 120-32-1).....	10.91%
Other Ingredients.....		78.04%
<b>Total.....</b>		<b>100.00%</b>

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

**FIRST AID**  
**IF IN EYES:** If splashed 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 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 by a poison control center or doctor. Do not give anything to an unconscious person.  
**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans and Domestic Animals.**  
**DANGER, Corrosive.** Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear long-sleeved shirt and long pants, shoes and socks, and chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**DIRECTIONS FOR USE**  
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read the label before using.  
**SI usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.**  
**Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.**  
*This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

**DECON-PHENE® Plus** is effective in hard water (200 ppm). The use dilution of this product, is formulated to clean, disinfect and deodorize. Use this product on washable, hard, non-porous, non-food contact environmental services.  
**LOCATIONS OF USE:** Disinfects clean rooms and controlled areas such as those in health care institutions, compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces. It is compatible with most non-porous hard surface materials.

**DECON-PHENE® Plus** is a multi-purpose detergent.  
This product was tested using the AOAC Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:20 use dilution with a 10 minute contact time.  
This product eliminates odors by killing odor-causing bacteria.

**PREPARE CLEANING AND DISINFECTION USE SOLUTION:**  
Pre-clean all surfaces to be treated.

**For 2 Ounce (60 mL) Unit Dose:** Add the contents of this container to two gallons (156 liters) of water or an equivalent 1:20 dilution. Mix 15 seconds until the solution is uniform.

**For 4 Ounce (120 mL) Unit Dose:** Add the contents of this container to four gallons (15.6 liters) of water or an equivalent 1:20 dilution. Mix 15 seconds until the solution is uniform.

**For Concentrate:** To make a cleaning and disinfecting solution, add one fluid ounce (30 mL) per gallon of water (3.79 liters) and mix for 15 seconds until the solution is uniform. An equivalent 1:20 dilution can also be used. If extra detergency is desired, increase dilution to 2 ounces per gallon of water.

**Do not mix or dilute with other chemicals.**

**TO CLEAN, DEODORIZE, AND DISINFECT:**  
After mixing the use solution, apply this product using a cloth, mop, sponge, brush or course sprayer. Thoroughly wet surface with this product and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry or after 10 minutes rinse and wipe dry with sterilized cloth wiper, if desired.  
Prepare a fresh solution at least daily or as solution becomes dirty, discard and replace with a fresh one.

**STORAGE AND DISPOSAL**  
Do not contaminate water, food, or feed by storage and disposal.  
**Pesticide Storage:** Store in original container in a cool dry place. Avoid storage at temperature extremes or in sunlight.  
**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or residue 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 Disposal:**  
Nonrefillable container. Do not reuse or refill this container. Dispose of container by permitted onsite incinerator or by transport to effate permitted incineration service. OR Triple rinse container (or equivalent) promptly after emptying.  
**Triple rinse as follows:** Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinse into application equipment or mix tank or store rinse for later use or disposal. Repeat this procedure two more times.  
Follow Pesticide Disposal instructions for rinse disposal. Then offer for recycling or dispose of in a sanitary landfill.

**Net Contents: 2 oz x 24 (59 mL)**  
(Total 15 Quarts / 14.2 L)

**Net Contents: 1 Gallon x 4 (3.79 L)**  
(Total 4 Gallons (15.1 L))

**Net Contents: 4 oz x 24 (118 mL)**  
(Total 3 Quarts / 2.8 L)

Made in USA

SDS #: VML-142 - Red dot indicates Sterile - Case Label: DPP-00 - Rev 5/20 - 1-19  
EPA Reg. No. 68959-13 - EPA Est. No. 68959-PA-01  
Patents: www.sterile.com/patents

**Veltek Associates, Inc.**  
15 Lee Blvd, Malvern, PA 19355-1234  
Tel: 610-644-8335 - www.sterile.com

Case Label DPP-00 Rev05/20

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Other Ingredients.....		78.04%
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**DANGER**

