



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-PHENE[®] II

High pH Phenolic
Sterile Pharmaceutical Cleanroom Formula

Product Description

DECON-PHENE II is a high pH, phosphate free, sterile pharmaceutical cleanroom formula phenolic that is acceptable for use by the pharmaceutical and biotechnology industries. **DECON-PHENE II** has been formulated for effective aseptic controlled environment “cleanroom” sanitation on hard, inanimate surfaces in aseptic filling and gowning rooms and general manufacturing areas. **DECON-PHENE II** is an effective sanitizer on inanimate, non-porous, non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC# 6538) and *Klebsiella pneumonia* (ATCC# 4352) in 5 minutes.

Sanitizer

DECON-PHENE II is filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently terminally sterilized to 10⁻⁶ sterility assurance level. Each lot of **DECON-PHENE II** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-PHENE II** is delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

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

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron air before assembly
- Gamma irradiated at a 10⁻⁶ SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

DECON-PHENE II – Sodium Based Phenolic	
Certificate of Analysis	Specification
Appearance:	Clear, Color varies and darkens with age
Odor:	Slight Camphor
Specific Gravity:	1.03 – 1.04
Combined Phenates (Reported as Phenols)	8.26% - 9.13%
pH (Concentrate)	11.34 – 12.34
Expiration Period	2 years

Uses

DECON-PHENE II has been formulated for effective hospital, health care facility, and aseptic controlled environment (cleanroom) sanitation. **DECON-PHENE II**, when used as directed, can be used on hard, nonporous surfaces materials, and components such as: stainless steel, chrome plated steel, brass, copper, aluminum, fiberglass, formica, nylon, lexan, Plexiglas, acrylic, vinyl, glazed porcelain, glass, latex, and enamel. **DECON-PHENE II** is for use on hard, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, and walls.

Features and Benefits

- US EPA Registered; EPA Registration Number: 211-65-68959
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Individually labeled with lot number and expiration
- Multiple convenient container sizes – Unit Dose, 16oz, 1 Gallon, and 200 L either sterile or non-sterile
- Acceptable for use by pharmaceutical and biotechnology industries in aseptic filling and gowning rooms and general manufacturing areas
- Effective sanitizer on inanimate, non-porous, non-food contact surfaces
- Effective against *Staphylococcus aureus* (ATCC# 6538) and *Klebsiella pneumonia* (ATCC# 4352) in five minutes
- Sterile pharmaceutical cleanroom formula
- Phosphate free

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. 200L SimpleMix systems are activated through a hose and valve system connecting the cubcontainer 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.

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

Ordering Information

DECON-PHENE II – Sodium Based Phenolic		
Part number	Description	Qty/cs
DP2-01	DECON-PHENE II, 1 Gallon Concentrate, Non-Sterile	4
DP2-02	DECON-PHENE II, 1 Gallon Concentrate, Sterile	4
DP2-03-2Z	DECON-PHENE II, 2 oz Concentrate, Unit Dose, Sterile	24
DP2-03-4Z	DECON-PHENE II, 4 oz Concentrate, Unit Dose, Sterile	24
DP2-04-1Z	DECON-PHENE II, 1 Gallon SimpleMix, Use Dilution 1:128, Sterile	4
DP2-04-2Z	DECON-PHENE II, 1 Gallon SimpleMix, Use Dilution 1:64, Sterile	4
DP2-05-1Z	DECON-PHENE II, 1 Gallon SimpleMix, Use Dilution 1:128, Non-Sterile	4
DP2-05-2Z	DECON-PHENE II, 1 Gallon SimpleMix, Use Dilution 1:64, Non-Sterile	4
DP2-06-16Z-01	DECON-PHENE II, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:128, Sterile	12
DP2-06-16Z-02	DECON-PHENE II, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:64, Sterile	12
DP2-07-16Z-01	DECON-PHENE II, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:128, Non-Sterile	12
DP2-07-16Z-02	DECON-PHENE II, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:64, Non-Sterile	12
DP2-10-200L-CI-01	DECON-PHENE II, 200 L, SimpleMix Drum, Use Dilution 1:128, Sterile	1
DP2-10-200L-CI-02	DECON-PHENE II, 200 L, SimpleMix Drum, Use Dilution 1:64, Sterile	1



DP2-01



DP2-03-2Z



DP2-06-16Z-01



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-PHENE® II High pH Phenolic

(Any specific product label is available upon request.)



