



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-CLEAN®

Residue Remover and Cleaner

Sterile Pharmaceutical Cleanroom Formula

15FEB2023

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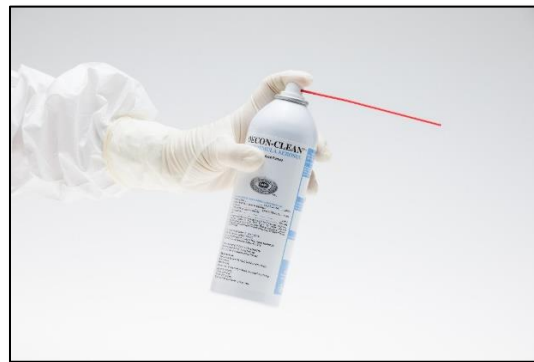
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*DECON-CLEAN
Sterile 11 oz Aerosol Spray
DCWFI-SP-11Z*

PRODUCT OVERVIEW

VAI® manufactures an effective one-step residue remover and cleaner, **DECON-CLEAN®**. Using **DECON-CLEAN**, one can ensure that noticeable and unnoticeable residues are removed, thus returning the surface to its original form. Residues left behind from disinfectants, sanitizers, and sporicides, including sodium hypochlorite can be easily removed using **DECON-CLEAN**. Returning the surface to its original form assures that future decontamination will be able to penetrate to the surface.

DECON-CLEAN is designed for and processed to meet the standards required by pharmaceutical, biotechnology, healthcare, and lab animal research operations that demand a cleaning agent to remove residues left behind from disinfecting agents. Due to **DECON-CLEAN**'s formulation it is an excellent cleaner designed for all washable, non-porous environmental surfaces.

DECON-CLEAN is an effective one-step residue remover when diluted at 1:128 (1 oz per 1 gallon) of hard or soft water (400 ppm hard as CaCO³).

DECON-CLEAN is filled in an ISO 7 cleanroom (Grade B), filtered, and then subsequently terminally sterilized to 10⁻⁶ sterility assurance level. Each lot of **DECON-CLEAN** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-CLEAN** is delivered each time with a lot specific analytical, irradiation, and sterility data, tested to current USP compendium.

DECON-CLEAN is available in multiple container sizes and in our patented SimpleMix® system that allows for safe and fresh dilutions every single time. Each sterile container of **DECON-CLEAN** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Please see the “TESTING SUMMARY” on page 14 for information on using **DECON-CLEAN** to remove representative disinfecting agents.

Quality and Manufacturing

- Filled in an ISO 7 cleanroom (Grade B)
- Filtered
- 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

Features and Benefits

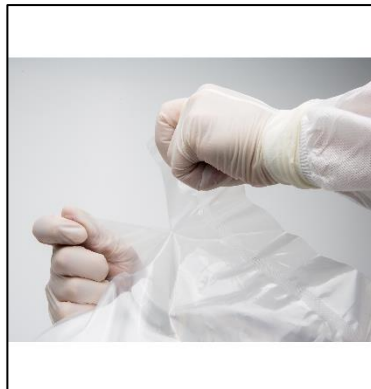
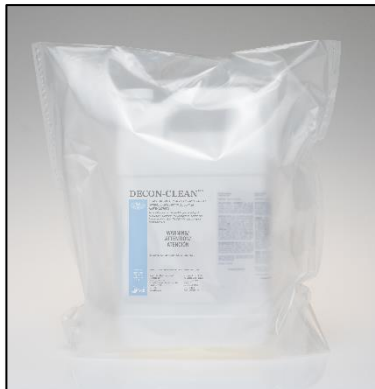
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System made with USP Water for Injection (< 0.25 EU/mL)
- Removes residues left behind by sanitizers, disinfectants, and sporicides
- Excellent cleaning characteristics

Product Uses

- All washable, non-porous, environmental surfaces
- Aseptic filling suites, controlled corridors
- Aseptic connections, process lines
- Walls, floors, ceilings, counter tops
- Stainless steel

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.



