

O V E R V I E W

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STER-AHOL[®] WFI

WFI FORMULA

Sterile Pharmaceutical Clean Room Formula

70% Denatured Ethanol made with USP Water for Injection



Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355

Tel: (610) 644-8335 Fax: (610) 644-8336 E-mail: vai@sterile.com VL-109-1 Rev. 12/03

STER-AHOL[®] Sterile WFI Formula

USP Denatured Ethanol made with USP Water for Injection

PRODUCT DESCRIPTION

STER-AHOL Sterile is a 70% Denatured Ethanol that is made with USP Water for Injection, filtered at 0.2 microns, double bag packaged and gamma irradiated. The product is available in aerosol spray (nitrogen propellant), 16-ounce trigger spray, 1 and 5 gallon containers. The product is completely tested according to USP specifications and is delivered with a lot specific Certificate of Irradiation,, Certificate of Analysis and Sterility Report (LAL Lot Specific Test Report on File) The products are completely traceable and have been completely validated for sterility and shelf life. The product is formulated to 70% and denatured with a small percentage of Methyl Alcohol and Isopropyl Alcohol.

The highest quality container package is the nitrogen propelled aerosol. This package does not permit aspiration of the room air into the master reservoir. Therefore, sterile alcohol is delivered each and every time.

Uses: STER-AHOL Sterile is used for the decontamination of items such as gloves, surfaces, carts, counter tops, process lines, aseptic connections, and many other applications that require the use of a sterile alcohol solution.

ORDERING INFORMATION

Order#	Description	Quan/cs.
DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile	24
DSTER-WFI-ST-70	70% 11 oz. Aerosol Stream Spray Sterile	24
DSTER-WFI-B-70	70% 1 Gallon Sterile	4
DSTER-WFI-04	70% 16 oz. Trigger Spray Sterile	12
DSTER-WFI-70-5G	70% 5 Gallon Sterile	1
DSTER-WFI-BAG-01	STER-AHOL 32 oz. Bags for Asepti-Cleanse	8

Available Technical Data Supplements (Upon Request)

VL-101: STER-AHOL Spray Product Validation

VL-102: STER-AHOL Bulk Container Product Validation

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STER-AHOL[®] Sterile WFI Formula

Manufacturing and Testing

The first consideration in choosing STER-AHOL[®] WFI products is to review the GMP manufacturing and testing that is incorporated into Veltek Associates, Inc. manufacturing and testing operations. They are unequalled in the industry! **We offer and suggest you audit VAI operations!**

Manufacturing
All STER-AHOL [®] raw material components such as ethanol, cans, bottles, valves, etc are incoming inspected, per GMP standards, to internally written specification and released upon acceptance by the QA department.
All VAI Chemical operations are EPA and FDA registered and follow cGMP's
All STER-AHOL [®] Products are Manufactured in accordance with cGMP's
All STER-AHOL [®] Products are made with USP Water for Injection
All STER-AHOL [®] Containers Washed in WFI Prior to Filling
All STER-AHOL [®] Valves Washed in WFI Prior to Filling
All STER-AHOL [®] manufacturing areas (Class 100-Class 10,000) are monitored for particulate and microbials.
All STER-AHOL [®] Containers are cleaned after filling
All STER-AHOL [®] Sterile products are packaged in Class 100 environment into double bags and then the case contents are packaged into a third polyethylene case liner in the carton.
All STER-AHOL [®] packaging bags are Class 100 Certified Bags
All STER-AHOL [®] products are filtered through a pre-sterilized 0.2 um filter
All filters are Bubble Point Tested Before and After
All STER-AHOL [®] Sterile packages are then sterilized through a validated gamma sterilization cycle as proven by both an AAMI validation and a 10 ⁻⁶ reduction of b. pumilus spores that were implemented into the sterilization load.
All STER-AHOL [®] products are released and shipped by VAI's Document Control Department
Testing
All STER-AHOL [®] products are assayed and delivered with the lot specific Certificate of Analysis
All STER-AHOL [®] products are Lot Sterility Tested to USP 24 (14 Day)
Lab testing included the completion of Bacteriostasis per USP 24
Lab testing included the completion of Fungistasis per USP 24
All STER-AHOL [®] products are validated as Sterile to AAMI Guidelines
All STER-AHOL [®] products are validated as Sterile by 10 ⁻⁶ reduction of b. pumilus
VAI's Water for Injection System is tested to meet USP 24 criteria
All STER-AHOL [®] products are Lot LAL Tested and Released at <0.45 eu/ml.

