



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-CYCLE[®] II

Low pH Phenolic
Sterile Pharmaceutical Cleanroom Formula

Product Description

DECON-CYCLE II is a low pH phenolic that is effective as hard non-porous surface disinfectant/detergent formulated for effective aseptic and controlled environment sanitation. **DECON-CYCLE II** is acceptable for use by pharmaceutical and biotechnology industries, medical device manufacturers, hospitals, and any healthcare institutions that are dedicated to controlling the hazards of cross contamination. **DECON-CYCLE II**'s sterile pharmaceutical cleanroom formula is for broad spectrum disinfection use, as demonstrated by US EPA A.O.A.C efficacy testing against gram negative *Pseudomonas aeruginosa* and gram positive *Staphylococcus aureus* bacteria. **DECON-CYCLE II** can be used on surfaces in aseptic filling and gowning rooms, in general manufacturing areas, or on numerous other surfaces that require cleaning.

Disinfectant – Detergent – Deodorizer

DECON-CYCLE 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-CYCLE II** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-CYCLE II** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

DECON-CYCLE II is available in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200L drum. **DECON-CYCLE 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-CYCLE 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 filtered 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-CYCLE II – Low pH Phenolic	
Certificate of Analysis	Specification
Appearance:	Clear Amber Solution
Odor:	Mild Phenolic/Alcohol
pH (Concentrate):	1.50 - 2.50
Specific Gravity:	1.082 - 1.102
Ortho-benzyl-para-clorophenol	6.32 – 6.98%
Ortho-phenylphenol	7.68 – 8.49%
Expiration Period	2 years

Veltek Associates, Inc.

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

DECON-C Rev 27Oct2021 ML Rev: H-19

Uses

DECON-CYCLE II is acceptable for use by pharmaceutical and biotechnology industries, medical device manufacturers, hospitals, and any health care institutions that are dedicated to controlling the hazards of cross contamination in their establishments. 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, glazed porcelain, glass, and chrome.

Features and Benefits

- EPA Registered; EPA Registration Number: 211-64-68959
- Each sterile container is double bagged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- 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
- Sterile pharmaceutical cleanroom formula
- Multiple convenient container sizes – Unit Dose, 16oz, 1 Gallon, and 200L
- Broad spectrum efficacy confirmed by using A.O.A.C protocol testing at a use dilution of 1:256
- Effective against gram negative *Pseudomonas aeruginosa* and gram positive *Staphylococcus aureus* bacteria
- Formulated for effective aseptic controlled environment (cleanroom) sanitation

The SimpleMix® System Technology Alternative

Veltek Associates, Inc. has developed the patented SimpleMix System Technology to eliminate measuring and additional containers. It provides for the transfer of the sterile concentrated disinfectant or sporicide and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System Gallon, 16oz, and 200L systems provide a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the VAI WFI Quality Water. The 16 ounce side container houses the concentrate and the bottom reservoir houses the VAI WFI Quality Water. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. 200L SimpleMix systems are activated through a hose and valve system connecting the 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-CYCLE II – Low pH Phenolic Germicidal Detergent		
Part number	Description	Qty/cs
DCY2-02-C	DECON-CYCLE II, 1 Gallon Concentrate, Sterile	4
DCY2-03-2Z-C	DECON-CYCLE II, 2 oz Concentrate, Unit Dose, Sterile	24
DCY2-06-16Z-01-C	DECON-CYCLE II, 16 oz SimpleMix, Attached Trigger, Use Dilution 1:256, Sterile	12



DCY2-01-C



DCY2-03-1Z-C



DCY2-06-16Z-01-C



VAI's Product Label Colors:

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 91%	WHITE	COOL GREY		
DECON-AHOL FORMULA 99%	WHITE	COOL GREY		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	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		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
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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DECON-C Rev 27Oct2021 ML Rev: H-19

PRODUCT LABELING

DECON-CYCLE® II Low pH Phenolic

(Any specific product label is available upon request.)



DECON-CYCLE II Family of Products

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DECON-CYCLE® II

Hard Non-Porous Surface Disinfectant/Detergent

ACTIVE INGREDIENTS:

Ortho-Phenylphenol.....	8.209%
Orthobenzyl-para-Chlorophenol.....	6.650%
<u>INERT INGREDIENTS.....</u>	<u>85.141%</u>
Total	100.00%

SEE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Keep Out of Reach of Children
DANGER

SDS# DCY-98-01

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. 211-64-68959

EPA Est. No. 68959-PA-1

PELIGRO: Si no puede leer in inglés, pregunte a su supervisor sobre las instrucciones de su uso apropiadas antes de trabajar con este producto.



DECON-CYCLE II

DECON-CYCLE II is acceptable for use by pharmaceutical and biotechnology industries, medical device manufacturers, hospitals, and any health care institutions that are dedicated to controlling the hazards of cross contamination in their establishments. 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, glazed porcelain, glass, and chrome.

DECON-CYCLE II is effective against gram negative (as demonstrated by efficacy against *Pseudomonas aeruginosa*) and gram positive (as demonstrated by efficacy against *Staphylococcus aureus*) bacteria. The broad spectrum efficacy of **DECON-CYCLE II** has been confirmed using A.O.A.C. protocol testing at a use- dilution of 1:256 in deionized water, at 20°C with an exposure time of 10 minutes.

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. - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to do so by a poison control center or doctor. - 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.	

Emergency Number: 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 or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing (long-sleeve shirt and long pants, socks, plus shoed and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

USER SAFETY REQUIREMENTS

Users 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 the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. 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 the 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 your State Water Board or Regional Office of the EPA.