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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 concentrate and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System provides a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The small chamber holds the concentrate, and the bottom reservoir contains 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. The solution and water mix together. 200L SimpleMix systems are activated through a hose and valve system connecting the cubcontainer of concentrate to the VAI WFI Quality Water. The SimpleMix System design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

SimpleMix Directions for Use

How to use the SimpleMix Trigger Spray

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.

For pictorial directions, see page 7.

How to use the SimpleMix Gallon Size

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.

For pictorial directions, see page 8.

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How to use the SimpleMix 200 Liter Drum

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.

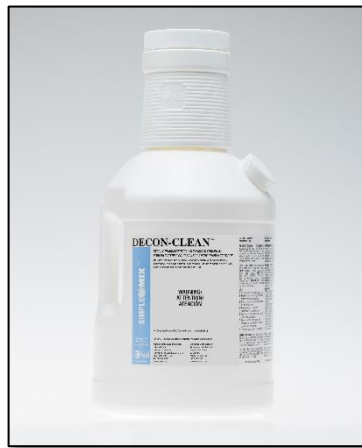
For pictorial directions, see page 9.



SimpleMix Trigger

16 oz

DC-06-16Z-01



SimpleMix Gallon

1 Gallon

DC-04-1Z



SimpleMix Drum

200L

DC-10-200L-CI

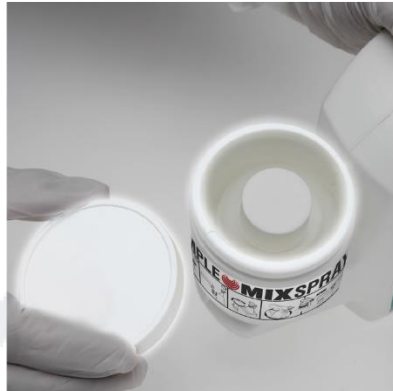
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SimpleMix Trigger Spray

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.



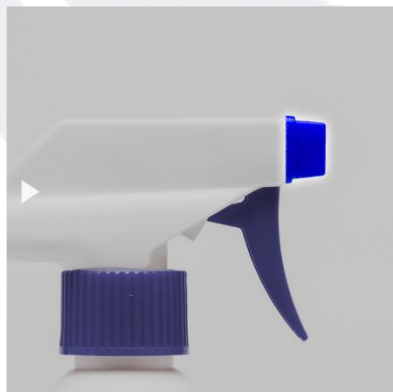
- 4) Replace cap and tighten.



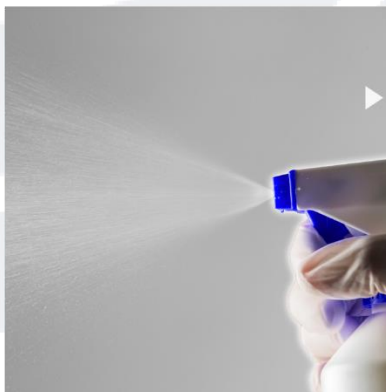
- 5) Slowly swirl for 15 seconds.



- 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.



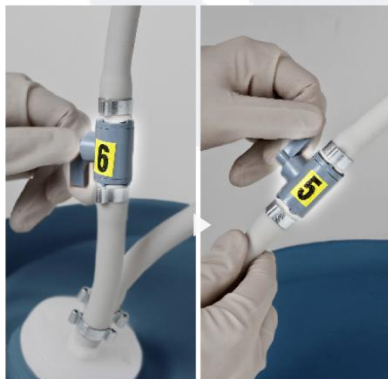
5) START pump to empty cubic container. 6) When cubic container is empty, turn pump OFF.



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

| DECON-CLEAN – Residue Remover and Cleaner | |
|--|--------------------------------|
| Certificate of Analysis | Specification |
| Appearance | Clear free of suspended matter |
| Solubility in Water | Completely |
| % Nonvolatile Matter | <=20.0% |
| pH of Concentrate | 9.0-11.0 |
| Specific Gravity @20 degrees | 1.010-1.040 |
| Expiration Period | 2 years |

