



VELTEK ASSOCIATES, INC.

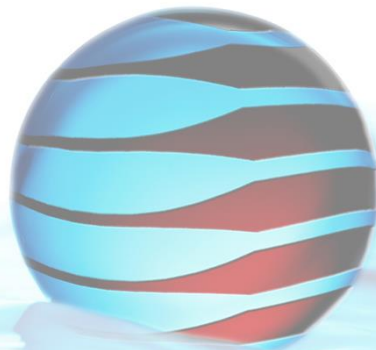
# TECHNICAL DATA FILES



## DECON-AHOL<sup>®</sup> Products

USP Isopropyl Alcohol formulated with USP Water for Injection

DECON-AHOL WFI<sup>®</sup> Formula 70%, DECON-AHOL<sup>®</sup> Aerosol WFI<sup>®</sup> Formula 70%,  
DECON-AHOL<sup>®</sup> 61%, DECON-AHOL<sup>®</sup> 91%, DECON-AHOL<sup>®</sup> 99%



## **Product Description: DECON-AHOL WFI® Formula 70%**

After years of development, Veltek Associates, Inc., has been able to produce **DECON-AHOL WFI Formula**, a USP Isopropyl Alcohol with USP Water for Injection formula that is not only sterile, but low in endotoxin levels. VAI was aware that simply filtering IPA might not result in acceptable endotoxin levels, therefore, creating a potential concern for cGMP/GLP operations. Addressing this concern, VAI formulated 70% USP IPA with 30% USP WFI that has very low levels of endotoxins, thus, making it an excellent choice for the critical ISO 5 (Grade A/B, Former Class 100) and ISO 7 (Grade C, Former class 10,000) aseptic manufacturing conditions. All assurances of environmental control during manufacture of **DECON-AHOL WFI Formula** were taken into account including: designing a closed system of manufacture, controlling endotoxin levels in elements such as tubing and final containers, formulation with endotoxin free WFI, and air washing raw material components with 0.2 micron filtered air.

**DECON-AHOL WFI Formula 70%** is an EPA registered hard surface disinfectant and sanitizer when used as directed. This USP IPA has been designed specifically for pharmaceutical, biotechnology, health care, and medical device cleaning rotations for use in both aseptic and non-aseptic environments. **DECON-AHOL WFI Formula** can be used for decontamination on numerous surfaces within any cleanroom operation while ensuring a low remaining residue and endotoxin levels.

Sanitizer – Disinfectant

**DECON-AHOL WFI Formula** is 70% USP Isopropyl Alcohol with 30% Water for Injection 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-AHOL WFI Formula** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-AHOL WFI Formula** is delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report tested to current USP compendium.

**DECON-AHOL WFI Formula** is available in multiple container sizes including an 11 oz aerosol, 16 oz trigger spray, 16 oz “bag in bottle” technology trigger, 16 oz squeeze bottle, 32 oz trigger spray, 32 oz “bag in bottle” technology trigger, 32 oz ASEPTI-CLEANSE (automatic touchless dispenser) bottle, 1 gallon container, 5 gallon container, and a 55 gallon container. Each sterile container is double bagged and packaged quadruple bagged using the ABCD Cleanroom Introduction System®. **DECON-AHOL WFI Formula** is packaged to comply with the requirements for transportation into a classified area.

VAI offers an innovative and convenient container size for **DECON-AHOL WFI Formula**: the 11 oz aerosol spray can, **DECON-AHOL® Aerosol WFI Formula**. This, high quality, nitrogen propelled, aerosol spray can precipitates in a broad spray/mist or stream without aspiration of the room’s air during use. Non-aspiration ensures that the master reservoir of Isopropyl Alcohol and WFI Quality Water remains sterile from the first drop to the last drop. 11oz spray cans are also available in an “inverta spray” can that allows for the can to be turned upside down, right side up, or horizontally during use.

## **Quality and Manufacturing**

- Formulated with Water for Injection (0.25 EU/mL)
- Assayed according to current USP compendium
- Manufactured within a closed system where endotoxin levels are controlled
- Components are air washed with 0.2 micron filtered air before assembly
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Gamma irradiated at a  $10^{-6}$  SAL
- Lot sterility tested according to current USP compendium
- Completely lot traceable from start to finish
- Completely validated for sterility and shelf life



11 oz. Aerosol “Inverta Spray”  
DECWFI-SP-70-B

Veltek Associates, Inc.