**FIRST AID**  
**IF IN EYES:** If splashed 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 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 by a poison control center or doctor. Do not give anything to an unconscious person.  
**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans and Domestic Animals.**  
**DANGER, Corrosive.** Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear long-sleeved shirt and long pants, shoes and socks, and chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**DIRECTIONS FOR USE**  
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read the label before using.  
**SI usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.**  
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*This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

**DECON-PHENE® Plus** is effective in hard water (200 ppm). The use dilution of this product, is formulated to clean, disinfect and deodorize. Use this product on washable, hard, non-porous, non-food contact environmental services.  
**LOCATIONS OF USE:** Disinfects clean rooms and controlled areas such as those in health care institutions, compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces. It is compatible with most non-porous hard surface materials.

**DECON-PHENE® Plus** is a multi-purpose detergent.  
This product was tested using the AOAC Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:20 use dilution with a 10 minute contact time.  
This product eliminates odors by killing odor-causing bacteria.

**PREPARE CLEANING AND DISINFECTION USE SOLUTION:**  
Pre-clean all surfaces to be treated.

Follow SIMPLIMIX® System Container instructions.

**1 Gallon Size Bottle:**

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.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and pour off excess as above.
7. Four solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.

**16 Ounce Trigger Spray Bottle:**

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.
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.

**STORAGE AND DISPOSAL**  
Do not contaminate water, food, or feed by storage and disposal.  
**Pesticide Storage:** Store in original container in a cool dry place. Avoid storage at temperature extremes or in sunlight.  
**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or residue 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 Disposal:**  
Nonrefillable container. Do not reuse or refill this container. Dispose of container by permitted onsite incinerator or by transport to effate permitted incineration service. OR Triple rinse container (or equivalent) promptly after emptying.  
**Triple rinse as follows:** Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinse into application equipment or mix tank or store rinse for later use or disposal. Repeat this procedure two more times.  
Follow Pesticide Disposal instructions for rinse disposal. Then offer for recycling or dispose of in a sanitary landfill.

**Net Contents: 16 oz x 12 (473 mL)**  
(Total 15 Gallons / 56.8 L)

**Net Contents: 1 Gallon x 4 (3.79 L)**  
(Total 4 Gallons (15.1 L))

Made in USA

SDS #: VML-142 - Red dot indicates Sterile - Case Label: DPP-00-SM - Rev 5/20 - 1-19  
EPA Reg. No. 68959-13 - EPA Est. No. 68959-PA-01  
Patents: www.sterile.com/patents

**Veltek Associates, Inc.**  
15 Lee Blvd, Malvern, PA 19355-1234  
Tel: 610-644-8335 - www.sterile.com

Case Label DPP-00-SM Rev05/20



**Product Labeling (Continued)**

# DECON-PHENE® Plus

**For Use in Cleanrooms and Controlled Areas**

**Broad Spectrum Disinfectant • Hospital Disinfectant**

**Aseptically Filtered at 0.2 µm • Sterile Pharmaceutical Cleanroom Formula**

**Formulated for Use in Aseptic and Controlled Environments (Cleanrooms)**

**Active Ingredients:**

Ortho-Phenylphenol.....(CAS# 90-43-7).....	11.05%
Orthobenzyl-para-Chlorophenol.....(CAS# 120-32-1).....	10.91%
<b>Other Ingredients</b> .....	<u>78.04%</u>
<b>Total</b> .....	100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**Red dot indicates Sterile**

EPA Reg. No. 68959-13 • EPA Est. No. 68959-PA-01

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

**Veltek Associates, Inc.**

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335 • [www.sterile.com](http://www.sterile.com)

**Made in USA**

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**Veltek Associates, Inc.**

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8336 [www.sterile.com](http://www.sterile.com)

Rev: 15MAR2024 ML Rev: D-19

## Product Labeling (Continued)

### DECON-PHENE Plus

**DECON-PHENE Plus** disinfects clean rooms and controlled areas such as those in health care institutions, compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces. It is compatible with most non-porous hard surface materials.

