



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-QUAT[®] 100

Phosphate Free Quaternary Ammonium Solution



Product Description

DECON-QUAT 100 disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. This product may be used to disinfect non-food contact, non-porous, inanimate, hard surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories. It may be used on surfaces, such as: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, plastic and glass. It is compatible with most hard surface materials.

Cleaner – Disinfectant – Deodorizer

DECON-QUAT 100 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-QUAT 100** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. All shipments are delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

DECON-QUAT 100 is available in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200L drum. **DECON-QUAT 100** 1 gallon, 16 oz, and 200L containers come in our 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-QUAT 100** 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-QUAT 100 – Phosphate Free Quaternary Ammonium Solution	
Certificate of Analysis	Specification
Appearance:	Clear to straw yellow
Alkyl (C14, 60%, C16, 30%, C12, 5%, C18, 5%) Dimethyl Benzyl Ammonium Chloride:	4.75-5.25%
Alkyl (C12, 68%, C14, 32%) Dimethyl Ethylbenzyl Ammonium Chloride:	4.75-5.25%
pH:	6.0-9.0
Expiration Period:	2 years

Uses

DECON-QUAT 100 is for use on hard, non-porous surfaces in medical device manufacturing facilities, biotechnology firms, pharmaceutical manufacturing facilities, healthcare facilities, lab animal research, and laboratories. General hard, non-porous surfaces include floors, finished floors, walls, ceilings, glass, aluminum, brass, copper, laminated surfaces, metal, plated steel, stainless steel, plastic (such as polycarbonate, polyvinylchloride, polystyrene or polypropylene), chrome, Plexiglas®, enameled surfaces, Formica®, and vinyl.

Features and Benefits

- Canadian Drug Identification Number: DIN 02368390
- US EPA registered; EPA Registration Number: 10324-63-68959
- 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, ready-to-use, SimpleMix System
- Individually labeled with lot number and expiration
- Multiple convenient container sizes – Unit Dose, 16 oz, 1 Gallon, and 200L
- One-step disinfectant that is effective against a broad spectrum of bacteria, is virucidal*, and inhibits the growth of mold and mildew and their odors when used as directed
- Effective in the presence of organic soil (5% blood serum)
- Kills 99% of common institutional bacteria and/or germs
- Non-abrasive formula will not harm or scratch surfaces, is non-staining, and non-dulling
- Is efficient and stable in use dilution
- Contains no fragrances or phosphates and will not leave grit or soap scum

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 cubicontainer 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



DECON-QUAT 100 16 oz SimpleMix

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-QUAT 100 – Phosphate Free Quaternary Ammonium Solution		
Part number	Description	Qty/cs
DQ100-01-C	DECON-QUAT 100, 1 Gallon Concentrate, Non-Sterile	4
DQ100-02-C	DECON-QUAT 100, 1 Gallon Concentrate, Sterile	4
DQ100-03-8Z-C	DECON-QUAT 100, 8 oz Concentrate, Unit Dose, Sterile	24
DQ100-06-16Z-01-C	DECON-QUAT 100, 16 oz SimpleMix, Attached Trigger, Sterile	12



DQ100-01-C



DQ100-03-8Z-C



DQ100-06-16Z-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		

Veltek Associates, Inc.

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Rev: 07Oct2021 ML Rev: J-21 DECON-C

PRODUCT LABELING

DECON-QUAT® 100 Phosphate Free Quaternary Ammonium Solution

(Any specific product label is available upon request.)



DECON-QUAT 100 Family of Products

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DECON-QUAT 100® MC
[Sterile or Non-Sterile]
Quaternary Ammonium Hard Surface Disinfectant and Deodorizer

For Use in Clean Rooms and Controlled Areas

Aseptically Filtered at 0.2 µm
[Sterilized by Gamma Irradiation]

Active Ingredients:

Alkyl (C₁₂ 5%, C₁₄ 60%, C₁₆ 30% C₁₈ 5%) DimethylBenzyl Ammonium Chloride CAS# 68391-01-5...5.0%
Alkyl (C₁₂ 68%, C₁₄ 32%) Dimethyl Ethylbenzyl Ammonium Chloride.CAS# 85409-23-0.....5.0%

Other Ingredients:

USP water for injection CAS# 7732-18-5.....90.0%
Total**100.0%**

KEEP OUT OF REACH OF CHILDREN
DANGER



Store at room temperature
Read the label and leaflet before using.