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

Rev: 06Apr2022, ML Rev Aerosol: G-16, ML Rev Disinfectant: G-16

<b>DECON-AHOL WFI® Formula– 70% USP Isopropyl Alcohol and 30% USP Water for Injection</b>	
<b>Certificate of Analysis</b>	<b>Specification</b>
Appearance:	Clear colorless
Assay:	68.0 - 72.0%
Acidity:	<= 1.0 ml
Nonvolatile Residue:	< 5.0 mg
Specific gravity @ 20 degrees C:	0.872 - 0.883
Expiration Period:	3 years

### **Features and Benefits**

- EPA registered disinfectant and sanitizer; EPA Registration Number: 68959-2
- EPA registered aerosol disinfectant and sanitizer; EPA Registration Number: 65959-4
- Each sterile container is double bagged
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report tested to current USP compendium
- Individually labeled with lot number and expiration
- Low remaining residue
- Low in endotoxin levels
- For use on a multitude of surfaces
- Ready-to-use
- Multiple convenient sterile and non-sterile container sizes including an 11 oz aerosol can
- 16 and 32 oz bottles come packaged with an attached trigger spray

### **Uses**

**DECON-AHOL WFI Formula** is for use where a sterile alcohol solution that is formulated with USP Water for Injection is required. It is recommended for routine use in spray and wipe downs on hard, non-porous, inanimate surfaces such as in aseptic filling, gowning rooms, general manufacturing areas, process lines, machinery, tools, tables, counters, laminar flow benches, carts, shelves made of glass, plastic, vinyl, stainless steel, table top surfaces, exterior packaging, accessories, and gloves. It is compatible with most hard surface materials.

### **DECON-AHOL WFI Formula: Parametric Release**

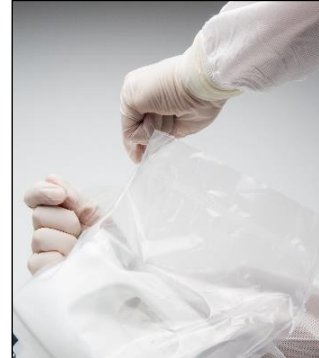
In addition to a lot sterility tested **DECON-AHOL WFI Formula**, VAI offers a 16 oz. trigger spray bottle that is released according to defined gamma irradiation parameters rather than through lot sterility testing. This product, DECTR-08, receives a lower dose of irradiation compared to **DECON-AHOL WFI Formula** products, at 10.0 - 30.0 K Gy. However, all of the same quality assurances are taken to ensure quality of the product.



DECTR-08

## 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.



## ASEPTI-CLEANSE® Dispenser

The ASEPTI-CLEANSE dispenser is a hands-free dispensing system that allows for dosed quantities of **DECON-AHOL WFI® Formula** to be delivered without user contact. This dispensing system is the most advanced infrared sensor dispensing system available in the pharmaceutical and biotechnology industries. The ASEPTI-CLEANSE can be mounted directly to glass or walls, which makes it an excellent choice for gowning rooms and aseptic manufacturing areas. It can be set to dispense approximately 1, 2, or 3 mL of solution. Simply place your gloved hand underneath to deliver a pre-measured dose of solution, with no contact between the user and the ASEPTI-CLEANSE. The ASEPTI-CLEANSE is an excellent solution for glove disinfection.



ASEPTI-CLEANSE  
DEC-301



32 oz. Bottle  
DECWFI-BOT-02



DEC-50 with  
DECWFI-SP-70

## DEC-50 Aerosol Dispenser

The DEC-50 Dispenser is an additional dispensing system for **DECON-AHOL® Aerosol WFI Formula** cans. VAI developed the DEC-50 Dispenser to meet the requirements of cGMP cleanroom operations by reducing cross contamination and preventing overuse. The user is able to simply place the back of their gloved hand on the actuation arm to dispense the IPA rather than handling the aerosol container itself. The DEC-50 can be mounted directly to the wall, is made of 316L stainless steel, and is fully autoclavable. It is excellent for glove disinfection. The compatible part number is DECWFI-SP-70.