**DECON-PHENE Plus** is a hard surface, broad spectrum, hospital grade disinfectant. **DECON-PHENE Plus** is bactericidal. The results of the AOAC Efficacy Tests show that **DECON-PHENE Plus** is an effective hard surface disinfectant on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538) in 10 minutes. **DECON-PHENE Plus** eliminates odors by killing odor-causing bacteria.

(For the state of California) **ATTENTION:** This product can expose you to chemicals including ortho-phenylphenol, which is known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### **FIRST AID**

**IF IN EYES:** If splashed 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 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 by a poison control center or doctor. Do not give anything to an unconscious person.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

## Product Labeling (Continued)

### **PRECAUTIONARY STATEMENTS**

#### **Hazards to Humans and Domestic Animals.**

**DANGER.** Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear long-sleeved shirt and long pants, shoes and socks, and chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Store in original container in a cool dry place. Avoid storage at temperature extremes or in sunlight.

**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 Disposal:**

Nonrefillable container. Do not reuse or refill this container. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration service. OR Triple rinse container (or equivalent) promptly after emptying.

**Triple rinse as follows:** Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

## Product Labeling (Continued)

### DIRECTIONS FOR USE

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

**Read the label before using.**

**Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.**

*This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

**DECON-PHENE® Plus** is effective in hard water (200 ppm). The use dilution of this product, is formulated to clean, disinfect and deodorize. Use this product on washable, hard, non-porous, non-food contact environmental services.

**LOCATIONS OF USE:** Disinfects clean rooms and controlled areas such as those in health care institutions, compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces. It is compatible with most non-porous hard surface materials.

**DECON-PHENE® Plus** is a multi-purpose detergent.

This product was tested using the AOAC Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:128 use dilution with a 10 minute contact time.

This product eliminates odors by killing odor-causing bacteria.

### **PREPARE CLEANING AND DISINFECTION USE SOLUTION:**

**Pre-clean all surfaces to be treated.**

**For 2 Ounce (60 mL) Unit Dose:** Add the contents of this container to two gallons (7.58 liters) of water or an equivalent 1:128 dilution. Mix 15 seconds until the solution is uniform.

**For 4 Ounce (120 mL) Unit Dose:** Add the contents of this container to four gallons (15.16 liters) of water or an equivalent 1:128 dilution. Mix 15 seconds until the solution is uniform.

**For Concentrate:** To make a cleaning and disinfecting solution, add one fluid ounce (30 mL) per gallon of water (3.79 liters) and mix for 15 seconds until the solution is uniform. An equivalent 1:128 dilution can also be used. If extra detergency is desired, increase dilution to 2 ounces per gallon of water.





**Product Labeling (Continued)**

**Follow SIMPLEMIX® System Container instructions.**

<b>SIMPLEMIX® System Container Instructions:</b>	
<b>1 Gallon Size Bottle:</b>	<b>16 Ounce Trigger Spray Bottle:</b>
<ol style="list-style-type: none"> <li>1. To prepare use solution, open cap.</li> <li>2. Peel off inner seal by grasping tab at far edge and pulling off.</li> <li>3. Firmly push small, inner container all the way.</li> <li>4. Replace cap and tighten.</li> <li>5. Slowly swirl for 15 seconds.</li> <li>6. Open small side spout and peel off inner seal, as above.</li> <li>7. Pour solution from small side spout onto surfaces to be treated or alternate containers.</li> <li>8. Follow directions for use on label.</li> </ol>	<ol style="list-style-type: none"> <li>1. To prepare use solution, open cap.</li> <li>2. Peel off inner seal by grasping tab at far edge and pulling off.</li> <li>3. Firmly push small, inner container all the way.</li> <li>4. Replace cap and tighten.</li> <li>5. Slowly swirl for 15 seconds.</li> <li>6. Move spray nozzle to open position.</li> <li>7. Follow directions for use on label.</li> </ol>

**Do not mix or dilute with other chemicals.**

**TO CLEAN, DEODORIZE, AND DISINFECT:**

After mixing the use solution, apply this product using a cloth, mop, sponge, brush or course sprayer. Thoroughly wet surface with this product and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes rinse and wipe dry with sterilized cloth wiper, if desired.

