

# DECON-QUAT 100

Sterile Pharmaceutical Clean Room Formula  
Quaternary Ammonium



SEE THE NEW  
**Veltek**  
SimpleMix®  
SYSTEM



**Veltek Associates, Inc.**  
15 Lee Boulevard • Malvern, PA 19355-1234  
Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com VL-750-99-2 12/18/03

# O V E R V I E W

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## DECON-QUAT 100

### PRODUCT DESCRIPTION:

DECON-QUAT 100 is a quaternary ammonium solution for use in hospital/medical and health care institutions. Effective as a broad spectrum hospital disinfectant, fungicide, deodorizer, hard surface disinfectant, food and non-food contact sanitizer (USDA D2) effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis*.

DECON-QUAT 100 when used on hard, non-porous, inanimate environmental surfaces at 1 ounce per gallon of water for 10 minutes of contact (5% organic soil) is effective against Hepatitis B Virus (HBV)\*. This product also kills Human Immunodeficiency Virus Type 1 (HIV)\* after 30 seconds contact time. (\*SPECIAL INSTRUCTIONS FOR CLEANING OR DECONTAMINATING AGAINST HIV-1 AND HBV OR SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS)

DECON-QUAT 100 is a concentrate solution with active ingredients of 5% Alkyl (C14, 60%, C16, 30%, C12, 5%, C18, 5%) Dimethyl Benzyl Ammonium Chloride and 5% Akly (C12, 68%, C14, 32%) Dimethyl Ethylbenzyl Ammonium Chloride, and 90% Inert Ingredients.

DECON-QUAT 100 is produced sterile by filtration at 0.2 microns in a GMP Class 100 manufacturing area and subsequently gamma radiated to a  $10^{-6}$  SAL level. DECON-QUAT 100 is available sterile and non-sterile in 8 ounce bottles and a 1 gallon containers. Each container is double bag packaged and delivered each time with the lot specific Certificate of Analysis and Sterility Report. DECON-QUAT 100 is completely traceable and has been validated for sterility and shelf life.

### The SimpleMix<sup>®</sup> System Technology Alternative:

As a innovating step to address this problematic situation, Veltek Associates, Inc has developed the SimpleMix<sup>®</sup> System Technology. The system provide for the transfer of the sterile disinfectant and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminated all internal and external concerns for the use of a sterile, compliant disinfectant or sporicide.

The Patent Pending SimpleMix<sup>®</sup> System provides a sealed multi-chamber container that when activated mixes the two solutions. The top part contains the concentrate disinfectant or sporicide and the bottom part contains the USP WFI Quality Water. **Just open the cap, pull the tab and they instantly mix together.** The system design permits the easy transfer of the sterile disinfectant or sporicide and sterile water to the aseptic manufacturing area without concern for the transfer of contamination See VAI Technical Document (SMix-01 Rev. 02/03)

Use Areas: Used to disinfect inanimate, hard, non-porous environmental surfaces such as walls, ceilings, floors and countertops .

### ORDERING INFORMATION

<u>Order#</u>	<u>Description</u>	<u>Quan/cs.</u>
DQ100-01	DECON-QUAT 100 1 Gallon Concentrate Non-Sterile	4
DQ100-02	DECON-QUAT 100 1 Gallon Concentrate Sterile	4
DQ100-03-8Z	DECON-QUAT 100 8 oz. Concentrate Bottle Sterile	24
DQ100-04-2Z	DECON-QUAT 100 SimpleMix Sterile 1 Gallon	4
DQ100-05-2Z	DECON-QUAT 100 SimpleMix Sterile 1 Gallon	4

### Available Technical Data Supplements (Upon Request)

SC-001: Sterile Chemical Product Guide

VL-750: DECON-QUAT Technical Data Report

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# **DECON-QUAT 100**

**Sterile Pharmaceutical Clean Room Formula**  
**Quaternary Ammonium**

## **PRODUCT LABELING**

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(LEFT PANEL) 1 Gallon (DQ100-01, DQ100-02 and DQ100-03-8Z)

## DECON-QUAT 100

**Disinfectant-Sanitizer-Fungicide-Virucide\***  
**Deodorizer for Hospital, Institutional,**  
**Industrial, School, Dairy and Other,**  
**Farm Use and for the Control of Mollusks and Algal,**  
**Bacterial and Fungal Slimes in Once-Through and Closed-Cycle,**  
**Fresh and Sea Water Cooling Systems**

Alkyl (C <sub>14</sub> , 60%; C <sub>16</sub> , 30%; C <sub>12</sub> , 5%; C <sub>18</sub> , 5%) Dimethyl Benzyl Ammonium Chloride	5.0%
Alkyl (C <sub>12</sub> , 68%; C <sub>14</sub> , 32%) Dimethyl Ethylbenzyl Ammonium Chloride	5.0%
Inert Ingredients:	90.0%
	100.0%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 6836-57-068959