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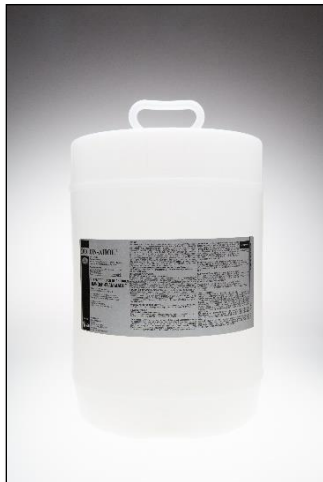
Rev: 06Apr2022, ML Rev Aerosol: G-16, ML Rev Disinfectant: G-16

## Ordering Information

DECON-AHOL WFI Formula– 70% USP Isopropyl Alcohol and 30% USP Water for Injection		
Part number	Description	Qty/cs
DECWFI-SP-70	DECON-AHOL Aerosol WFI Formula, 11 oz Aerosol Spray/Mist, Sterile	24
DECWFI-SP-70-B	DECON-AHOL Aerosol WFI Formula, 11 oz Aerosol “Inverta” Spray/Mist, Sterile	24
DECWFI-ST-70	DECON-AHOL Aerosol WFI Formula, 11 oz Aerosol Stream, Sterile	24
DECWFI-SQ-16Z	DECON-AHOL WFI® Formula, 16 oz Squeeze, Attached Nozzle, Individually Bagged, Sterile	12
DECWFI-TR-04	DECON-AHOL WFI Formula, 16 oz Attached Trigger, Sterile	12
DECWFI-TR-04-BB	DECON-AHOL WFI Formula, 16 oz Bag in Bottle, Attached Trigger, Sterile	12
DECTR-08	DECON-AHOL WFI Formula, 16 oz Attached Trigger, Sterile, Parametric Release	12
DECTR-01	DECON-AHOL WFI Formula, 16 oz Attached Trigger, Non-Sterile	12
DECWFI-TR-05	DECON-AHOL WFI Formula, 32 oz Attached Trigger , Sterile	12
DECWFI-TR-05-BB	DECON-AHOL WFI Formula, 32 oz Bag in Bottle, Attached Trigger, Sterile	12
DECTR-07	DECON-AHOL WFI Formula, 32 oz Attached Trigger, Non-Sterile	12
DECWFI-BOT-02	DECON-AHOL WFI Formula, 32 oz bottle for ASEPTI-CLEANSE®, Sterile	12
DECWFI-BOT-01	DECON-AHOL WFI Formula, 32 oz bottle for ASEPTI-CLEANSE, Non-Sterile	12
DECWFI-B-70	DECON-AHOL WFI Formula, 1 Gallon, Sterile	4
DECWFI-B-70-NS	DECON-AHOL WFI Formula, 1 Gallon, Non-Sterile	4
DECWFI-B-5G-70	DECON-AHOL WFI Formula, 5 Gallon Drum, Sterile	1
DECB-55G-70	DECON-AHOL WFI Formula, 55 Gallon Drum, Non-Sterile	1
DEC-301	ASEPTI-CLEANSE Hands Free Dispenser, for 32oz ASEPTI-CLEANSE Bottles	1
DEC-50	DEC-50 Dispenser, for 11 oz Aerosol Cans, 316L Stainless Steel	1



DECWFI-B-70



DECWFI-B-5G-70



DECWFI-TR-04



DECWFI-SQ-16Z

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Rev: 06Apr2022, ML Rev Aerosol: G-16, ML Rev Disinfectant: G-16

**Product Description: DECON-AHOL® Products**

Veltek Associates, Inc. offers three additional concentrations of our **DECON-AHOL** USP Isopropyl Alcohol that have been designed for pharmaceutical, biotechnology, health care, and medical device cleaning rotations for use in both aseptic and non-aseptic environments. These concentrations include **DECON-AHOL® 60%** a 60% USP Isopropyl Alcohol and 40% USP Water for Injection, **DECON-AHOL® 91%** a 91% USP Isopropyl Alcohol and 9% USP Water for Injection, and finally, **DECON-AHOL® 99%** a filtered 99% USP Isopropyl Alcohol. All three concentrations are for use on a multitude of cleanroom surfaces.

The same quality and manufacturing requirements for **DECON-AHOL WFI Formula** are taken for the other **DECON-AHOL 60%, 91%, and 99%** products. **DECON-AHOL 60%** and **DECON-AHOL 91%** are filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently gamma irradiated. **DECON-AHOL 99%** is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100). Each lot is sterility tested according to the current USP compendium and is completely traceable from start to finish. Lot specific documentation, including all certificates, and safety materials are delivered each time with the shipment.

**DECON-AHOL 60%, 91% and 99%** are all available in sterile one gallon containers, double bagged, and packaged quadruple bagged in our ABCD Cleanroom Introduction System®.

