



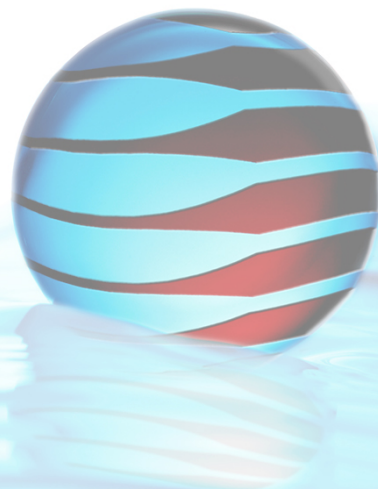
VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STER-AHOL[®] WFI Formula and STER-AHOL Aerosol WFI Formula

70% USP Denatured Ethanol formulated with 30% USP Water for Injection



Product Description

STER-AHOL® WFI Formula is an EPA registered, 70% Denatured Ethanol with 30% Water for Injection, disinfectant and sanitizer that is made for use in pharmaceutical, biotechnology, medical device, healthcare, and diagnostic manufacturing facilities. **STER-AHOL WFI Formula** has been developed for cleaning rotation cycles where hard surface disinfectants are essential to maintaining a clean environment. In both aseptic and non-aseptic environments, **STER-AHOL WFI Formula**, can be used for the disinfection and decontamination of cleanrooms, controlled areas, hard non-porous environmental surfaces, and many other applications that require the use of a sterile alcohol solution.

Sanitizer - Disinfectant

STER-AHOL WFI Formula is formulated with Ethanol denatured with a small percentage of methyl alcohol and USP Water for Injection then 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 **STER-AHOL WFI Formula** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STER-AHOL WFI Formula** is delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report.

STER-AHOL WFI Formula is available in multiple container sizes including an 11 oz aerosol, a 16 oz trigger spray, a 1 gallon container, and a 5 gallon container. The innovative 11 oz container size is a high quality, nitrogen propelled, aerosol spray can that precipitates in a broad spray/mist without aspiration of the room's air during use. Non-aspiration ensures that the master reservoir of **STER-AHOL Aerosol WFI Formula** remains sterile from the first drop to the last drop. 5 gallon drums are delivered with an attachable faucet that allows users to easily control pouring and prevent overuse. Each sterile container is double bagged and packaged quadruple bagged using the ABCD Cleanroom Introduction System®. **STER-AHOL WFI Formula** is packaged to comply with the requirements for transportation into a classified area.

Quality and Manufacturing

- Filled in ISO 5 (Grade A/B, Former Class 100)
- Formulated with USP Water for Injection
- Components are air washed with 0.2 micron filtered air before assembly
- Filtered at 0.2 microns
- Gamma irradiated to a sterility assurance level of 10⁻⁶
- Sterility tested according to Current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

STER-AHOL WFI Formula – 70% Denatured Ethanol with 30% USP Water for Injection

Certificate of Analysis	Specification
Appearance:	Clear colorless
Assay:	68.0-72.0
Non-volatile Residue:	<0.5mg
Specific Gravity:	0.882-0.892
Expiration Period:	3 years

Veltek Associates, Inc.

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

DECON Rev: 11Oct2017, ML Rev Aerosol: F-16, Disinfectant: F-16

Features and Benefits

- EPA registered disinfectant and sanitizer; EPA Registration Number: 68959-1
- EPA registered aerosol disinfectant and sanitizer; EPA Registration Number: 68959-3
- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with a lot specific Certificates of Analysis, Certificate of Irradiation, Certificate of Sterility, and LAL Test Report
- For use on a multitude of surfaces
- Ready-to-use
- Multiple convenient sterile container sizes including an 11 oz aerosol
- 16 oz bottle comes packaged with an attached trigger spray that has the option of spray or stream
- 5 gallon container delivered with an optional unattached faucet for pour control
- Available in an individually packaged saturated wipe: see **STER-AHOL® Wipe***

Uses

STER-AHOL WFI Formula disinfects and sanitizes cleanrooms and controlled areas and is for use on non-food contact, hard non-porous, inanimate surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories, or on machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves made of hard non-porous materials such as glass, plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

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.



DSTER-WFI-B-70

*STER-AHOL Wipe is not EPA Registered

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DEC-50 Aerosol Dispenser

The DEC-50 Dispenser is an additional dispensing system for **STER-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 denatured ethanol 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 DSTER-WFI-SP-70.