EPA Est. No. 068959-PA-01

Net Contents:           DQ100-01 and DQ100-02: 1 Gallon (Case Quantity: 4 X 1 Gallon)  
                                  DQ100-03-8Z: 8 Ounces (Case Quantity: 24 X 8 Ounces)

Contents/Reorder#:    1 Gallon Non-sterile: DQ100-01    1 Gallon Sterile:DQ100-02    8 Ounce Sterile: DQ100-03-8Z

Manufactured by:  
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*(CENTER LEFT PANEL) 1 Gallon (DQ100-01 and DQ100-02)*  
*(RIGHT PANEL) 8 Ounce (DQ100-03-8Z)*

## STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution\; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

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

## **PRECAUTIONARY STATEMENTS** **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** **DANGER**

Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Wash thoroughly with soap and water after handling of container.

## **ENVIRONMENTAL HAZARDS (FOR CONTAINERS 5 GALLONS AND LARGER)**

This pesticide is toxic to fish. 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 (FOR CONTAINER SIZES OF ONE GALLON OR LESS)**

Do not store on side.  
Avoid creasing or impacting of side walls.  
Do not reuse empty container. Wrap container and put in trash.

## **STORAGE AND DISPOSAL (FOR CONTAINER SIZES GREATER THAN ONE GALLON)**

Do not contaminate water, food or feed by storage and disposal.  
Do not store on side.  
Avoid creasing or impacting of side walls.

## **PESTICIDE DISPOSAL**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, spray or mixture of 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.

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## CONTAINER DISPOSAL

### **(PLASTIC CONTAINER)**

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

### **(METAL CONTAINER)**

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

## DIRECTIONS FOR USE

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

Mix 1 ounce per 1 gallon of water. Apply DECON-QUAT 100 with a cloth, mop or mechanical spray device. When applied with a mechanical spray device, surface must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Fresh solution should be prepared daily or when the use solution becomes visibly dirty.

## MIXING INSTRUCTIONS:

For DQ100-01 and DQ100-02: Mix 1 ounce per 1 gallon of water. For FUNGICIDAL 1.6 ounces per 1 gallon of water

For DQ100-03-8Z: Mix the entire contents of this bottle (6.4 oz. DECON-QUAT 100 concentrate) with 4 gallons of water

*(RIGHT CENTER PANEL) 1 Gallon (DQ100-01 and DQ100-02)*

*(CARTON FULL LABEL - RIGHT CENTER PANEL) 8 Ounce (DQ100-03-8Z)*

## PRODUCT USE INSTRUCTIONS:

### HIV-1 and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS

This product when used on hard, non-porous, inanimate environmental surfaces at 1 oz. per gallon of water for a 10 minute contact (5% organic soil) is effective against Hepatitis B Virus (HBV). This product also kills human immunodeficiency virus Type 1 (HIV-1) after 30 second contact time.

'KILLS HIV-1 and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings In which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 or HBV.

"SPECIAL INSTRUCTIONS FOR CLEANING OR DECONTAMINATING AGAINST HIV-1 AND HBV OR SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS."-

## PERSONAL PROTECTION:

Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gown, masks or eye coverings.

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## **CLEANING PROCEDURE:**

Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

## **CONTACT TIME:**

Leave surfaces wet for 30 seconds and 10 minutes for HIV-1 and HBV respectively. The 30 second contact time will not control other common types of bacteria and viruses.

## **DISPOSAL OF INFECTIOUS MATERIAL:**

Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious medical waste disposal.

## **SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD CONTACT LOCATIONS**

For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous surfaces.

Wash and rinse all articles thoroughly, then apply a solution of 1 oz. DECON-QUAT 100 in 4 gallons of water (200 ppm active). Surfaces should remain wet for at least one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when use solution becomes visibly dirty. For mechanical application, use solution may not be reused for sanitizing applications.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth or brush.

Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in a 1 oz./4 gallon dilution of DECON-QUAT 100. No potable water rinse is required.

At 1 oz./4 gallons, DECON-QUAT 100 has a hard water tolerance of 750 ppm of hardness calculated as CaCO<sub>3</sub> when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against Escherichia coli and Staphylococcus aureus.

*(RIGHT PANEL) 1 Gallon (DQ100-01 and DQ100-02)*

*(CARTON FULL LABEL - RIGHT PANEL) 8 Ounce (DQ100-03-8Z)*

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## **PRODUCT USE INSTRUCTIONS (cont'):**

### **DISINFECTION IN HOSPITALS, NURSING HOMES AND OTHER HEALTH CARE INSTITUTIONS**

For disinfecting floors, walls, countertops, bathing areas, lavatories, bedframes, tables, chairs, garbage pails and other hard non-porous surfaces.