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All STER-AHOL® products have been validated for an expiration period of 3 years (via assay and sterility testing).

STER-AHOL® Sterile WFI Formula **SPECIFICATIONS**

Specification	70% STER-AHOL® WFI
Filtration:	0.2 Micron Absolute
Appearance:	Colorless Liquid
Assay:	68.0%-72.0% v/v
Acidity:	<1 ml.
Specific Gravity @ 20°C:	0.882-0.892 g/cc
Nonvolatile Residue:	<5 mg. (<0.01%)
Irradiation Range:	25.0 - 50.0 kGy
Sterility:	USP 24, 14-day Filter
Pressure:	90-130 psi. (aerosol)
Max. Temperature:	120 degrees F
Min. Temperature:	32 degrees F
Flash Point:	75 degrees F
Expiration:	3 Years
Water (formulation):	USP Water for Injection System is tested to the USP 24 monograph (less than 0.25 eu/ml.)
LAL Testing	Less than 0.45 eu/ml.
Testing Parameters:	USP 24 N 19 (**Assay is a modified version of the USP Monograph for "Ethyl Alcohol")
Filled in:	Class 100 cGMP Manufacturing Conditions for all STER-AHOL® products
Containers:	Pre-washed in WFI prior to filling for all STER-AHOL® products

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Manufactured by:	Veltek Associates, Inc. VAI is an EPA and FDA Registered Manufacturing Facility (Audits are encouraged and welcomed)
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** As no monograph for assay exists in USP 24 NF 19, testing ranges were established using the 70% monograph

Available Containers



STER-AHOL® WFI Aerosol Mist:

In use since 1988, the STER-AHOL® aerosol container is available in an 11 ounce stream spray (precipitating like a squirt bottle) and an aerosol mist (broader fine droplet spray). This container does not aspirate the room air to the master reservoir of alcohol and assures a sterile solution is precipitated from first use until last. This is important as one can eliminate contaminants from entering the solution from the clean room environment. This container fits easily into the STER-AHOL® DEC-50 Forearm Activated Dispenser or the DEC-100 Hands Free Dispenser



STER-AHOL® WFI Trigger Spray Containers:

The STER-AHOL® 16-ounce Trigger Spray Containers are available with or without the trigger mechanism attached to the container. The trigger sprayer attached containers eliminate the need for an aseptic connection to be made by the end user before use. All trigger spray containers afford the user the ability to choose a mist, stream and off position by easily adjusting the nozzle. These containers are an excellent choice where the use of the aerosol or non-aerosol containers are not possible.



STER-AHOL® WFI 1-Gallon Containers:

The STER-AHOL® 1-gallon containers are an excellent choice for GMP operations that require a larger volume of sterile alcohol to be used at one time or over a short time period. While pouring of such containers to a trigger spray or a squeeze bottle is acceptable, concerns for sterility of the solution during this in-house operation need to be considered. These containers are better used within the package provided by VAI. These containers may incorporate either the 300-T Trigger mechanism or the 200-P Pump unidose dispensing mechanism by VAI.



STER-AHOL® WFI 5-Gallon Containers:

The STER-AHOL® 5-gallon containers are an excellent choice for GMP operations that require a larger volume of sterile alcohol to be used at one time or over a short time period. While pouring of such containers to a trigger spray or a squeeze bottle is acceptable, concerns for sterility of the solution during this in-house operation need to be considered. These containers are better used within the package provided by VAI. These containers include a pour top dispensing mechanism within the sterile package provided by VAI.

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Which Container to Choose?