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, or 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 - Non-refillable 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 procedure 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 a 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 and 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 pump 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 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.

For other 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.

NOTICE: The State of California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals.

DIRECTIONS FOR USE

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

CLEANING AND DISINFECTION

For broad spectrum disinfection of gram negative (as demonstrate by efficacy against *Pseudomonas aeruginosa*) and gram positive (as demonstrated by efficacy against *Staphylococcus aureus*) bacteria, and ½ ounce **DECON-CYCLE II** per 1 gallon of deionized water or follow mixing directions. Pre-clean all surfaces then apply solution with a mop, cloth, sponge, or hand-pump trigger sprayer so as to wet surface thoroughly. Allow to remain wet for 10 minutes and then air dry. If higher detergency is desired, increase dilution to 1 ounce per gallon of water. This product may be applied only by the methods specified on the labeling.

EFFICACY PERFORMANCE

The broad spectrum efficacy of **DECON-CYCLE II** has been confirmed using A.O.A.C. protocol testing at a use dilution of 1:256 in deionized water, at 20°C with an exposure time of 10 minutes.

DIRECTIONS FOR USE

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

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

PREPARATION OF CLEANING AND DISINFECTION USE SOLUTION: Pre-Clean all surfaces. Mix 1 ounce of **DECON-CYCLE II** with 2 gallons of deionized water (or equivalent use dilution) or mix solution according to SimpleMix® System Container instructions (at 580 ppm active) to disinfect hard non-porous, inanimate, environmental surfaces.

Apply use solution to hard non-porous surfaces, using a brush, sponge, cloth, moth, auto scrubber, mechanical spray deice (hand pump, course pump, or trigger spray device) or by immersion so as to thoroughly wet surfaces. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Treated surfaces must remain wet for 10 minutes. Rinse or wipe up excess liquid, or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. Prepare a fresh solution at least daily or more often if use solution becomes visibly dirty, soiled, or diluted.

TO DEODORIZE: For heavily soiled areas, a preliminary cleaning is required. Mix 1 ounce of **DECON-CYCLE II** per 2 gallons of water use solution (or equivalent use dilution) or mix solution according to SimpleMix System Container Instructions (580 ppm active). Apply use solution to hard, non-porous, inanimate, environmental, non-food contact surfaces, thoroughly wetting as required. Apply with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device (hand pump, coarse pump, or trigger spray device) or by immersion. For sprayer applications, spray 6-8 inches from surface.

SIMPLEMIX:

SimpleMix System Technology is a convenient self-contained mixing system for disinfectant use solution equivalent to 580 ppm active without measuring. *(To be used on applicable container)*

SIMPLEMIX SYSTEM CONTAINER SYSTEM INSTRUCTIONS**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 Lid:

(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.



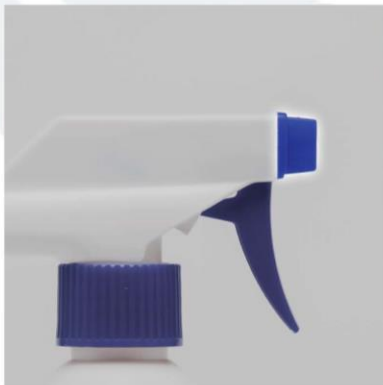
- 4) Replace cap and tighten.



- 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.

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DECON-C Rev 27Oct2021 ML Rev: H-19

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-CYCLE® II Low pH Phenolic

DECON-CYCLE II Efficacy Summary

DECON-CYCLE II is effective against gram negative (as demonstrated by efficacy against *Pseudomonas aeruginosa*) and gram positive (as demonstrated by efficacy against *Staphylococcus aureus*) bacteria. The broad spectrum efficacy of **DECON-CYCLE II** has been confirmed using A.O.A.C. protocol testing at a use- dilution of 1:256 in deionized water, at 20°C with an exposure time of 10 minutes.

Efficacy of DECON-CYCLE II Against *S. aureus* and *P. aeruginosa*

Study Summary:

Study Title: AOAC Use-Dilution Test *Staphylococcus aureus* and *Pseudomonas aeruginosa* confirmatory
 Test Microorganism: *Staphylococcus aureus*, ATCC 6538 and *Pseudomonas aeruginosa*, ATCC 15442
 Test Substance: **DECON-CYCLE II**
 Test Substance Dilution: Liquid test substance diluted 1:256 in sterile deionized water
 Carrier Type: Stainless Steel penicylinders
 Contact Time: 10 minutes
 Exposure Temperature: 20±1°C
 Neutralizer: Lethen Broth

Study Results:

DECON-CYCLE II – Low pH Phenolic		
Microorganism	Results Expressed as Number of Tubes Exhibiting Growth/Total Number of Tubes	
	Lot# 1	Lot# 2
<i>Staphylococcus aureus</i> ATCC 6538	0/10	0/10
	0/10	0/10
<i>Pseudomonas aeruginosa</i> ATCC 15442	0/10	0/10
	0/10	0/10

Conclusion:

According to the EPA, the test substance passes the AOAC Use Dilution Test Confirmatory if no visible growth is observed in any of the tubes (0/10) per lot and the controls meet their stipulated criteria. When tested as described, **DECON-CYCLE II** passed the AOAC Use Dilution Test Confirmatory.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheets
 - **DECON-CYCLE II** Concentrate SDS# DCY-98-01
 - **DECON-CYCLE II** 0.8% Dilution After Mixing SDS# VEL-134
- Product Validation
- In-use validation
- 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

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DECON-C Rev 27Oct2021 ML Rev: H-19