DEC-50

Ordering Information

STER-AHOL WFI Formula – 70% Denatured Ethanol with 30% USP Water for Injection		
Part number	Description	Qty/cs
DSTER-WFI-SP-70	STER-AHOL WFI Formula, 11 oz Aerosol Spray/Mist, Sterile	24
DSTER-WFI-TR-04	STER-AHOL WFI Formula, 16 oz Attached Trigger, Sterile	12
DSTER-WFI-B-70	STER-AHOL WFI Formula, 1 Gallon, Sterile	4
DSTER-WFI-70-5G	STER-AHOL WFI Formula, 5 Gallon Drum, Unattached Faucet, Sterile	1
DEC-50	DEC-50 Dispenser, for 11 oz Aerosol Cans, 316L Stainless Steel	1



DSTER-WFI-SP-70



DSTER-WFI-TR-04



DSTER-WFI-70-5G

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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	WHITE		
DECON-AHOL WFI FORMULA 91%	WHITE	WHITE		
DECON-AHOL FORMULA 99%	WHITE	WHITE		
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		
HYP0-CHLOR 0.25%	WHITE	WHITE		
HYP0-CHLOR 0.52%	WHITE	WHITE		
HYP0-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

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PRODUCT LABELING

STER-AHOL® WFI Formula

70% Denatured Ethanol and 30% USP Water for Injection

(Any specific product label is available upon request.)



STER-AHOL WFI Formula Family of Products

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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

STER-AHOL® Aerosol

WFI Formula

•Mist

*Gamma Irradiated • Sterile
 For Use in Clean Rooms and Controlled Areas
 Hard Surface Disinfectant*

Active Ingredients:

*Ethanol Mixture 70.0%

Other Ingredients:

**Water..... 30.0%

Total 100.0%

*Ethyl alcohol denatured with methyl alcohol and isopropyl alcohol; contains less than 3.5% methyl alcohol

**USP Water for Injection



**KEEP OUT OF REACH OF CHILDREN
 WARNING – FLAMMABLE**

**Keep away from heat or open flame
 Contents under pressure**

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.

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French, and Spanish (and 23 other languages) call CARECHEM24 866-928-0789.

SDS# VEL-109A

Veltek Associates, Inc.

US EPA Reg. No.: 68959-3
US EPA Est. No.: 68959-PA-001
Canadian DIN: 02351226

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

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

In Canada: Distributed by:
Canada Clean Room
200 Terence Matthews
Kanata, ON K2M 2C6
Inquiries: (888)595-8070

Made in USA

US Patent: 6,123,900, 6,333,003, 6,607,695

STER-AHOL Aerosol WFI Formula

STER-AHOL Aerosol WFI Formula is sterilized via gamma irradiation to 10^{-6} SAL and is for use in controlled, aseptic, or sterile areas. **STER-AHOL Aerosol WFI Formula** is bactericidal per the results of AOAC Efficacy Tests showing that **STER-AHOL Aerosol WFI Formula** is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538), *Salmonella enterica* (ATCC# 10708) in 10 minutes. **STER-AHOL Aerosol WFI Formula** is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC# 6538) and *Klebsiella pneumonia* (ATCC# 4352) in 5 minutes.

FIRST AID

If 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.

If inhaled: Immediately remove the affected person to fresh air. Call a poison control center or doctor for treatment advice. If not breathing, call 911 or an ambulance, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen if qualified personnel are available.

EMERGENCIES and FIRST RESPONDERS: 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 at 866-928-0789.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wear protective eyewear. Wash thoroughly with soap and water after handling and before, eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL AND CHEMICAL HAZARDS: Flammable liquid and vapor. Vapor may cause flash fire. Contents under pressure. Keep away from heat, sparks, direct sunlight, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 48.8°C (120°F) may cause bursting.

Veltek Associates, Inc.

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DECON Rev: 11Oct2017, ML Rev Aerosol: F-16, Disinfectant: F-16

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: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. If 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 Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture or incinerate. Offer for recycling, or dispose of in a sanitary landfill.

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 offense to use this product in a way that is inconsistent with the directions on the label.

USE: Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on non-food contact, hard non-porous, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories, or on machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves made of hard non-porous material 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 such as eye protection and gloves. Use with adequate ventilation and spray away from eyes and face. **STER-AHOL Aerosol WFI Formula** is ready to use. Pre-clean all surfaces prior to disinfecting. Hold can upright 6-8 inches (15-20 cm) from surface. Thoroughly wet surface with **STER-AHOL Aerosol WFI Formula** 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.

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 normal sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

SANITIZATION: Follow all disinfection directions and allow to remain wet for a minimum of 5 minutes.

*Disinfectant***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

STER-AHOL® Disinfectant*{Alternate Brand Name: STER-AHOL®}***WFI Formula**

Gamma Irradiated • Sterile
For Use in Clean Rooms and Controlled Areas
Hard Surface Disinfectant

Active Ingredients:

*Ethanol Mixture 70.0%

Other Ingredients:

**Water..... 30.0%

Total 100.0%

*Ethyl alcohol denatured with methyl alcohol and isopropyl alcohol; contains less than 3.5% methyl alcohol

**USP Water for Injection



KEEP OUT OF REACH OF CHILDREN
WARNING – FLAMMABLE
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.

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French, and Spanish (and 23 other languages) call CARECHEM24 866-928-0789.