ORDERING INFORMATION

| DECON-CLEAN – Residue Remover and Cleaner | | |
|--|---|---------------|
| Part Number | Description | Qty/cs |
| DCWFI-SP-11Z | DECON-CLEAN, 11 oz Aerosol Spray Mist, Sterile | 24 |
| DC-01 | DECON-CLEAN, 1 Gallon Concentrate, Non-Sterile | 4 |
| DC-02 | DECON-CLEAN, 1 Gallon Concentrate, Sterile | 4 |
| DC-03-4Z | DECON-CLEAN, 4 oz Concentrate, Unit Dose, Sterile | 24 |
| DC-04-1Z | DECON-CLEAN, 1 Gallon SimpleMix®, Sterile | 4 |
| DC-05-1Z | DECON-CLEAN, 1 Gallon SimpleMix, Non-Sterile | 4 |
| DC-06-16Z-01 | DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Sterile | 12 |
| DC-07-16Z-01 | DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Non-Sterile | 12 |
| DC-100-200L-CI | DECON-CLEAN, 200L SimpleMix Drum, Sterile | 1 |



*Unit Dose
DC-03-4Z*



*Aerosol Spray
DCWFI-SP-11Z*



*Concentrate
DC-01*

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 | 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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Product Labeling

DECON-CLEAN

Sterile Pharmaceutical Cleanroom Formula

Residue Remover and Cleaner

| | | | | | |
|--|--|---|--|--|---|
| <p>DECON-CLEAN® MD</p> <p>STERILE PHARMACEUTICAL CLEANROOM FORMULA/ FORMULE STÉRILE POUR SALLE BLANCHE PHARMACEUTIQUE</p> <p><i>Residue Remover and cleaner/Décapant et nettoyant pour résidus - Fragrance Free/Sans parfum - Filtered and Gamma Irradiated at 10⁴ SAL</i></p> <p style="text-align: center;">WARNING/ ATTENTION/ ATENCIÓN</p> <p>Net Contents/Contenu Net/Contenido Neto:</p> <table style="width: 100%; border: none;"> <tr> <td style="border: 1px solid black; padding: 2px;">4 fl. oz. (118 mL) x 24 [0.75 Gallon (2.8 L)]</td> <td style="border: 1px solid black; padding: 2px;">1 Gallon (3.79 L) x 4 [4 Gallons (15.2 L)]</td> </tr> </table> <p>Reorder/Commandez à nouveau/ Para Órdenes Adicionales # DC-03-4Z</p> <p>Reorder/Commandez à nouveau/ Para Órdenes Adicionales # DC-02</p> <p>Label/étiquette/etiqueta #: DC-00 - Sterile/Stérile/Estéril Rev 10/22 - Patents/Les Brevets/Patentes: www.sterile.com/patents</p> <p>Made in USA Fabrique aux États-Unis Hecho en los EE. UU.</p> <p>Manufactured by/Fabriqué par/ Fabricado por: Velték Associates, Inc. 15 Lee Blvd. Malvern, PA 19355-1234 USA, Etats-Unis, EE.UU. Tel: 610-644-8335 www.sterile.com</p> <p>In Canada, Distributed By/ Au Canada, Distribué par: Canada Clean Room 291 Cope Dr. Kanata, ON K2M 2V8 (888) 595-8070 www.ccrccanada.com</p> | 4 fl. oz. (118 mL) x 24 [0.75 Gallon (2.8 L)] | 1 Gallon (3.79 L) x 4 [4 Gallons (15.2 L)] | <p>EN STERILE PHARMACEUTICAL CLEANROOM FORMULA <i>Residue Remover and cleaner - Fragrance Free - Filtered and Gamma Irradiated at 10⁴ SAL</i></p> <p>INGREDIENTS: Tall oil, fatty acids, potassium salts (CAS# 61790-44-1) 75% CS-11 Alcohol ethoxylated (CAS# 68439-46-3) 2.0% OTHER INGREDIENTS: Water, tetrasodium EDTA, Tetrasodium pyrophosphate* *elemental phosphate less than 0.2% by weight of concentrate before use dilution</p> <p>WARNING. Causes eye irritation.</p> <p>PRECAUTIONARY STATEMENTS: Wash hands thoroughly after handling. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.</p> <p>DIRECTIONS FOR USE: Mix 1 ounce of DECON-CLEAN® with 1 gallon of water (1:28). Apply product generously to wet entire surface and use mechanical action to loosen residue. Squeeze off, wipe dry or rinse with clean water and dry.</p> <p style="text-align: center;">Red dot indicates Sterile See container for lot #/ Expiration Date See Safety Data Sheet for first aid and additional product information.