The choice of a container is based on the intended use of the product and confines of the manufacturing process where the product is to be used. Most GMP facilities use a variety of containers within their operations to satisfy the unique needs of each situation. This is an excellent methodology that will not only assure the use of the correct container but also reduce the volume of alcohol used on an annual basis.

Your local VAI Technical Support Representative can assist you in assuring all consideration are made prior to use of a container size. Please contact VAI at **1-888-4-STERILE (1-888-478-3745)** for your local representative.

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STER-AHOL®
WFI FORMULA

Sterile Pharmaceutical Clean Room Formula
70% Denatured Ethanol made with USP Water for Injection

PRODUCT LABELING

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(Aerosol Center Panel)

Veltek Associates, Inc.

STER-AHOL[®]
WFI FORMULA
STERILE

70% Denatured Ethanol

Mist

Stream

RED IRRADIATION DOT INDICATES SPRAY PATTERN

CONTENTS UNDER PRESSURE

DANGER - FLAMMABLE

KEEP FROM HEAT OR OPEN FLAME

READ PRECAUTIONS ON THE BACK PANEL

Veltek Associates, Inc.
1039 West Bridge Street
Phoenixville, PA 19460-4218
Tel: (610) 983-4949

Contents: 11 oz.
Reorder #:

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(Aerosol Back Panel)

DIRECTIONS

Product contains 70% filtered USP Denatured Ethanol. Hold can upright and spray away from eyes and face. Allow to air dry. Use with adequate ventilation. If you experience eye watering, headaches, or dizziness, discontinue aerosolizing and inhaling fumes. For optimal dispensing of the alcohol contents, do not tilt the can past 45° when spraying. Tilting past 45° will cause a loss of the propellant

FIRST AID:

INHALATION: May cause headaches, drowsiness and lassitude, loss of appetite, and inability to concentrate. Irritation of the throat. **FIRST AID:** Immediately remove to fresh air. If breathing has stopped give artificial respiration and get medical attention immediately **INGESTION:** Can cause depression of the central nervous system, nausea, vomiting, diarrhea. Do not ingest. Ingestion may cause blindness or death. **FIRST AID:** If conscious, have victim drink water or milk to dilute. Contact Chemtrec Poison Control Center immediately. **CHEMTREC:** 1-800-424-9300 **EYE OR SKIN CONTACT:** Liquid or vapor may cause irritation. **FIRST AID:** Flush effected area with plenty of cool water for at least 15 minutes. Get medical attention immediately if irritation persists.

CONTENTS:

63.4% Ethyl Alcohol	CAS# 64-17-5
3.2% Methyl Alcohol	CAS# 67-56-1
3.4% Isopropyl Alcohol	CAS# 67-63-0
30.0% USP Water for Injection	
* Nitrogen Propellant	CAS# 7727-37-9

**Aerosol Product only*

Reorder#

<All products part #'s below, Container = Reorder # for specific product>

DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile
DSTER-WFI-ST-70	70% 11 oz. Aerosol Stream Spray Sterile
DSTER-WFI-B-70	70% 1 Gallon Sterile
DSTER-WFI-04	70% 16 oz. Trigger Spray Sterile

Expiration: 3 years from the date of manufacture

HMIS STER-AHOL Sterile 70% Ethanol	
H Health	1
F Flammability	3
R Reactivity	0
P Personal Protection	B
MSDS# REV	

**FOR EXTERNAL USE ONLY.
KEEP OUT OF REACH OF CHILDREN**

CAUTION - FLAMMABLE

The contents of this can are under pressure. Keep away from flame or intense heat. Do not puncture or burn empty can. Do not store in direct sunlight or temperatures above 120°F. Spray in a well ventilated area.

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Actual Aerosol

DIRECTIONS

Product contains 70% filtered USP Denatured Ethanol. Hold can upright and spray away from eyes and face. Use with adequate ventilation. If you experience eye watering, headaches, or dizziness, discontinue aerosolizing and inhaling fumes.

For optimal dispensing of the alcohol contents, do not tilt the can past 45° will cause a loss of the propellant.