**Quality and Manufacturing**

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- 60% and 91% formulated with USP Water for Injection
- Raw components are air washed with 0.2 micron filtered air
- Completely lot traceable
- 60% and 91% are gamma irradiated sterile; 99% manufactured via aseptic filtration
- Lot sterility tested according to current USP Compendium

<b>DECON-AHOL Products</b>	<b>60%</b>	<b>91%</b>	<b>99%</b>
<b>Certificate of Analysis</b>	<b>Specification</b>	<b>Specification</b>	<b>Specification</b>
Appearance:	Clear	Clear Colorless	Clear Colorless
Assay:	58.0-62.0%	91.0-93.0	>= 99.0%
Acidity:	<1.0 mL	<= 0.7 mL	<=0.7 mL
Limit of Non-volatile Residue:	< 5.0 mg	<= 2.5 mg	<=2.5 mg
Specific gravity @ 20 degrees C:	0.896-0.906	0.810-0.815	0.783-0.787
Refractive Index:	N/A	1.376-1.378	1.376-1.378
Identification A:	N/A	N/A	IR absorption
Identification B:	N/A	N/A	Match
Limit of Volatile Impurities:	N/A	<1.0%	NMT 1.0%
Water Determination	N/A	N/A	NMT 0.5%
Expiration Period:	3 years	3 years	3 years

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## Features and Benefits

- Each container is double bagged packaged sterile
- Packaged quadruple bagged in our ABCD Cleanroom Introduction System®
- 60% and 91% delivered with a Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation
- 99% delivered with a Certificate of Analysis and Certificate of Sterility
- For use on a multitude of surfaces
- Ready-to-use
- Individually labeled with lot number and expiration
- 1 Gallon containers are an excellent choice for GMP operations that require a large volume solution

## Product Uses

DECON-AHOL® products are for customer specific use on non-porous, environmental, surfaces that require the use of a sterile 60%, 91%, or 99% Isopropyl Alcohol with Water for Injection solution. These environmental surfaces include gowning rooms, general manufacturing areas, machinery, tools, tables, counters, laminar flow benches, carts, shelves made of glass, plastic, vinyl, stainless steel, and gloves.

## Ordering Information

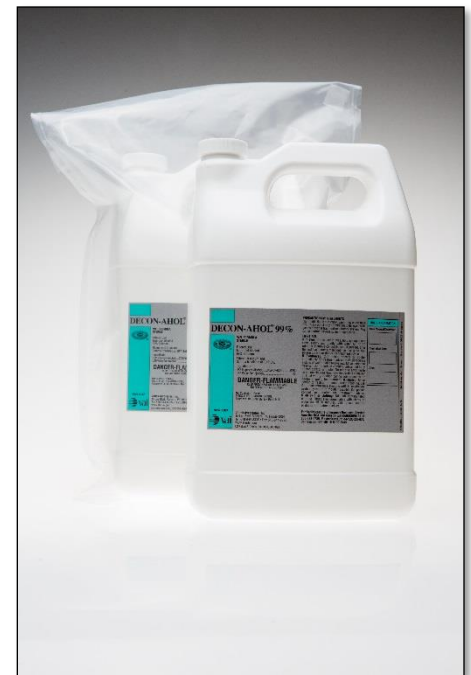
<b>DECON-AHOL Products – 60%, 91%, and 99%</b>		
<b>Part number</b>	<b>Description</b>	<b>Qty/cs</b>
DECWFI-B-60	DECON-AHOL 60% WFI Formula, 1 Gallon, Sterile	4
DECWFI-B-91	DECON-AHOL 91% WFI Formula, 1 Gallon, Sterile	4
DECB-99	DECON-AHOL 99%, 1 Gallon, Sterile	4



DECWFI-B-60



DECWFI-B-91



DECB-99

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**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		



# PRODUCT LABELING

DECON-AHOL WFI® Formula

70% USP Isopropyl Alcohol and 30% USP Water for Injection

(Any specific product label is available upon request.)



**DECON-AHOL WFI Formula Family of Products**

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*Bottle Container*

**IMPORTANT NOTICE**

This product is registered in both the U.S. and Canada. It has BOTH U.S. and Canadian Labeling.  
WHEN USING THIS product in the U.S. follow the U.S. information, where indicated.  
WHEN USING THIS product in Canada, follow the Canadian information, where indicated.

**DECON-AHOL®*mc***

*WFI Formula*

*Gamma Irradiated Sterile*

*For Use in Clean Rooms and Controlled Areas*

*Hard Surface Disinfectant*

**Active Ingredient:**

Isopropyl Alcohol CAS# 67-63-0.....70.0%

**Other Ingredients:**

\*Water.....30.0%

**Total:**.....100.0%

\*USP Water for Injection

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**FLAMMABLE**

**Keep away from heat or open flame.**

**Store at room temperature below 48.8°C (120°F)**

See panel for first aid, additional precautions, and directions for use.