See other panel for first aid and additional precautions

Canadian DIN: 02368390

Container and Product Packaged by:
Veltek Associates, Inc.
15 Lee Blvd. Malvern PA USA 19355 – 1234
Tel: 610-644-8335, Fax: 610-644-8336, www.sterile.com

In Canada, distributed by:
Canada Clean Room (CCR) www.ccrkanata.com , phone #613-591-0044

Refer to product leaflet for complete distributor contact information
See container for lot number and storage expiration date

Made in USA VAI



FIRST AID*

EYE CONTACT:	<ul style="list-style-type: none"> • If splashed or sprayed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. <u>Do not</u> use hot water. • Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. • Call Poison Control or doctor for treatment advice. Get medical attention immediately if irritation persists.
IF INGESTED or SWALLOWED:	<ul style="list-style-type: none"> • Do not induce vomiting unless told to by Poison Control or doctor. • Contact Poison Control or seek medical attention immediately. • Do not give anything to an unconscious person.
IF INHALED:	<p>Move person to fresh air.</p> <p>If not breathing, give artificial respiration preferably mouth-to-mouth. Call a physician immediately.</p>
SKIN CONTACT:	<p>Wash with plenty of soap and water. Immediately take off all contaminated clothing. Get medical attention, if needed.</p> <p>Wash contaminated clothing before reuse.</p>

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – KEEP OUT OF REACH OF CHILDREN -CORROSIVE

IMPORTANT: Not for personal use. Not for use on or around food. Do not get on skin or in eyes. Do not take internally and do not inhale vapor.

PHYSICAL AND CHEMICAL HAZARDS: This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not puncture or incinerate container. Mix only with water. Do not mix this product with other chemicals.

PERSONAL PROTECTIVE EQUIPMENT: Wear eye protection goggles or face shield. Wear chemical resistant gloves, apron or protective coveralls. If ventilation is not sufficient to effectively prevent buildup of vapors, use appropriate NIOSH/MSHA air respirators. Eyewash fountain and emergency showers recommended.

DIRECTIONS FOR USE:

Read the label and leaflet before using.

This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

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.

LOCATIONS OF USE: Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. This product may be used to disinfect non-food contact, non-porous, inanimate, hard surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories. It may be used on surfaces, such as: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, plastic and glass. It is compatible with most hard surface materials.

DISINFECTION: Mix this product with water as directed below before use. Wear personal protection such as eye protection goggles or face shield. Wear chemical resistant gloves. Use with adequate ventilation and spray away from eyes and face. If you experience eye watering, headaches or dizziness discontinue aerosolizing and inhaling fumes. [Dilute DECON-QUAT 100®^{MC} prior to use with deionized water (sterilized when used in cleanrooms). Dilute by adding 6.25 mL DECON-QUAT 100®^{MC} concentrate to 1 Liter of water, or equivalent, to make larger or smaller proportions.

See leaflet for additional uses and directions for additional uses.

Storage and Disposal:

Storage and Disposal

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

Storage: Store in the original container at room temperature in a dry cool place. Do not store on side

Disposal: Product and product wastes are toxic. Follow Provincial regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product or container rinsate is a violation of Provincial Laws. If wastes cannot be disposed of by use according to label instructions, contact your Provincial or Local/Municipal environmental control agency for guidance. Never place unused product down any indoor or outdoor drain.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Do not puncture container and do not incinerate container. Triple rinse container with water, and include rinsate with product wastes. Offer for recycling or dispose of in a sanitary landfill or dispose by other procedures approved by Provincial and Local/Municipal environmental control agency.

EMERGENCIES and FIRST RESPONDERS – For Spill/Exposure Emergency Response Service in English, French and Spanish (and 23 other languages), call CARECHEM24 at 866-928-0789. For Arabic call 011-44-1235-239-671, for Chinese call 011-86-10-5100-3039.

SIMPLEMIX® SYSTEM CONTAINER:

Trigger Spray Bottle lid label:

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.

See page 11 for pictorial directions.

Gallon Size Bottle lid label:

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.

See page 12 for pictorial directions.



200 Liter Drum Lid Label:

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 page 13 for pictorial directions.



16 oz SimpleMix System Directions

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.



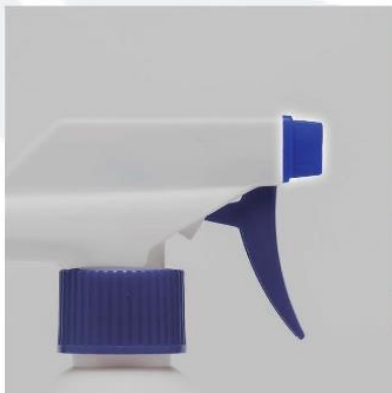
- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



1 Gallon SimpleMix System Directions

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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200L SimpleMix System Directions

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.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet – SDS# DQ-98-01
- Product Validation
- In-use Validation
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Analysis, and Certificates of Irradiation



SCMD

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

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