FIRST AID:

In case of accidental eye contact, flush thoroughly with water and call a Physician. If ingested, seek professional assistance or contact a Poison Control Center.

CONTENTS:

63.4% Ethyl Alcohol CAS#64-17-5
3.2% Methyl Alcohol CAS#67-56-1
3.4% Isopropyl Alcohol CAS#67-63-0
30.0% USP Water for Injection
Nitrogen Propellant CAS#7727-37-9

Reorder#:

DSTER-WFI-SP-70 for Spray Mist
DSTER-WFI-ST-70 for Stream Spray

**FOR EXTERNAL USE ONLY.
KEEP OUT OF REACH OF CHILDREN**

CAUTION-FLAMMABLE

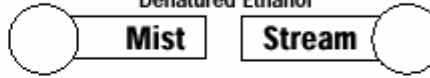
The contents of this can are under pressure. Keep away from flame or intense heat. Do not puncture or burn empty can. Do not store in direct sunlight or temperatures above 120°F. Spray in a well-ventilated area.



STER-AHOL™ WFI FORMULA

STERILE

70% Filtered (0.2 um)
Denatured Ethanol



RED IRRADIATION DOT INDICATES SPRAY PATTERN

CONTENTS UNDER PRESSURE

DANGER-FLAMMABLE

KEEP FROM HEAT OR OPEN FLAME

READ PRECAUTIONS ON BACK PANEL

Contents 11 oz. (330 ml)



Veltek Associates, Inc.

1039 W. Bridge Street • Phoenixville, PA 19360
Tel (610) 983-4949 • Fax (610) 983-9494

Label

Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355

Tel: (610) 644-8335 Fax: (610) 644-8336 E-mail: vai@sterile.com VL-109-1 Rev. 12/03

Bulk Container Labeling



STER-AHOL™
WFI FORMULA

STERILE

70% Filtered (0.2 um)
Denatured Ethanol

Ingredients:
Ethyl Alcohol CAS# 64-17-563.4%
Methyl Alcohol CAS# 67-56-1 3.2%
Isopropyl Alcohol CAS# 67-63-0..... 3.4%
USP Water for Injection.....30.0%

CAUTION - FLAMMABLE
WARNING: KEEP FROM HEAT OR OPEN FLAME, DO NOT STORE ABOVE 120 F. KEEP OUT OF REACH OF CHILDREN.

Made in U.S.A.



Veltek Associates, Inc.
1039 West Bridge Street
Phoenixville, PA 19460-4218
TEL (610) 983-4949
FAX (610) 983-9494

INHALATION: May cause headaches, drowsiness and lassitude, loss of appetite, and inability to concentrate. Irritation of the throat. **FIRST AID:** Immediately remove to fresh air. If breathing has stopped, give artificial respiration and get medical attention immediately.

INGESTION: Can cause depression of the central nervous system, nausea, vomiting, diarrhea. DO NOT ingest. Ingestion may cause blindness or death. **FIRST AID:** If conscious, have victim drink water or milk to dilute. Contact Chemtrec Poison Control Immediately. **CHEMTREC: 1-800-424-9300.**


EYE OR SKIN CONTACT: Liquid or vapor may cause irritation. **FIRST AID:** Flush effected area with plenty of cool water for at least 15 minutes. Get medical attention immediately.

H Health	1
F Flammability	3
R Reactivity	0
P Personal Protection	B

MSDS #: 98A-STER-001 REV10/99 DSTER-WFI-B-70

Contents: 1 Gallon (3.78L) Quan/Case: 4x1 gallon Recorder #: DSTER-WFI-B-70

DSTER-WFI-B-70



STER-AHOL™
WFI FORMULA


STERILE TRIGGER SPRAY

70% Filtered (0.2 um)
Denatured Ethanol

Ingredients:
Ethyl Alcohol CAS# 64-17-563.4%
Methyl Alcohol CAS# 67-56-1 3.2%
Isopropyl Alcohol CAS# 67-63-0..... 3.4%
USP Water for Injection.....30.0%

CAUTION - FLAMMABLE
WARNING: KEEP FROM HEAT OR OPEN FLAME, DO NOT STORE ABOVE 120 F. KEEP OUT OF REACH OF CHILDREN.