Peel back for Spanish and additional information.

See container for lot number and storage expiration date.

**US EPA Reg. No.:** 68959-2

**US EPA Est. No.:** 68959-PA-001

**Canadian DIN:** 02351374

**Manufactured by:**

Veltek Associates, Inc.  
15 Lee Blvd.  
Malvern, PA 19355-1234  
Inquiries: (888) 478-3745

**In Canada: Distributed by:**

Canada Clean Room  
200 Terrence Matthews  
Kanata, ON K2M 2C6  
Inquiries: (888) 595-8070

Net Contents: (In Canada XXXX mL or liters) (In US XXX oz or gallons)

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**First Aid**

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>- If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>- Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>- Call a poison control center or doctor immediately for treatment advice.</li> <li>- Have a person sip a glass of water if able to swallow.</li> <li>- Move person to fresh air.</li> <li>- Do not induce vomiting unless told by a poison control center or doctor.</li> <li>- Do not give anything to an unconscious person.</li> <li>- Have product container or label with you when calling poison control or doctor, or going for treatment.</li> </ul>
<b>In inhaled</b>	<ul style="list-style-type: none"> <li>- Move person to fresh air.</li> <li>- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>- Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>- Take off contaminated clothing.</li> <li>- Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>EMERGENCIES:</b> For Spill/Exposure/Poison Control Emergency Response Service [from the USA and Canada in English, French, and Spanish (and 23 other languages)] call CARECHEM24 toll free 866-928-0789.</p>	

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Wash thoroughly with soap and water after handling, before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

This product may be irritating to the eyes, skin, gastrointestinal tract, and respiratory system. May cause central nervous system depression.

**PHYSICAL AND CHEMICAL HAZARDS: Flammable** liquid and vapor. Keep away from heat or open flame. Exposure to temperatures above 48.8°C (120°F) may cause bursting. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts.

**Storage and Disposal**

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

**Storage:** Store in the original container in a dry cool place below 48.8°C (120°F). Absorb spills with inert dry absorbent or sand. Absorb spills with inert material (e.g., dry sand or earth), then place in a chemical waste container.

**Disposal:** Product and product wastes are toxic. Follow Federal/Provincial/State regulations and Local/Municipal

ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance. Contaminated absorbent in drums must be disposed of via an authorized waste disposal contractor. Never place unused product down and indoor or outdoor drain.

**Container Disposal:** Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsate). Triple rinse container promptly after emptying. Triple rinse as follows: [(for containers less than 5 gallons) Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after flow begins to drip. Repeat two more times.][(for containers greater than 5 gallons) Fill container ¼ full with water. Tip container on its side and roll in back and forth several times. Follow Pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after flow begins to drip. Repeat two more times.] Offer for recycling where available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

## **DIRECTIONS FOR USE**

### **Read the label before using**

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: 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.

*This product is **NOT** to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly in to the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact 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.*

**USE:** Disinfects and sanitizes clean rooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device, and diagnostic manufacturing facilities. Use on hard non-porous inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, carts shelves mad of hard non-porous materials, such as, glass plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

**DISINFECTION:** Use this product while wearing personal protection. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Use with adequate ventilation and spray away from eyes and face. **DECON-AHOL** is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold can upright 6-8 inches from surface. Thoroughly wet surface with **DECON-AHOL** and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

**DECON-AHOL** is bactericidal. The results of AOAC Efficacy Tests show that **DECON-AHOL** is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATTC# 6538), and *Salmonella enterica* (ATCC# 10708) in the presence of fetal bovine serum organic load in 10 minutes.

**SANITATION:** Use 5 minute contact time on hard, non-porous surfaces (made from: stainless steel, glass Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, clean rooms, sterile and controlled areas, gowning rooms, and on process lines, gloves, work surfaces, tools and equipment.

**DECON-AHOL** is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATTC# 6538), and *Klebsiella pneumoniae* (ATCC# 4352) in the presence of fetal bovine serum organic load in 5 minutes.



*Aerosol Can*

**IMPORTANT NOTICE**

This product is registered in both the U.S. and Canada. It has BOTH U.S. and Canadian Labeling.  
WHEN USING THIS product in the U.S. follow the U.S. information, where indicated.  
WHEN USING THIS product in Canada, follow the Canadian information, where indicated.