DECON-PHENE II Family of Products

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234 T: 610-644-8335 F: 610-644-8336 www.sterile.com

Rev: 07Apr2022 ML Rev: D-19



DECON-PHENE® II

High pH Phenolic Sanitizer

Formulated for Effective Aseptic Controlled Environment (“Clean Room”) Sanitation

ACTIVE INGREDIENTS:

Ortho-benzyl-para-chlorophenate.....	4.21%
Ortho-phenylphenate.....	2.52%
Para-tertiary-amylphenate.....	2.22%
Other Ingredients.....	<u>90.29%</u>
	100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

SDS# VEL-030

Container and Product Sterilized and Distributed By:

Veltek Associates, Inc.
 15 Lee Boulevard
 Malvern, PA 19355-1234
 Tel: 610-644-8335
 Fax: 610-644-8336
www.sterile.com
 Patents: www.sterile.com/patents

EPA Reg. No. 211-65-68959
 EPA Est. No. 68959-PA-1



DECON-PHENE II

DECON-PHENE II is a high pH, phosphate free, sterile pharmaceutical clean room formula phenolic that is acceptable for use by pharmaceutical and biotechnology industries. **DECON-PHENE II** is an effective sanitizer on inanimate, non-porous, non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC# 6583) and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes. When used as directed, **DECON-PHENE II** may be used on hard, non-porous surfaces, materials, and components such as: metals: stainless steel, chrome plated steel, brass, copper, & aluminum, plastics: Fiberglas™, Formica™, nylon, ABS, Lexan™, Plexiglass™, acrylics and vinyl, glazed porcelain, glass, ceramic tile, latex, enamel & epoxy painted surfaces, Vinyl, rubber terrazzo, marble, ceramic and quarry tile floor surfaces, Urethane, lacquer, and shellac wood finished surfaces, and other surfaces not harmed by water based cleaners. In addition, **DECON-PHENE II**, can be used on hard, inanimate surfaces in aseptic filling and gowning rooms, or on machinery, tables, counters, laminar flow benches, floors, and walls.

First Aid

FIRST AID	
If in eyes	<ul style="list-style-type: none"> - Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lens, if present, after the first 5 minutes, then continue rinsing. - Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> - 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.
In inhaled	<ul style="list-style-type: none"> - Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-mouth, if possible. - Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> - Call a poison control center or doctor immediately for treatment advice. - Do not induce vomiting unless told to do so by a poison control center or doctor. - Do not give any liquid to this person. - Do not give anything by mouth to an unconscious person.
HOTLINE NUMBER	
In case of emergency, call your local poison control center or a doctor. Have the product container or label with you when calling a poison control center or doctor or going in for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

For USA toll free: +1-866-928-0789 (24 hours). For Canada toll free: +1-800-579-742. For Americas: +1-215-207-0061. For Mexico: +52 55 5004 8763. For Europe: +44 1235 239 670 (for English and 23 European Languages) (24 hours) or +44 1235 239 671 (Arabic) (24 hours) . For Ireland: +353 (0)1 809 2166 (Available to the public 08.00-22.00). For Middle East/Africa: +44 1235 239 671 (24 hours). For China: 0532 8388 9090 or +86 512 8090 3042 (alternative). For Korea: +82 2 3479 8401 (24 hour, Korean). For Australia toll free: +61 2 8014 4558. For Hindi: 000 800 100 7479 (24 hours).

Precautionary Statements

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing spray mist.

USER SAFETY REQUIREMENTS

User must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. User must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. Do not use or store the product near heat or open flame.

ENVIRONMENTAL HAZARDS

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

Storage and Disposal

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE – Store in a securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food and feed. 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. Offer for recycling, if available.

Or

Puncture and dispose of in a sanitary landfill, or by incineration.

Less than or equal to 5 gallons:

Clean container promptly after emptying.

Or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this process two more times.