Made in U.S.A.



Veltek Associates, Inc.
1039 West Bridge Street
Phoenixville, PA 19460-4218
TEL (610) 983-4949
FAX (610) 983-9494

INHALATION: May cause headaches, drowsiness and lassitude, loss of appetite, and inability to concentrate. Irritation of the throat. **FIRST AID:** Immediately remove to fresh air. If breathing has stopped, give artificial respiration and get medical attention immediately.

INGESTION: Can cause depression of the central nervous system, nausea, vomiting, diarrhea. DO NOT ingest. Ingestion may cause blindness or death. **FIRST AID:** If conscious, have victim drink water or milk to dilute. Contact Chemtrec Poison Control Immediately. **CHEMTREC: 1-800-424-9300.**

EYE OR SKIN CONTACT: Liquid or vapor may cause irritation. **FIRST AID:** Flush effected area with plenty of cool water for at least 15 minutes. Get medical attention immediately.

H Health	1
F Flammability	3
R Reactivity	0
P Personal Protection	B

MSDS #: 98A-STER-001 REV10/99 DSTER-WFI-TR-04

Contents: 16 ounces (472 ml) Quan/Case: 12x16 ounce Recorder #: DSTER-WFI-TR-04

DSTER-WFI-TR-04

Cost Evaluation versus In-house Manufacture

**Assure all the costs are included in your evaluation or you are losing money!
Presented is a simple guide to assist you in your evaluation.**

Purchase Alcohol	Receiving Inspection	Formulation	Sterilizing Components	Create Sterilization Records for Components
Purchase Alcohol	Receive	Batch Formula Records	Containers	
	Quarantine	Formulations Area	Caps	Sterility
	Sample	Formulation Equipment	Labels	Particulate Matter
	Release	Change Over Procedure		LAL
	Solvent Storage	Sterile Records:		
	Cert. of Analysis	- Filter		
		- Lines		
		- Receiving Vessel		
		- Sterile Receive Vessel		
Total = \$ 4.00/gallon	Total = \$ 4.00/gallon	Total = \$ 10.00/gallon	Total = \$ 5.00/gallon	Total = \$ 3.00/gallon
Perform QA Testing	Quarantine Product	Safety Storage	Overhead	Total Costs
Sterility	7 days	Bagged	Amortization of Equip.	
Particulate Matter		Shelf Life Records/ inventory	Space	
Cert. of Analysis			Insurance	
			Training	
Total = 6.00/gallon	Total = \$ 1.50/gallon	Total = \$ 1.00/gallon	Total = \$ 18.00/gallon	Total \$52.50/gallon

- Calculations do not include terminal sterilization of the final contents
- Calculations do not include Double bagging of final sterile product
- Calculations do not include validation studies and expiration testing

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STER-AHOL[®]

Sterile
WFI FORMULA

Sterile Pharmaceutical Clean Room Formula
Denatured Ethanol with Water for Injection (WFI)

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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STER-AHOL® WFI 70%

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: STER-AHOL® Sterile WFI Formula

MSDS #: VEL-109

Description: 70% USP Denatured Ethanol with USP Water for Injection

<u>MSDS Information</u>	<u>Manufacturer Information</u>	<u>Emergency Telephone Information</u>
Date Prepared: November 6, 2002	Veltek Associates, Inc.	Notify your Supervisor
Prepared by:	1039 West Bridge Stree	Emergencies Chemtrec (800) 424-9300
Art Vellutato, Jr.	Phoenixville, PA 19460	24-hour service
V.P. Technical Support Operations	TEL: (610) 983-4949	
Reviewed by:		Effective Date: November 6, 2002
Art Vellutato, Sr.		Date Supercedes: 02/15/02
Technical Director		

II. Composition/Data on Components:

PRODUCT NAME: STER-AHOL Sterile

CHEMICAL OR COMMON NAME: ALCOHOL

Aerosol Containers: 11 ounce aerosol (UN1950 aerosols, n.o.s., Flammable gas)