**DECON-AHOL®*mc* AEROSOL**

*WFI Formula*

●Mist or ●Stream

Red Dot indicates spray pattern.

*Gamma Irradiated      The Inverta-Spray System      Sterile*

*For Use in Clean Rooms and Controlled Areas*

*Hard Surface Disinfectant*

**Active Ingredient:**

Isopropyl Alcohol CAS# 67-63-0.....70.0%

**Other Ingredients:**

\*Water.....30.0%

**Total:**.....100.0%

\*USP Water for Injection

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**FLAMMABLE**

**Keep away from heat or open flame.**

**Store at room temperature below 48.8°C (120°F)**

See panel for first aid, additional precautions, and directions for use.

Peel back for Spanish and additional information.

See container for lot number and storage expiration date.

**US EPA Reg. No.:** 68959-4

**US EPA Est. No.:** 68959-PA-001

**Canadian DIN:** 02351382

**Manufactured by:**

Veltek Associates, Inc.  
15 Lee Blvd.  
Malvern, PA 19355-1234  
Inquiries: (888)478-3745

**In Canada: Distributed by:**

Canada Clean Room  
200 Terrence Matthews  
Kanata, ON K2M 2C6  
Inquiries: (888)595-8070

Net Contents: (In Canada XXXX mL or liters) (In US XXX oz or gallons)

US Patent: 6,123,900, 6,333,006, 6,607,695

Veltek Associates, Inc.

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

Rev: 06Apr2022, ML Rev Aerosol: G-16, ML Rev Disinfectant: G-16



Made in USA

**First Aid**

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>- If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>- Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>- Call a poison control center or doctor immediately for treatment advice.</li> <li>- Have a person sip a glass of water if able to swallow.</li> <li>- Move person to fresh air.</li> <li>- Do not induce vomiting unless told be a poison control center or doctor.</li> <li>- Do not give anything to an unconscious person.</li> <li>- Have product container or label with you when calling poison control or doctor, or going for treatment.</li> </ul>
<b>In inhaled</b>	<ul style="list-style-type: none"> <li>- Move person to fresh air.</li> <li>- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-mouth, if possible.</li> <li>- Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>- Take off contaminated clothing.</li> <li>- Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>EMERGENCIES:</b> For Spill/Exposure/Poison Control Emergency Response Service [from the USA and Canada in English, French, and Spanish (and 23 other languages)] call CARECHEM24 toll free 866-928-0789.</p>	

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER: Corrosive.** Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**PHYSICAL AND CHEMICAL HAZARDS: Contents under pressure. Flammable liquid and vapor.** Vapor may cause flash fire. Keep away from heat, sparks, and open flame. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases, and metal salts. Do not puncture or incinerate container. Exposure to temperatures above 48.8°C (120°F) may cause bursting.

## **Storage and Disposal**

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

**Storage:** Store in the original container in a dry cool place below 48.8°C (120°F).

**Disposal:** Product and product wastes are toxic. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

**Container Disposal:** Non-refillable pressurized container. Do not re-use or refill this container. Do not puncture or incinerate. If empty, offer for recycling, if available. If partly filled: call local solid waste agency for disposal instructions.

## **DIRECTIONS FOR USE**

### **Read the label before using**

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: 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.

*This product is **NOT** to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly in to the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact 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.*

**USE:** Disinfects and sanitizes clean rooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device, and diagnostic manufacturing facilities. Use on hard non-porous inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves mad of hard non-porous materials, such as, glass plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

**DISINFECTION:** Use this product while wearing personal protection. Wear protective eyewear such as goggles of face shield, protective clothing and chemically resistant gloves. Use with adequate ventilation and spray away from eyes and face. **DECON-AHOL AEROSOL** is ready to use. Pre-clean surface or item of heavy soil or gross filth before application. Hold can upright 6- 12 inches from surface. Thoroughly wet surface with **DECON-AHOL AEROSOL** and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

**DECON-AHOL AEROSOL** is bactericidal. The results of AOAC Efficacy Tests show that **DECON-AHOL AEROSOL** is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATTC# 6538), and *Salmonella enterica* (ATCC# 10708) 10 minutes.

**SANITATION:** Use 5 minute contact time on hard, non-porous surfaces (made from: stainless steel, glass Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, cleanrooms, sterile and controlled areas, gowning rooms, and on process lines, gloves, work surfaces, tools and equipment.

**DECON-AHOL AEROSOL** is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATTC# 6538), and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes.

Veltek Associates, Inc.