Add 1 oz. DECON-QUAT 100 per gallon of water. Apply to previously cleaned hard surface with mop or cloth.

At this use-level, DECON-QUAT 100 is effective against *Pseudomonas aeruginosa*, Hepatitis B Virus (HBV) and Human Immunodeficiency Virus Type I (HIV-1).

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

### **DISINFECTANT IN INSTITUTIONS, INDUSTRY AND SCHOOLS**

For disinfecting floors, walls, bedframes, countertops, tables, chairs, garbage pails, bathroom fixtures and other hard, nonporous surfaces. Add 0.6 oz. of DECON-QUAT 100 per gallon Of water. Apply to previously cleaned hard surface with mop or cloth. At 0.6 oz. per gallon of water use-level, DECON-QUAT 100 is effective against *Staphylococcus aureus* and *Salmonella choleraesuis*.

### **FUNGICIDAL ACTIVITY**

At 1.6 oz. per gallon of water use-level DECON-QUAT 100 is effective against *Trichophyton mentagrophytes* (athlete's foot fungus) on inanimate hard, non-porous surfaces.

### **DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS**

Poultry brooders, watering founts, feeding equipment and other animal quarters (such as stalls and kennel areas) can be disinfected after thorough cleaning by applying a solution of 1 oz. DECON-QUAT 100 per gallon of water with a mop, cloth or brush. Small utensils should be immersed in this solution.

Prior to disinfection, all poultry, other animals and their feeds must be removed from the premises. This includes emptying all troughs, racks and other feeding and watering appliances. Remove all litter and droppings from floors, walls and other surfaces occupied or traversed by poultry or other animals. After disinfection, ventilate building, coops and other closed spaces. Do not house poultry, or other animals, or employ equipment until treatment has been absorbed, set or dried.

All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

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# DECON-QUAT 100<sup>®</sup>

**Sterile Pharmaceutical Clean Room Formula  
Quaternary Ammonium**

## **MATERIAL SAFETY DATA SHEET**

**COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200  
(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)**



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**DECON-QUAT<sup>®</sup> 100****MATERIAL SAFETY DATA SHEET**

**COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200  
(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)**

**I. Identification of Substance:**Product Name: DECON-QUAT<sup>®</sup>

MSDS #: DQ-98-01

Description: Quaternary Ammonium Solution at 10%

<b>MSDS Information</b>	<b>Manufacturer Information</b>	<b>Emergency Telephone Information</b>
Date Prepared: November 6, 2002	Veltek Associates, Inc.	Notify your Supervisor
<b>Prepared by:</b>	15 Lee Boulevard	Emergencies Chemtrec (800) 424-9300
Art Vellutato, Jr.	Malvern, PA 19355	24-hour service
V.P. Technical Support Operations	TEL: (610)644-8335	
<b>Reviewed by:</b>		Effective Date: November 6, 2002
Art Vellutato, Sr.		Date Supersedes: 05/05/98
Technical Director		

**II. Composition/Data on Components:**

Formula/Mixture: Chemical Name (Actives) Mixture of N-Alkyl(c<sub>12-18</sub>)-N,N-dimethyl-N-benzylammonium chloride and N-Alkyl (c<sub>12-14</sub>)-N,N-dimethyl-N-ethylbenzylammonium chloride

	<b>Approx. Weight %</b>	<b>TWA/TLV</b>
N-Alkyl(c <sub>12-18</sub> )-N,N-dimethyl-N-benzylammonium chloride (CAS No. 68391-01-5)	5.0	None established
N-Dodecyl-N,N-dimethyl-N-ethylbenzylammonium chloride (CAS No. 27479-28-3)	3.4	None established
N-Tetradecyl-N,N-dimethyl-N-ethylbenzylammonium chloride (CAS No. 27479-29-4)	1.6	None established
Water (CAS No. 7732-18-5)	90	None established
HEALTH: 3      FLAMMABILITY: 1      REACTIVITY: 0      PERSONAL PROTECTION: B		

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## V. Firefighting Measures:

FLASH POINT >200°F (Setaflash)      AUTO IGNITION TEMPERATURE: Not known  
LOWER EXPLOSION LIMIT (%): Not applicable      UPPER EXPLOSION LIMIT (%): Not applicable  
EXTINGUISHING MEDIA: FOAM      ALCOHOL FOAM: YES      CO<sub>2</sub>: YES  
      DRY CHEMICAL: YES      WATER: YES      OTHER: N/A

**SPECIAL FIRE FIGHTING PROCEDURES:** Must wear NIOSH/MSHA approved self-contained breathing apparatus and protective clothing. Cool fire-exposed containers with water spray.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** Products of combustion are toxic.