Bulk Containers: 16 ounce Trigger Spray, 1 Gallon, and 5 Gallon. (UN1219 Flammable Liquid)

<u>INGREDIENTS</u>	<u>WEIGHT %</u>	<u>EXPOSURE LIMIT</u>
Ethyl Alcohol	63.4%	<u>Oral</u> -5840 mg/kg-Rats
Isopropanol CAS# 67-63-0	3.4%	<u>Dermal</u> -1300 mg/kg-Rabbit
Methyl Alcohol CAS#	3.2%	<u>Inhalation</u> - 1200mg/kg-Rats
30% USP Water for Injection	30.0%	NA
Nitrogen Propellant (Aerosol Spray Only) CAS# 7727-37-9	NE	NA

HAZARD RATING

HIMIS RATING HEALTH 1 REACTIVITY 0 FLAMMABILITY 3 PERSONAL B

HAZARD RATINGS: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Extreme A = Safety Glasses B = Safety Glasses & Gloves

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III. Hazards Identification:

UN1219 Flammable Liquid

DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile	24
DSTER-WFI-ST-70	70% 11 oz. Aerosol Stream Spray Sterile	24
DSTER-WFI-B-70	70% 1 Gallon Sterile	4
DSTER-WFI-04	70% 16 oz. Trigger Spray Sterile	12
DSTER-WFI-70-5G	70% 5 Gallon Sterile	1
DSTER-WFI-BAG-01	STER-AHOL 32 oz. Bags for Asepti-Cleanse	8

IV. First Aid Measures:

PEL/TWA: 400 ppm TLV/TWA: 400 PPM TLV/STEL: 500 ppm

INHALATION: May cause mild irritation to nose, respiratory tract and may result in central nervous system (CNS) depression.

SKIN CONTACT: Mildly irritating to skin (Do not use on skin)

SKIN ABSORPTION: Mildly irritating to skin (Do not use on skin)

EYE CONTACT: Moderately irritating

INGESTION: Generally considered a low order of acute oral toxicity

ACUTE: Irritation as noted above. CNS depression may be evidenced by giddiness, headache, dizziness, and nausea. CHRONIC: Pre-existing skin, eye, and respiratory disorders may be aggravated by exposure to IPA.

FIRST AID PROCEDURES:

EYES: Immediately flush with plenty of water for at least 15 minutes while holding eyelids open. Obtain immediate medical attention.

SKIN: Flush skin with plenty of water. If Irritation occurs seek medical attention.

INHALATION: Remove victim to fresh air and provide oxygen if breathing is difficult, obtain medical attention.

INGESTION: Do not induce vomiting if victim is unconscious or drowsy. Otherwise, if within the first 15 minutes give syrup of IPECAC, upon directions of physician or poison control center.

NOTES TO PHYSICIAN: Do not induce vomiting - FIRST contact poison control center, treatment depends on volume of substance, time elapsed, due to faster absorption.

V. Firefighting Measures:

FLASH POINT (°F): 75°F

FLAMMABLE LIMITS: % Vol in Air UPPER-2% LOWER-12%

EXTINGUISHING MEDIA: Water Fog, Alcohol Foam, Dry Chemical, CO₂

SPECIAL FIRE FIGHTING PROCEDURES: Clear Fire area of unprotected personnel. Do not enter fire area without full bunker gear, helmet w/face shield, Bunker Coats, Gloves, Rubber Boots, Include a Positive pressure NIOSH Approved Self-Contained Breathing Apparatus, Cool fire exposed containers with water.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Containers exposed to intense heat should be cooled with water to prevent vapor build-up which could result in container rupture.

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VI. Accidental Release Measures:

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Spill or Leak Procedures: WARNING-FLAMMABLE. Eliminate all ignition sources. Equipment must be grounded to prevent sparking. Contain liquid with absorbent material and place in non-leaking container, seal tightly for disposal

VII. Handling and Storage:

PRECAUTIONARY LABELING: See carton label for precautions

OTHER HANDLING AND STORAGE CONDITIONS: Do not Store above 120°F, Do not store in sunlight, spray in well ventilated area. Flammable Liquid. The contents are under pressure. Do not puncture, crush or incinerate the container in unapproved manner.