SDS# VEL-109NA

US EPA Reg. No.: 68959-1

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

Canadian DIN: 02351250

Veltek Associates, Inc.

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DECON Rev: 11Oct2017, ML Rev Aerosol: F-16, Disinfectant: F-16

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

Manufactured by:

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

In Canada: Distributed by:

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

Made in USA

STER-AHOL WFI Formula

STER-AHOL WFI Formula is sterilized via gamma irradiation to 10^{-6} SAL and is for use in controlled, aseptic, or sterile areas. **STER-AHOL WFI Formula** is bactericidal per the results of AOAC Efficacy Tests showing that **STER-AHOL WFI Formula** is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538), *Salmonella enterica* (ATCC# 10708) in 10 minutes. **STER-AHOL WFI Formula** is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC# 6538) and *Klebsiella pneumonia* (ATCC# 4352) in 5 minutes.

FIRST AID

If 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.

If inhaled: Immediately remove the affected person to fresh air. Call a poison control center or doctor for treatment advice. If not breathing, call 911 or an ambulance, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen if qualified personnel are available.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Move person to fresh air. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

EMERGENCIES and FIRST RESPONDERS: 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 at 866-928-0789.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wear protective eyewear. Wash thoroughly with soap and water after handling and before, eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL AND CHEMICAL HAZARDS: Flammable liquid and vapor. Vapor may cause flash fire. Contents under pressure. Keep away from heat, sparks, direct sunlight, and open flame. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts.

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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: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. If 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 Handling: Non-refillable container. Do not reuse or refill this container. Do not puncture container and do not incinerate container. Offer for recycling, or dispose of in a sanitary landfill.

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 offense to use this product in a way that is inconsistent with the directions on the label.

USE: Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on non-food contact, hard non-porous, inanimate surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories, or on machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves made of hard non-porous material 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 such as eye protection and gloves. Use with adequate ventilation and spray away from eyes and face. **STER-AHOL WFI Formula** is ready to use. Do not dilute. Pre-clean all surfaces prior to disinfecting. Hold container upright 6-8 inches (15-20 cm) from surface or apply with saturated cloth or immerse item in a basin. Thoroughly wet surface with **STER-AHOL WFI Formula** 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. Do not replace excess product into original container after use or after removal from original container, even if it was not used.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that is (1) introduced directly into 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 normal sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

SANITATION: Follow all disinfection directions and allow to remain wet for a minimum of 5 minutes.

EFFICACY TEST SUMMARY

STER-AHOL® WFI FORMULA – 70% Denatured Ethanol 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% fetal bovine serum organic soil load on hard inanimate surfaces in EPA OPP Method “Disinfectants for Use on Hard surfaces, DIS/TSS-1” and “Supplemental Recommendations DIS/TSS-2, Germicidal Spray Products as Disinfectants”, 961.02 in Official Methods of analysis of the AOAC Ch. 6, when not more than 1 out of 60 carriers per Lot per organism are positive for growth in 10 minutes. 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	1.40×10^7 CFU/Carrier	A, B, and C	60	0/60
<i>Salmonella enterica</i> ATCC #10708	2.16×10^5 CFU/Carrier	A, B, and C	60	0/60
<i>Staphylococcus aureus</i> ATCC #6538	2.03×10^6 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 in the presence of 5% organic soil 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.

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	3.74×10^6	A, B, and C	$<2 \times 10^1$	>99.9
<i>Klebsiella pneumonia</i> ATCC #4352	4.02×10^6	A, B, and C	$<2 \times 10^1$	>99.9

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STER-AHOL® AEROSOL WFI FORMULA – 70% Denatured Ethanol 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 in EPA OPP Method “Disinfectants for Use on Hard surfaces, DIS/TSS-1” and “Supplemental Recommendations DIS/TSS-2, Germicidal Spray Products as Disinfectants”, 961.02 in Official Methods of analysis of the AOAC Ch. 6, when not more than 1 out of 60 carriers per Lot per organism are positive for growth in 10 minutes. 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	4.4×10^6 CFU/Carrier	A, B, and C	60	0/60
<i>Salmonella enterica</i> ATCC #10708	3.4×10^5 CFU/Carrier	A, B, and C	60	0/60
<i>Staphylococcus aureus</i> ATCC #6538	4.2×10^6 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.

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	1.51×10^6	A, B, and C	$<2 \times 10^1$	>99.9
<i>Klebsiella pneumonia</i> ATCC #4352	1.78×10^6	A, B, and C	$<2 \times 10^1$	>99.9

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DECOR Rev: 11Oct2017, ML Rev Aerosol: F-16, Disinfectant: F-16

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
 - **STER-AHOL Aerosol WFI Formula** - SDS# VEL-109A
 - **STER-AHOL WFI Formula** - SDS# VEL-109NA
- Product Validation
- In-use Validation Report
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Analysis, Certificates of Irradiation, and LAL Test Reports



VAI's Sterile Chemical Manufacturing Division - SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents

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