## VI. Accidental Release Measures:

### STEPS TO BE TAKEN IN CASE OF SPILL OR RELEASE

Danger! Corrosive material. Floors may become slippery. Wear appropriate protective gear and respiratory protection where mist or vapors of unknown concentrations may be generated (self-contained breathing apparatus preferred).

Dike and contain spill with inert material (sand, earth, etc.) and transfer the liquid and solid separately to containers for recovery or disposal. Keep spill out of sewers and open bodies of water.

## VII. Handling and Storage:

### PRECAUTIONS FOR STORAGE AND HANDLING:

Store at temperature below 140°F. Keep containers closed until used.

## VIII. Exposure Control and Personal Protection:

### VENTILATION TYPE

In processes where mists may be generated, proper ventilation must be provided in accordance with good ventilation practices.

### RESPIRATORY PROTECTION

Where mist or vapors are generated by the process a NIOSH/MSHA jointly approved respirator is advised in the absence of proper environmental controls.

### PROTECTIVE GLOVES

Rubber or neoprene, when needed, to prevent skin contact.

### EYE PROTECTION

Wear chemical splash goggles where there is a potential for eye contact. Use safety glasses with side shields under normal use conditions.

### OTHER PROTECTIVE EQUIPMENT

Eye wash\; safety shower\; protective clothing (long sleeves, coveralls or other, as appropriate), when needed, to prevent skin contact.

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## IX. Physical and Chemical Properties:

APPEARANCE	Clear colorless liquid	pH	6.5 to 8.3
VISCOSITY	<100 cps @ 25°C	ODOR:	Benzaldehyde-like
BOILING POINT:	102°C	MELTING OR FREEZING POINT:	Not known
VAPOR PRESSURE (Air=1):	Not known	VAPOR PRESSURE (mm Hg):	Not known
PERCENT VOLATILE (by weight):	90	SOLUBILITY IN WATER:	Soluble
EVAPORATION RATE (Butyl Acetate = 1):	Not known	SPECIFIC GRAVITY (water = 1):	0.99 @ 25°C

## X. Stability and Reactivity:

STABILITY:	STABLE	X	CONDITIONS TO AVOID
	UNSTABLE		None known

### HAZARDOUS DECOMPOSITION PRODUCTS

Thermal decomposition may produce toxic vapors/fumes of amines and other organic materials, and oxides of carbon and nitrogen.

### HAZARDOUS POLYMERIZATION

May occur	Will not occur	X	CONDITIONS TO AVOID
			None known

INCOMPATIBILITY (Materials to Avoid): Strong oxidizing or reducing agents

## XI. Toxicological Information:

### TOXICOLOGY INFORMATION \_\_\_\_\_

- skin irritation (rabbit): 0.5 ml applied to the intact and abraded skin for 24 hours under occlusion produced severe burns (eschar) and severe swelling (edema) that did not clear by 72 hours, post-dose (primary irritation index 6.91)

The information below is for a 50% active solution of the same quat mixture:

- oral LD<sub>50</sub> (rat): 250 mg/kg
- dermal LD<sub>50</sub> (rabbit): 3400 mg/kg
- inhalation LC<sub>50</sub> (rat): 86 mg/liter (1 hour exposure)
- eye irritation (rabbit): in two separate studies, 0.1 ml instilled to the eye without washing produced extreme irritation that did not clear by day 3 or day 4, post-dose respectively
- skin irritation (rabbit): 0.5 ml of a 50% active solution applied to the intact and abraded skin for 24 hours under occlusion produced severe irritation (primary irritation index 6.0)
- corrosive via DOT test for skin corrosivity
- not teratogenic in rats given oral doses of 10 to 50 mg/kg on days 6 to 15 of gestation
- in rabbits, 4.0 ml of a 1:500, 1:1000 or 1:4000 dilution (based on 100% activity) applied to the skin for 20 consecutive days produced mild, transitory redness and slight swelling of the skin but no overt signs of gross pathological or behavioral toxicity

## XII. Ecological Information:

Consult local authorities pertaining to the release of material to the environment.

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## **XIII. Disposal Considerations:**

### WASTE DISPOSAL METHODS

Dispose of in compliance with all Federal, state and local laws and regulations. Incineration is the preferred method.

### CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## **XIV. Transport Information:**

**DOT Hazard Classification:** Corrosive Material

**DOT Shipping Name:** CAS No. Mixture Disinfectant, Liquid

**DOT Label:** Corrosive

## **XV. Regulations:**

### FEDERAL LEVEL REGULATIONS:

This is an EPA registered pesticide (EPA Registration No. 6836-57).

This product may only be used in the specific applications listed on the EPA approved label.

### TOXIC SUBSTANCES CONTROL ACT (TSCA INVENTORY) STATUS:

Found on U.S. EPA TSCA inventory.