</p> <p style="text-align: center;">SDS: DC-01-98 EMERGENCY NUMBER: 1-866-928-0789 (toll free USA), 1-800-579-7421 (toll free Canada), 1-215-207-0061 (Americas) For Industrial Use Only</p> | <p>FR FORMULE STÉRILE POUR SALLE BLANCHE PHARMACEUTIQUE <i>Décapant et nettoyant pour résidus - Sans parfum - Filtré et irradié par rayons gamma à 10⁴ SAL</i></p> <p>INGRÉDIENTS: Acides gras de tallöl, sels de potassium (CAS# 61790-44-1) 75% Alcools en CS-11 éthoxylés (CAS# 68439-46-3) 2.0% AUTRES INGRÉDIENTS: Eau, Ethylène diamine tétraacétate de tétrasodium, pyrophosphate de tétrasodium* *phosphate élémentaire inférieure à 0,2% en poids de concentré de dilution avant l'utilisation</p> <p>ATTENTION. Provoque une sévère irritation des yeux.</p> <p>AVERTISSEMENTS. Se laver les mains soigneusement après manipulation. En cas de contact avec les yeux: Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. Si l'irritation oculaire persiste: Consulter un médecin.</p> <p>MODE D'EMPLOI: Mélanger 1 once de DECON-CLEAN® avec 1 gallon d'eau (1:28). Appliquer le produit généreusement pour mouiller toute la surface et utiliser une action mécanique pour détacher les résidus. Racler/essuyer ou rincer avec de l'eau propre et sec.</p> <p style="text-align: center;">Point rouge indique Stérile Voir le récipient pour le lot #/ date d'expiration Voir la fiche de données de sécurité pour les premiers secours et des informations complémentaires sur le produit.</p> <p style="text-align: center;">SDS: DC-01-98-CFR NUMÉRO D'URGENCE: 1-866-928-0789 (sans frais États Unis), 1-800-579-7421 (sans frais Canada), 1-215-207-0061 (Amérique)</p> <p style="text-align: center;">Pour Usage Industriel Seulement</p> | <p>ES FÓRMULA FARMACÉUTICA ESTÉRIL PARA SALAS BLANCAS <i>Eliminador de residuos y limpiador - Sin fragancia - Filtrado e irradiado con rayos gamma a 10⁴ SAL</i></p> <p>INGREDIENTES: Ácidos gras de tallöl, sels de potassium (CAS# 61790-44-1) 75% Alcoholes CS-11 etoxilado (CAS# 68439-46-3) 2.0% OTROS INGREDIENTES: Agua, Etilendiaminotetraacetato de tetrasodio, pirofosfato tetrasódico *fosfato elemental de menos de 0,2% en peso de concentrado antes de la dilución de uso</p> <p>ATENCIÓN. Provoca irritación ocular grave.</p> <p>DECLARACIONES DE PRECAUCIÓN: Lavarse las manos cuidadosamente después de la manipulación. En caso de contacto con los ojos: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado. Si la irritación ocular persiste, consultar a un médico.</p> <p>INSTRUCCIONES DE USO: Mezclar 1 onza de DECON-CLEAN® con 1 galón de agua (1:28). Aplique el producto generosamente para humedecer toda la superficie y utilizar la acción mecánica para aflojar los residuos. Escobilla de goma, seque ni enjuague con agua limpia y seca.</p> <p style="text-align: center;">Punto rojo indica Estéril Ver recipiente para el lote #/ Fecha de caducidad Consulte la Hoja de datos de seguridad para obtener información sobre primeros auxilios e información adicional sobre el producto.</p> <p style="text-align: center;">SDS: DC-01-98-ASP NÚMERO DE EMERGENCIA: 1-866-928-0789 (número gratuito), 1-215-207-0061 (América), +52 55 5004 8763 (México)</p> <p style="text-align: center;">Exclusivamente Para Uso Industrial</p> |
| 4 fl. oz. (118 mL) x 24 [0.75 Gallon (2.8 L)] | 1 Gallon (3.79 L) x 4 [4 Gallons (15.2 L)] | | | | |

Case Label DC-00 Rev10/22

Any specific product label is available upon request.