Prepare a fresh solution at least daily or as solution becomes dirty, discard and replace with a fresh one.



**Testing Summary**

**Efficacy Test Summary**

**DECON-PHENE® Plus**

**High pH Phenolic**

**DECON-PHENE Plus Efficacy Summary**

This product was tested using the AOAC Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:128 use dilution with a 10 minute contact time.

**Efficacy of DECON-PHENE Plus Against *P. aeruginosa***

**Study Summary:**

Study Title: AOAC Use-Dilution Test

Test Microorganism: *Pseudomonas aeruginosa* ATCC 15442

Test Substance: **DECON-PHENE Plus**

Test Substance Dilution: Liquid test substance diluted 1:128 in 180-210 ppm autoclaved sterilized Tap Water

Organic Soil Load: No organic soil was added to the inoculum

Carrier Type: Stainless Steel penicylinders

Numbers of Carriers Per Lot: 60

Contact Time: 10 minutes

Exposure Temperature: 20±1°C

Neutralizer: Lethen Broth

**Study Results:**

<b>DECON-PHENE Plus – High pH Phenolic</b>				
<b>Microorganism</b>	<b>Number of Confirmed Positive Carriers/Total Number Tested</b>			<b>Carrier Control Avg Log10 CFU/Carrier</b>
	<b>Lot# 1</b>	<b>Lot# 2</b>	<b>Lot# 3</b>	
<i>Pseudomonas aeruginosa</i> <b>ATCC 15442</b>	0/60	N/A	N/A	6.47
	N/A	0/60	N/A	6.28
	N/A	N/A	0/60	6.03

**Conclusion:**

Under the conditions of the assay, **DECON-PHENE Plus** met the requirements stated in the U.S. EPA Product Performance Test Guidelines – Disinfectants for Use on Environmental Surfaces as outlined in OCSPP 810.2200 and the success criteria detailed in the approved protocol.

## Testing Summary (Continued)

### Efficacy of DECON-PHENE Plus Against *S. aureus*

#### Study Summary:

Study Title: AOAC Use-Dilution Test

Test Microorganism: *Staphylococcus aureus* ATCC 6538

Test Substance: **DECON-PHENE Plus**

Test Substance Dilution: Liquid test substance diluted 1:128 in 180-210 ppm autoclaved sterilized Tap Water

Organic Soil Load: No organic soil was added to the inoculum

Carrier Type: Stainless Steel penicylinders

Numbers of Carriers Per Lot: 60

Contact Time: 10 minutes

Exposure Temperature: 20±1°C

Neutralizer: Lethen Broth

#### Study Results:

<b>DECON-PHENE Plus – High pH Phenolic</b>				
<b>Microorganism</b>	<b>Number of Confirmed Positive Carriers/Total Number Tested</b>			<b>Carrier Control Avg Log10 CFU/Carrier</b>
	<b>Lot# 1</b>	<b>Lot# 2</b>	<b>Lot# 3</b>	
<i>Staphylococcus aureus</i> ATCC 15442	0/60	N/A	N/A	6.94
	N/A	1/60	N/A	6.92
	N/A	N/A	0/60	6.69

#### Conclusion:

Under the conditions of this assay, **DECON-PHENE Plus** met the requirements stated in the U.S. EPA Product Performance Test Guidelines – Disinfectants for Use on Environmental Surfaces as outline in OCSPP 810.2200 and the success criteria detailed in the approved protocol.

## Additional Documentation

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample Lot Specific Documentation – Delivered with lot specific analytical, irradiation, 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 unit dose 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 [sales@sterile.com](mailto:sales@sterile.com) or visit our website at [www.sterile.com](http://www.sterile.com). Patents: [www.sterile.com/patents](http://www.sterile.com/patents)

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