CERCLA (Comprehensive Environmental Response, Compensation and Liability Act of 1980) requires notification of the National Response Center

(Telephone 1-800-424-8802) in the event of a release of quantities of the following hazardous materials contained in this product, if the release is equal to or greater than the Reportable Quantities (RQs) listed in 40 CFR 302.4:

<u>Chemical Name</u>	<u>Typical Maximum CAS No. Concentration</u>
None known	

SARA Title III, Sections 302/304 (Superfund Amendments and Reauthorization Act of 1986) - This act requires emergency planning, including agency notification, for possible release of the following components of this material, based upon the Threshold Planning Quantities (TPQs) and release Reportable Quantities (RQs) listed for the Components in 40 CFR 355:

<u>Chemical Name</u>	<u>Typical Maximum CAS No. Concentration</u>
None known	

SARA Title III, Sections 311/312 - This act requires reporting under the Community Right-to-Know provisions due to the inclusion of the following components of this material in one or more of the five hazard categories listed in 40 CFR 370:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>(Hazard *) Categories</u>
N-Alkyl (C <sub>12-18</sub> )-N,N-dimethyl-N-benzylammonium chloride	68391-01-5	A
N-Dodecyl-N,N-dimethyl-N-ethylbenzylammonium chloride	27479-28-3	A
N-Tetradecyl-N,N-dimethyl-N-ethylbenzylammonium chloride	27479-29-4	A

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\*) The five hazard categories are as follows: F=FIRE HAZARD\; S=SUDDEN RELEASE OF PRESSURE\; R=REACTIVE\; A=IMMEDIATE (ACUTE) HEALTH HAZARD\; C=DELAYED (CHRONIC) HEALTH HAZARD

SARA Title 313 - This act requires submission of annual reports of releases of the following components of this material if the threshold reporting quantities, as listed in 40 CFR 372, are met or exceeded:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Typical Maximum Concentration</u>
None known		

#### NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous injection of a short acting barbiturate drug.

#### STATE RIGHT-TO-KNOW REGULATIONS:

CALIFORNIA PROPOSITION 65 - Components present in this material which the State of California has found to cause cancer, birth defects or other reproductive harm are as follows:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Typical Maximum Concentration</u>
Benzene	71-43-2	20 ppm
Benzyl chloride	100-44-7	20 ppm
N-Nitrosodimethylamine	62-75-9	200 ppb
Propylene oxide	75-56-9	2 ppm
Toluene	108-88-3	40 ppm

MASSACHUSETTS Right-to-Know - The following components of this material are included in the Massachusetts Substance List and are present at or above reportable levels:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Typical Maximum Concentration</u>
Benzene	71-43-2	20 ppm
Benzyl chloride	100-44-7	20 ppm
Propylene oxide	75-56-9	2 ppm

MICHIGAN Critical Materials - The following components of this material are included in the Michigan Critical Materials list:

<u>Chemical Name</u>	<u>CAS No.</u>
None known	

NEW JERSEY Right-to-Know - The following components of this material are included in the New Jersey Hazardous Substance list and are present at or above reportable levels:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Typical Maximum Concentration</u>
N-Alkyl (C <sub>12-18</sub> )-N,N-dimethyl-N-benzylammonium chloride	68391-01-5	5.0%
N-Dodecyl-N,N-dimethyl-N-ethylbenzylammonium chloride	27479-28-3	3.4%
N-Tetradecyl-N,N-dimethyl-N-ethylbenzylammonium	27479-29-4	1.6%

**Veltek Associates, Inc.**

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Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com VL-750-99-2 12/18/03

# O V E R V I E W

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chloride

PENNSYLVANIA Right-to-Know - The following components of this material are included in the Pennsylvania Hazardous Substance List and are present at or above reportable levels:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Typical Maximum Concentration</u>
None known		

## **XVI. Other Information:**

NOTE: *The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, expressed or implied is given. It is the responsibility of the user to comply with all Federal, State and Local laws and regulations.*

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**DECON-QUAT 100**  
**Sterile Pharmaceutical Clean Room Formula**  
**Quaternary Ammonium**

**Lot Specific**  
**Sterile Documentation**  
(received with each shipment)

**Certificate of Analysis**  
**Certificate of Sterility**  
**Certificate of Irradiation**

(Please contact VAI for a sample of this documentation)

# DECON-QUAT 100

Sterile Pharmaceutical Clean Room Formula  
Quaternary Ammonium

## Antimicrobial Test Results

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## Summary of Antimicrobial Test Results

Formulation **DECON-QUAT 100** is a "One-Step" Hospital Disinfectant, Virucide, Fungicide, Mildewstat, and Cleaner. Listed below, and in the following pages, is a summary of the Antimicrobial Claims and a review of the Antimicrobial Test Results.