DC-10-200L-CI Drum

DECON-CLEAN

STERILE PHARMACEUTICAL CLEANROOM FORMULA

Residue Remover and Cleaner • Fragrance Free • Filtered and Gamma Irradiated at 10⁶ SAL

INGREDIENTS:

Tall oil, fatty acids, potassium salts (CAS# 61790-44-1)7.5%

C9-11 Alcohol ethoxylated (CAS# 68439-46-3)2.0%

OTHER INGREDIENTS: Water, Tetrasodium EDTA, Tetrasodium pyrophosphate*

*elemental phosphate less than 0.2% by weight of concentrate before use dilution

WARNING. Causes eye irritation.

PRECAUTIONARY STATEMENTS: Wash hands thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

DIRECTIONS FOR USE: Mix 1 ounce of DECON-CLEAN® with 1 gallon of water (1:128). Apply product generously to wet entire surface and use mechanical action to loosen residue. Squeegee off, wipe dry or rinse with clean water and dry.

Red dot indicates Sterile

See container for lot #/ Expiration Date

See Safety Data Sheet for first aid and additional product information.

EMERGENCY NUMBER:

1-866-928-0789 (toll free USA)

1-800-579-7421 (toll free Canada)

1-215-207-0061 (Americas)

For Industrial Use Only

Label#: DC-00 • Rev10/22 • **Patents:** www.sterile.com/patents

Manufactured By:

Veltek Associates, Inc.

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Tel: 1-610-644-8335 • www.sterile.com

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TESTING SUMMARY

DECON-CLEAN

Residue Remover and Cleaner for Hard Surfaces

Sterile Pharmaceutical Clean Room Formula

Surface Evaluation for Determining the Residual Levels of VAI Sterile Chemicals and Disinfectants

Discussion and Purpose of Testing

The aim of this study was to evaluate the cleaning efficiency of the new environmentally friendly and biodegradable DECON-CLEAN formula. In accordance with recent EPA regulations (Significant New Use Rule, 25 Sep 2014) the DECON-CLEAN formula was updated and the alkylphenol based detergent was replaced with environmentally friendly ethoxylated alcohol surfactant.

Chemical residues can be quantified and appropriate operating procedures can be developed to reduce their existence on surfaces. VAI developed DECON-CLEAN residue remover to assure the removal of existing chemical residues. By removing these residues, a class 100 aseptic facility is less likely to transfer existing residues from their initial location to critical manufacturing sites.

Particulate Impurities

Particulate impurities can cause contamination problems and may provide a nutrient source for existing organisms in the aseptic manufacturing area. Particulate impurities can be removed from solution by filtration. All VAI sterile chemicals and disinfectants receive a level of filtration.

Chemical Ingredient Residues

Chemical ingredient residues pose a complicated problem associated with both buildup and cross-contamination. The removal of such residues should be considered as a standard practice to eliminate the possibility of these concerns.

DECON-CLEAN as a Residue Remover

DECON-CLEAN has been developed to cope with the removal of residues within the ISO 5 (Grade A/Class 100) aseptic manufacturing operation. The patented formula assures the breakdown of VAI's DECON-AHOL[®], STER-AHOL[®], DECON-PHENE[®] II, DECON-CYCLE[®] II, DECON-QUAT[®] 100, HYPO-CHLOR[®], STERI-PEROX[®], DECON-QUAT 200, Cage2Wash[®], Process2Clean[®] and DECON-SPORE 200[®] Plus products. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

TESTING SUMMARY (Continued)

DECON-CLEAN's Effectiveness Test Procedure

DECON-CLEAN was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

- DECON-AHOL[®] (70% and 91% RTU)
- DECON-CYCLE[®] II (1:256 Use Dilution)
- DECON-PHENE[®] II (1:128 Use Dilution)
- DECON-QUAT[®] 100 (2:128 Use Dilution)
- DECON-SPORE[®] 200 Plus (5%)
- HYPO-CHLOR[®] (5.25%, 0.52%, 0.25%)
- STER-AHOL[®] (70% RTU)
- STERI-PEROX[®] (3% and 6%)