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# PRODUCT LABELING

## DECON-AHOL® Products

A 60% USP Isopropyl Alcohol and 40% USP Water for Injection, a 91% USP Isopropyl Alcohol and 9% USP Water for Injection, and a filtered 99% USP Isopropyl Alcohol

(Any specific product label is available upon request.)



DECON-AHOL 60%, 91%, and 99% Family of Products

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# DECON-AHOL® 60% and 91%

WFI Formula

Sterile

USP Filtered Isopropyl Alcohol 60% Solution, USP Filtered Isopropyl Alcohol 91% Solution

Filtered at 0.2µ and Gamma Irradiated at 10<sup>-6</sup> SAL

**Active Ingredient:**

Isopropyl Alcohol CAS# 67-63-0.....60.0%

**Other Ingredients:**

\*Water.....40.0%

**Total:**.....100.0%

\*USP Water for Injection

**Active Ingredient**

Isopropyl Alcohol CAS# 67-63-0..... 91.0%

**Other Ingredients:**

\*Water.....9.0%

**Total:**.....100.0%

\*USP Water for Injection

## DANGER - FLAMMABLE

KEEP FROM HEAT OR OPEN FLAME

DO NOT STORE ABOVE 120°F

Net Contents: 1 Gallon

**Veltek Associates, Inc.**

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335 • Fax: 610-644-8336

www.sterile.com

US Patent: 6,123,900, 6,333,006, 6,607,695

### PRECAUTIONARY STATEMENTS

Flammable liquid and vapor. Vapor may cause flash fire. This product may be irritating to the yes, skin, gastrointestinal tract and respiratory system. May cause central nervous system depression.

### FIRST AID

**If Swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Move person to fresh air. Do not induce vomiting unless told by a poison control center or doctor. Do not give anything to an unconscious person. Have the product container label with you when calling a poison control center or doctor or going for treatment.

**If inhaled:** Move person to fresh air. If person is not breath, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call poison control center or doctor for treatment advice.

**If in eyes:** If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**For Spill/Exposure Emergency Response Service from the USA and Canada call CARECHEM 24 at 866-928-0789. For Arabic call 011-44-1235-239-671, Chinese call 011-86-10-5100-3039.**

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# DECON-AHOL® 99%

## For Use in Cleanrooms and Controlled Areas

**Active Ingredient:**

Isopropyl Alcohol CAS# 67-63-0.....99.0%



**FOR INDUSTRIAL USE ONLY**

**DANGER**

**FLAMMABLE**

Keep away from heat and open flame. Store at room temperature below 48.8°C (120°F).

See other panel for first aid and additional precautions.

Net contents: 1 Gallon (3.79L)

**Manufactured by:**

Veltek Associates, Inc.  
15 Lee Blvd.  
Malvern, PA 19355-1234  
Inquiries: (888)478-3745

**In Canada: Distributed by:**

Canada Clean Room  
200 Terrence Matthews  
Kanata, ON K2M 2C6  
Inquiries: (888)595-8070

**FIRST AID**

**If in eyes:** If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If Swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Move person to fresh air. Do not induce vomiting unless told by a poison control center or doctor. Do not give anything to an unconscious person. Have the product container label with you when calling a poison control center or doctor or going for treatment.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**EMERGENCIES:** For Spill/Exposure Emergency Response Service from USA and Canada call CARECHEM 24 at 866-928-0789.

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## PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS. DANGER:** Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. This product may be irritating to eyes, skin, gastrointestinal tract and respiratory system. May cause central nervous system depression.

**PHYSICAL AND CHEMICAL HAZARDS:** Flammable liquid and vapor. Keep away from heat or open flame. Exposure to temperatures above 48.8°C (120°C) may cause bursting. Do not mix this product with other chemicals including acids, oxidizing materials, combustible materials, halogens, peroxides, bases, and metal salts.

## STORAGE AND DISPOSAL

**Storage:** Store in the original container in a dry cool place below 48.8°C (120°F). Absorb spill with inert material (e.g. dry sand or earth) then place in a chemical waste container.

**Disposal:** Product and product wastes are toxic. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Contaminated absorbent in drums must be disposed of via an authorized waste disposal contractor. Never place unused product down any indoor or outdoor drain.

**Container Disposal:** Non-refillable container. Do not reuse this container. Offer for recycling where available or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.



DECWFI-SP-70 Spray/Mist Aerosol

Veltek Associates, Inc.