<b>Claim:</b> Disinfectant	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Official Method of the AOAC, 14 Edition Use-Dilution Method			

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
<i>Pseudomonas aeruginosa</i>	15442	600 ppm (0.5 oz/gal)	400 ppm	60, 60, 60	0/60, 0/60, 0/60
<i>Staphylococcus aureus</i>	6538	600 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
<i>Salmonella choleraesuis</i>	10708	600 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
<i>Acinetobacter calcoaceticus</i>	23055	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Bordetella bronchiseptica</i>	31427	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Chlamydia psittaci</i>	VR-854	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterobacter aerogenes</i>	13048	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterobacter cloacae</i>	23355	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterococcus (Streptococcus) faecalis (Vancomycin Resistant)</i>	51299	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Escherichia coli</i>	11229	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Escherichia coli</i> <sup>1</sup> (Clinical Isolate)	(Clinical Isolate)	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Fusobacterium necrophorum</i>	27852	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Klebsiella pneumoniae</i> <sup>2</sup>	13883	600 ppm	400 ppm	10, 10	0/10, 0/10
<i>Legionella pneumophila</i>	33153	600 ppm (0.50 oz/gal)	400 ppm	10, 10	0/10, 0/10

<sup>1</sup>Resistant to the Antibiotics: Ampicillin, Carbenicillin, Kanamycin, and Tetracycline.

<sup>2</sup>Resistant to the Antibiotics: Ampicillin, Carbenicillin, Chloramphenicol, and Tetracycline.

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## Summary of Antimicrobial Test Results - (Continued)

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Listeria monocytogenes	15313	600 ppm (0.50 oz/gal)	400 ppm	10, 10	0/10, 0/10
Pasteurella multocida	7707	600 ppm	400 ppm	10, 10	0/10, 0/10
Proteus mirabilis	25933	600 ppm	400 ppm	10, 10	0/10, 0/10
Proteus vulgaris	13315	600 ppm	400 ppm	10, 10	0/10, 0/10
Pseudomonas aeruginosa <sup>3</sup>	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella enteritidis	13076	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella typhi	6539	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella typhimurium	14028	600 ppm	400 ppm	10, 10	0/10, 0/10
Serratia marcescens	8100	600 ppm	400 ppm	10, 10	0/10, 0/10
Shigella flexneri	12022	600 ppm	400 ppm	10, 10	0/10, 0/10
Shigella sonnei	9290	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus <sup>4</sup> (MRSA)	33592	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus <sup>5</sup>	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus epidermidis <sup>6</sup>	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis <sup>7</sup>	19433	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis	19433	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus pyogenes	19615	600 ppm	400 ppm	10, 10	0/10, 0/10

3 Resistant to the Antibiotics: Amikacin, Ampicillin, Carbenicillin, Cefamandole, Cefazolin, Cefoxitin, Chloramphenicol, Kanamycin, and Tetracycline.

4 Resistant to Gentamicin and Methicillin

5 Resistant to the Antibiotics: Cefazolin, Clindamycin, Erythromycin, Gentamicin, Kanamycin, Methicillin, Penicillin, Tetracycline and Tobramycin

6 Resistant to the Antibiotics: Cefazolin, Chloramphenicol, Clindamycin, Erythromycin, Gentamicin, Kanamycin, Methicillin, Penicillin, Tetracycline and Tobramycin

7 Resistant to the Antibiotics: Cefazolin, Chloramphenicol, Clindamycin, Erythromycin, Gentamicin, Kanamycin, Methicillin, Penicillin, Tetracycline and Tobramycin

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## O V E R V I E W

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**Conclusion:** All lots of Formulation **DECON-QUAT 100** effectively killed the above listed bacteria as specified in the test performance standards. Formulation **DECON-QUAT 100** meets EPA requirements for hard surface disinfectant claims for hospital and medical environments when diluted to 600 ppm active concentration in 400 ppm synthetic hard water, and in the presence of 5% organic soil.

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**O V E R V I E W**

**Summary of Antimicrobial Test Results - (Continued)**

<b>Claim:</b> Mildewstat	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Mildewstat (Mold and Mildew Control) - EPA - TSD 6-201 Mildewstat on Hard Surfaces			

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Aspergillus niger	6275	600 ppm (0.50 oz/gal)	400 ppm	10, 10	0/10, 0/10

**Conclusion:** All lots of Formulation **DECON-QUAT 100** were effective against *Aspergillus niger* under the test conditions outlined in the EPA test performance standards described above. Formulation **DECON-QUAT 100** is an effective mildewstat for non-porous inanimate hard surfaces when diluted to 600 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

<b>Claim:</b> Fungicide	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Official Method of Analysis of the AOAC Fungicidal Test.			