Greater than 5 gallons:

Clean container promptly after emptying.

Or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

For Non-refillable SimpleMix 200 Liter Drums

Non-refillable container. Do not reuse or refill this container. Completely empty container by running pimp to dispense all product left in system into application equipment. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container ¼ full with water. Shake for 10 seconds. Empty and collect rinsate if appropriate storage vessel for 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.

For SimpleMix 1 Gallon or Smaller That Will be Incinerated

Completely empty container allowing the product to drain for 10 seconds after the flow begins to drip. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container ¼ full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for 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.



This product contains a chemical known to the State of California to cause cancer.

DIRECTIONS FOR USE

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

PELIGRO: Si no puedes leer en ingles, pregunte a su supervisor sobre las instrucciones de su uso apropiadas antes de trabajar con este producto.

Non-Food Contact Sanitization: Remove heavy soil or gross filth. Mix 1 ounce of **DECON-PHENE II**

per 1 gallon of water use solution (or equivalent use dilution) or prepare solution according to SimpleMix System Container Instructions. Apply use solution to hard nonporous, inanimate, environmental surfaces using a brush, sponge, cloth, mop, auto scrubber or mechanical spray device ((hand pump) coarse pump or trigger spray device) or by immersion so as to thoroughly wet surface. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Allow surfaces to remain wet for 5 minutes. Rinse, wipe up excess liquid, or allow to air dry. Change cloth, sponge or towels frequently to avoid redeposition of soil. Prepare a fresh solution at least daily or more often if use solution becomes visibly dirty, soiled, or diluted.

DECON-PHENE II is acceptable for use by pharmaceutical and biotechnology industries. For use on hard, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, porcelain, glass, and chrome.

Sterile pharmaceutical clean room formula.

DECON-PHENE II is a phosphate free detergent.

SIMPLEMIX SYSTEM CONTAINER SYSTEM INSTRUCTIONS:

SimpleMix® System Technology is a convenient self-contained mixing system for use solution without measuring.

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.

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)

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.

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

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



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



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



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

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



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



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



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



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



- 8) Follow directions for use on label.

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.

EFFICACY TEST SUMMARY

DECON-PHENE® II High pH Phenolic

DECON-PHENE II Efficacy Summary

DECON-PHENE II is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes.

Efficacy of DECON-PHENE II Against *S. aureus* and *K. pneumoniae*

Study Summary:

Study Title: Sanitizer Test For Non-Food Contact Surfaces *Staphylococcus aureus* and *Klebsiella pneumoniae*

Challenge Microorganisms: *Staphylococcus aureus* ATCC 6538 and *Klebsiella pneumoniae* ATCC 4352

Test Substance: **DECON-PHENE II**

Dilution: 1:128

Neutralizer: Lethen Broth

Contact Time: 5 Minutes

Carriers: Glass squares

Study Results:

DECON-PHENE II – High pH Phenolic			
Challenge Organism	Lot No.	Geometric Mean CFU/ Carrier	Percent Reduction
<i>Staphylococcus aureus</i>	1	< 2.000 x 10 ²	>99.9%
	2	< 2.000 x 10 ²	>99.9%
	3	< 2.000 x 10 ²	>99.9%
<i>Klebsiella pneumoniae</i>	1	< 2.000 x 10 ²	>99.9%
	2	< 2.000 x 10 ²	>99.9%
	3	< 2.000 x 10 ²	>99.9%

Conclusion:

According to the EPA guidelines, the test substance meets effectiveness requirements if the test results exhibit a bacterial reduction of at least 99.9% over the parallel control within five minutes. In addition, all controls must meet the test acceptance criteria.

When tested as described, **DECON-PHENE II** passed the Sanitizer Test For Non-Food Contact Surfaces when *Staphylococcus aureus* and *Klebsiella pneumoniae* were exposed to the test substance for 5 minutes at 20-21°C and 53-54% relative humidity.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet SDS# VEL-030
- Product Validation
- In-use Validation Report
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Analysis, and Certificates of Irradiation



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

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234 T: 610-644-8335 F: 610-644-8336 www.sterile.com

Rev: 07Apr2022 ML Rev: D-19