Test Procedure

1. Residue and residue removal were determined gravimetrically.
2. Stainless steel coupons (316L) were used as the test surface.
3. Testing was conducted in a Class 100 laminar flow hood.
4. All appropriate safety precautions were taken. All safety precautions are to be taken referencing safety. This includes gowning, gloves and a NIOSH approved chemical mask.
5. 5 mL of each chemical was prepared and applied to separate stainless steel coupons.
6. The chemicals were permitted to air dry.
7. The chemical residue was determined gravimetrically.
8. Cleaning was performed with DECON-CLEAN by two separate methods; spray rinse only and mechanical cleaning.
9. Residue after cleaning was determined gravimetrically.

TESTING SUMMARY (Continued)

Chemical Residue after Drying

| Chemical Tested | Results |
|--------------------------------------|--|
| DECON-AHOL® 70% (RTU) | ppm of isopropyl alcohol = 0 ppm* |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm* |
| STER-AHOL® 70% (RTU) | ppm of ethanol = 0 ppm* |
| DECON-PHENE® II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 2 ppm |
| DECON-CYCLE® II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 3 ppm |
| DECON-QUAT® 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 3 ppm |
| HYPO-CHLOR® 5.25% | ppm of Sodium Chloride = 252 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 30 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 18 ppm |
| STERI-PEROX® 3% | ppm Hydrogen Peroxide = 1 ppm* |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 1 ppm* |
| DECON-SPORE® 200 Plus (5%) | ppm Peroxyacetic acid = 3 ppm |

* No residue detectable gravimetrically

Testing Residue Removal Ability of DECON-CLEAN as a SPRAY RINSE ONLY

After the chemical residue was established on the surface, the surface was cleaned with a RINSE ONLY of DECON-CLEAN at a use dilution of 1:128.

| Chemical Tested | Results |
|--------------------------------------|--|
| DECON-AHOL® 70% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| STER-AHOL® 70% (RTU) | ppm of ethanol = 0 ppm* |
| DECON-PHENE® II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-CYCLE® II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-QUAT® 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 0 ppm |
| HYPO-CHLOR® 5.25% | ppm of Sodium Chloride = 1 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 0 ppm |
| STERI-PEROX® 3% | ppm Hydrogen Peroxide = 0 ppm* |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 0 ppm* |
| DECON-SPORE® 200 Plus (5%) | ppm Peroxyacetic acid = 0 ppm |

* Visual residue spots, not detectable gravimetrically

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TESTING SUMMARY (Continued)

Testing Residue Removal Ability of DECON-CLEAN USING MECHANICAL CLEANING

After the chemical residue was established on the surface, the surface was cleaned with a DECON-CLEAN application at a use dilution of 1:128 and using a VEL8-12X12 Dry Wiper with a circular mechanical cleaning action.

| Chemical Tested | Results |
|--|--|
| DECON-AHOL [®] 70% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| STER-AHOL [®] 70% (RTU) | ppm of ethanol = 0 ppm* |
| DECON-PHENE [®] II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-CYCLE [®] II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-QUAT [®] 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 0 ppm |
| HYPO-CHLOR [®] 5.25% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 0 ppm |
| STERI-PEROX [®] 3% | ppm Hydrogen Peroxide = 0 ppm* |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 0 ppm* |
| DECON-SPORE [®] 200 Plus (5%) | ppm Peroxyacetic acid = 0 ppm* |

* No visual residue spots

Conclusion

It is concluded from the testing performed that the use of DECON-CLEAN is extremely effective as a chemical residue remover. Furthermore, the incorporation of mechanical cleaning further reduces the levels of residues as well as any visual, but gravimetrically undetectable, residue spots.

Written By: Boris Polanuyer Date: 05Oct2015

Approved By: Kelly Rocco Date: 05Oct2015

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 or visit our website at www.sterile.com. Patents: www.sterile.com/patents

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