Organism	ATCC#	Dilution	Replicates	Results		
				5 Min	10 Min	15 Min
Trichophyton mentagrophytes	9533	600 ppm (0.50 oz/gal)	4	0/4 +	0	0
Candida albicans	11651	600 ppm (0.50 oz/gal)	4	0/4 +	0	0

**Conclusion:** All lots of Formulation **DECON-QUAT 100** effectively killed *Trichophyton mentagrophytes* and *Candida albicans* as specified in the test performance standards. Formulation **DECON-QUAT 100** is an effective fungicide for non-porous inanimate hard surfaces when diluted to 600 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

**O V E R V I E W**

**Summary of Antimicrobial Test Results - (Continued)**

<b>Claim:</b> Virucide		<b>Contact Time:</b> Varies		<b>Organic Soil:</b> 5%		<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>	
<b>Test Method:</b>		EPA Guidelines					
<b>Organism</b>	<b>Source of Virus or ATCC#</b>	<b>Host System; Cytopathic Effect</b>	<b>Use-Dilution Concentration</b>	<b>Contact Time</b>	<b>Replicates</b>	<b>Reduction (Log 10) of Virus Titer</b>	
Adenovirus Type 4	ATCC VR-4 strain RI-67	H. Ep. #2 cells Cytopathic Effects	600 ppm (0.50 oz/gal)	10 Min.	8	5.5, 5.5	
Herpes Simplex Type 1	HSV-1; ATCC VR-733	VERO cells; lytic cytopathic effect	600 ppm	10 Min.	8	>7.5, 7.5	
Herpes Simplex Type 2	HSV-2; MS Strain	VERO cells; lytic cytopathic effect	600 ppm	10 Min.	8	>6.5, 6.5	
HIV-1 (AIDS Virus)	HTLV-III <sub>RF</sub> ; NCI	MT2 cells; lytic cytopathic effect	600 ppm	4 Min.	8	>3.0, 3.0	
Influenza A/ Hong Kong	ATCC 68-H3N2	MDCK cells; lytic cytopathic effect	600 ppm	10 Min.	8	>8.0, 8.0	
Rubella virus	Strain M-33	RK13 cells; cytopathic effect	600 ppm	10 Min.	8	>5.0, 5.0	
Rabies virus	ATCC VR-138		600 ppm	10 Min.	8	4.5, 4.5	
Respiratory Syncytical virus	ATCC VR-26		600 ppm	10 Min.	8	4.0, 4.5	
Vaccinia	Strain IHD	VERO Cells; lytic cytopathic effect	600 ppm	10 Min.	8	>7.0, 7.0	
Avian Infectious Bronchitis virus	ATCC VR-22		600 ppm	10 Min.	8	6.0, 6.25	
Avian Polyomavirus	lab isolate		600 ppm	10 Min.	8	4.0, 6.0	
Canine Distemper virus	ATCC-VR-256		600 ppm	10 Min.	8	3.5, 3.5	
Feline Leukemia virus	ATCC VR-717 Strain FL-237		600 ppm	10 Min.	8	4.5, 4.75	
Feline Picornavirus	ATCC VR-649		600 ppm	10 Min.	8	5.0, 5.0	
Infectious Bovine Rhinotracheitis	ATCC VR-793		600 ppm	10 Min.	8	8.0, 8.0	
Pseudorabies virus	ATCC VR-135		600 ppm	10 Min.	8	5.5, 5.5	
Transmissible Gastroenteritis	ATCC VR-763		600 ppm	10 Min.	8	3.5, 3.5	

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## **O V E R V I E W**

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**Conclusion:** All lots of Formulation **DECON-QUAT 100** effectively inactivated the above listed viruses as specified in the test performance standards. Formulation **DECON-QUAT 100** meets EPA requirements for hard surface virucidal claims in hospital and medical environments when diluted to 600 ppm in 400 ppm synthetic hard water all in the presence of 5% organic soil.

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**Summary of Antimicrobial Efficacy - Etiology<sup>8</sup>**