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# EFFICACY TEST SUMMARY

DECON-AHOL WFI® FORMULA – 70% Isopropyl Alcohol and 30% USP Water for Injection

## Bactericidal

This product is bactericidal according to the AOAC Use Dilution Test Germicidal Spray Method in the presence of 5% organic soil on hard inanimate surfaces when not more than 1 out of 60 carriers are positive for growth in 10 minutes, and for Canada Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 when not more than 2 out of 60 carriers are positive for growth in 10 minutes. (Total carriers = 540).

AOAC Use Dilution Test Germicidal Spray Method				
Organism	Carrier Population	Sample Lot (All >60 days old)	# Carriers	# Positive
<i>Pseudomonas aeruginosa</i> ATCC #15442	2.78 × 10 <sup>6</sup> CFU/Carrier	A, B, and C	60	0/60
<i>Salmonella enterica</i> ATCC #10708	1.81 × 10 <sup>5</sup> CFU/Carrier	A, B, and C	60	0/60
<i>Staphylococcus aureus</i> ATCC #6538	2.66 × 10 <sup>6</sup> CFU/Carrier	A, B, and C	60	0/60

## Sanitizer

Testing per ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Germicidal Spray Method in the presence of 5% organic soil showed sanitization was effective. Five carriers were used per 3 separate lots, all of which were > 60 days old. This product is considered a sanitizer in this test when test results show a reduction of at least 99.9% (3 Log10) in the average numbers of each test microorganism on each carrier count within 5 minutes.

ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Germicidal Spray Method				
Organism	Avg Carrier Population	Sample Lot	Avg Survivors/Carrier	Percent Kill
<i>Staphylococcus aureus</i> ATCC #6538	4.17 × 10 <sup>6</sup>	A, B, and C	<2 × 10 <sup>1</sup>	>99.9
<i>Klebsiella pneumonia</i> ATCC #4352	1.07 × 10 <sup>6</sup>	A, B, and C	<2 × 10 <sup>1</sup>	>99.9

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## DECON-AHOL® AEROSOLWFI FORMULA – 70% USP Isopropyl Alcohol and 30% USP Water for Injection

### Bactericidal

This product is bactericidal according to the AOAC Use Dilution Test Germicidal Spray Method on hard inanimate surfaces when not more than 1 out of 60 carriers are positive for growth in 10 minutes, and for Canada Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 when not more than 2 out of 60 carriers are positive for growth in 10 minutes. (Total carriers = 540).

<b>AOAC Use Dilution Test Germicidal Spray Method</b>				
<b>Organism</b>	<b>Carrier Population</b>	<b>Sample Lot (All &gt;60 days old)</b>	<b># Carriers</b>	<b># Positive</b>
<i>Pseudomonas aeruginosa</i> ATCC #15442	$7.5 \times 10^6$ CFU/Carrier	A, B, and C	60	0/60
<i>Salmonella enterica</i> ATCC #10708	$8.9 \times 10^4$ CFU/Carrier	A, B, and C	60	0/60
<i>Staphylococcus aureus</i> ATCC #6538	$4.6 \times 10^6$ CFU/Carrier	A, B, and C	60	0/60

### Sanitizer

Testing per ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Germicidal Spray Method and for Canada Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 showed sanitization was effective. Five carriers were used per 3 separate lots, all of which were > 60 days old. This product is considered a sanitizer in this test when test results show a reduction of at least 99.9% (3 Log10) in the average numbers of each test microorganism on each carrier count within 5 minutes.

<b>ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Germicidal Spray Method</b>				
<b>Organism</b>	<b>Avg Carrier Population</b>	<b>Sample Lot</b>	<b>Avg Survivors /Carrier</b>	<b>Percent Kill</b>
<i>Staphylococcus aureus</i> ATCC #6538	$1.78 \times 10^6$	A, B, and C	$<2 \times 10^1$	>99.9
<i>Klebsiella pneumonia</i> ATCC #4352	$8.32 \times 10^6$	A, B, and C	$<2 \times 10^1$	>99.9

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## **Additional Documentation**

Upon request or on our website at [www.sterile.com](http://www.sterile.com) the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheets:
  - **DECON-AHOL 60%** - SDS# VEL-122
  - **DECON-AHOL 91%** - SDS# VEL-123
  - **DECON-AHOL 99%** - SDS# VEL-124
  - **DECON-AHOL Aerosol WFI Formula 70%** - SDS# VEL-104-AEROSOL
  - **DECON-AHOL WFI Formula 70%** - SDS# VEL-104-NONAEROSOL
- Product Validation
- In-use Validation Report
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Analysis, Certificates of Irradiation, and LAL Test Report



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

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

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