<b>Pathogenic Microorganism</b>	<b>Description</b>
Pseudomonas aeruginosa	Gram negative bacteria identified as a major cause of hospital acquired (nosocomial) infections. Causes wound infections (especially burn), meningitis, pneumonia and eye infections. Required for Hospital Disinfectants.
Staphylococcus aureus	Gram positive bacteria identified as a major cause of hospital acquired (nosocomial) infections. Colonizes food and secretes enterotoxins which cause food poisoning after ingestion. Causes wound infections, septicemia, endocarditis, meningitis, osteomyelitis and pneumonia. Required for Hospital Disinfectants.
Salmonella choleraesuis	Gram negative bacteria associated with acute gastroenteritis and septicemia. Required for Hospital Disinfectants.
Acinetobacter calcoaceticus	Gram negative (spherical shape) bacteria. Occurs in soil, water and sewage. A nosocomial infection can cause septicemia, meningitis and urinary tract infections.
Aspergillus niger	Black mold, found in shower and dressing rooms. Environmental contaminant may also cause "Aspergillosis."
Bordetella bronchiseptica	Gram negative (spherical shape) bacteria. Causative agent for "puppy cough" in dogs. Bordetella pertussis is the causative agent for whooping cough in children.
Candida albicans	Fungi, yeast. This organism exhibits dimorphism; exists both as fungi and yeast. Causes skin rashes. Common cause for diaper rash. Can infect both oral and vaginal cavities. Causes itching and discomfort.
Chlamydia psittaci	Once believed to be a large virus but later found to be a parasitic bacterium. Infections cause fever, malaise and hacking cough. Most infections are occupational; poultry workers and other keepers of birds.
Enterobacter aerogenes	Gram negative bacteria spread by anal/oral route of infection. Associated with bacteremia, respiratory, wound and urinary tract infections.
Enterobacter cloacae	Gram negative bacteria spread by anal/oral route of infection. Associated with bacteremia, respiratory, wound and urinary tract infections.
Fusobacterium necrophorum	Gram negative (rod shape) bacteria. Causative agent of "hoof rot" in sheep, cattle and horses.

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<sup>8</sup> Microbiology, D. Kingsbury and G. Wagner Harwal Publishing 1990

**Summary of Antimicrobial Efficacy - Etiology - (Continued)**

Escherichia coli	Gram negative bacteria spread by anal/oral route of infection, resulting in diarrhea outbreaks. Associated with urinary tract infections and bacteremia.
Legionella pneumophila	Gram negative (rod shape) bacteria. Causative agent for “legionnaire disease.” First documented outbreak occurred in 1976 at Philadelphia American Legion convention.
Listeria monocytogenes	Gram positive (rod shape) bacteria. Considered a potent food pathogen. Found in raw meat and poultry. Infections can result in meningitis or sepsis.
Klebsiella pneumoniae	Gram negative bacteria associated with severe pneumonia, bacteremia and urinary tract infections.
Pasteurella multocida	Gram negative (spherical shape) bacteria. Human infections are a result of an animal bite. Indigenous flora of many animals respiratory tracts.
Proteus mirabilis	Gram negative (rod shape) bacteria. Highly motile bacteria. Opportunistic pathogen causes bacteremia, urinary tract infections, especially with the chronically ill.
Proteus vulgaris	Gram negative (rod shape) bacteria. Highly motile bacteria. Opportunistic pathogen causes bacteremia, urinary tract infections, especially with the chronically ill.
Salmonella enteritidis	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Salmonella schottmuelleri	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Salmonella typhi	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea, the causative agent for typhoid fever.
Salmonella typhimurium	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Serratia marcescens	Gram negative bacteria associated with urinary tract infections, meningitis and septicemia.
Shigella dysenteriae	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.
Shigella flexneri	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.

**Summary of Antimicrobial Efficacy - Etiology - (Continued)**

<b>Pathogenic Microorganism</b>	<b>Description</b>
Shigella sonnei	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.
Streptococcus (Enterococcus) faecalis	Gram positive (Enterococci) bacteria causing hemolysis, urinary tract infections and endocarditis.
Trichophyton mentagrophytes	Athlete's foot fungus. Found in shower and dressing rooms.
Adenovirus Type 4	Lipophilic (enveloped) DNA virus, (one of several) causative agent for colds and other respiratory ailments.
Canine Distemper	Lipophilic (enveloped) RNA virus. Highly contagious among dogs causes fever, gastrointestinal and respiratory symptoms.
Feline Leukemia Virus	Non-enveloped RNA virus. One of the causative agents of lymphosarcoma in cats.
Herpes Simplex Type 1&2	Lipophilic (enveloped) DNA virus may result in oral mucocutaneous lesions. Associated with most orofacial herpes and HSV encephalitis.
HIV-1 (AIDS Virus)	Lipophilic (enveloped) RNA retrovirus. Human Immunodeficiency Virus. Known to be the etiologic agent of Acquired Immunodeficiency Syndrome (AIDS).
Influenza A/Hong Kong	Lipophilic (enveloped) RNA virus. Causative agent in viral flu. Causes flu epidemics in nearly 2 of every 3 years.
Rabies	A member of the Rhabdoviridae family or RNA viruses. These bullet shaped viruses are enveloped by a lipid bilayer. The causative agent for "rabies", an encephalitis that causes neuronal degeneration-- almost always fatal.
Respiratory Syncytial Virus	A paramyxovirus type virus, lipophilic (enveloped). A causative agent of pneumonia and bronchiolitis in small children and infants. Highly contagious, transmitted by person-to-person contact.
Rubella	Lipophilic (enveloped) RNA togavirus. The causative agent of German measles.
Vaccinia	Lipophilic (enveloped) DNA poxvirus; causes poxvirus infections.