VIII. Exposure Control and Personal Protection:

RESPIRATORY PROTECTION: If exposure may or does exceed occupation exposure limits (Sec V), use a NIOSH approved respirator to prevent overexposure. In accord with 29 CFR 1810.134 use either an atmosphere supplying respirator or an air purifying respirator for organic compounds.

VENTILATION: Use Explosion Proof Ventilation as required to control vapor concentrations.

PROTECTIVE GLOVES: Chemical Resistant Gloves

EYE PROTECTION: Avoid Contact. Wear Chemical Goggles

PROTECTIVE CLOTHING: Wear recommended clothing to reduce exposure

OTHER PROTECTIVE MEASURES: Do not contact skin, eyes, mouth or ingest. Eye wash fountains and showers should be available for emergency use.

IX. Physical and Chemical Properties:

APPEARANCE/ODOR: Clear, Colorless Liquid

ODOR: Mild Alcohol Odor

VAPOR PRESSURE: 20°C

SOLUBILITY IN WATER: Complete

FREEZING POINT: -10°C

PH: 7.0

VOC (as packaged, minus H₂O): 8.4 oz

SPECIFIC GRAVITY (H₂O-1): 0.878

PERCENTAGE VOLATILE BY VOLUME (%): 70%

VAPOR DENSITY (Air-1): 1.6

BOILING POINT (°F): 170°F

EVAPORATION RATE (Butyl Acetate-1): 1.7

THEORETICAL VOC (lb/gal): 7.34

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X. Stability and Reactivity:

STABILITY: Stable (Analytical and Sterility, 3 yrs.)

STABILITY-CONDITIONS TO AVOID: Stable

INCOMPATIBILITY: see IPA requirements

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon Monoxide and unidentified organic compounds may be formed during combustion.

HAZARDOUS POLYMERIZATION: Will not occur

HAZARDOUS POLYMERIZATION-COND. TO AVOID: Will not occur

XI. Toxicological Information:

POISON CRITERIA:
5840mg/kg/Rat

Oral
1300mg/kg/Rabbit

Dermal
1200mg/L/Rat

Inhalation

XII. Ecological Information:

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

XIII. Disposal Considerations:

Disposal: Container disposal regulation may vary with amount of liquid content remaining in container. Refer to latest Federal and State Regulations regarding proper disposal of ALL containers. If needed, consult manufacturer for assistance to obtain proper disposal guidelines for your area.

XIV. Transport Information:

AEROSOL CONTAINER

DOT CLASS: Consumer Commodity (Ground)

DOT CLASS: Aerosols, flammable n.o.s. (Air)

DOT #: UN1950

SHIPPING NAME: Ethanol

DOT NOTES: Contents under pressure, do not puncture or incinerate. Transportation follows guidelines for hazardous characteristics of Flammable Liquids and Flammable Gas.

<u>Product</u>	<u>Description</u>	<u>Ground</u>
DSTER-WFI-ST-70	70% 11 oz. Aerosol Stream Spray Sterile	UN1950 Consumer Commodity
DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile	UN1950 Consumer Commodity
<u>Product</u>	<u>Description</u>	<u>Air</u>
DSTER-WFI-ST-70	70% 11 oz. Aerosol Stream Spray Sterile	UN1950 Flammable Gas
DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile	UN1950 Consumer Commodity

DOT SHIPPING NAME: AEROSOLS n.o.s. HAZARD CLASS: 2.1 ID NUMBER: UN1950

Shipping Instructions:

Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355

Tel: (610) 644-8335 Fax: (610) 644-8336 E-mail: vai@sterile.com VL-109-1 Rev. 12/03

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UN1950:

Ground: Consumer Commodity
Ocean: Consumer Commodity
Air: 1950 n.o.s. Flammable Gas

BULK CONTAINERS

<u>Product</u>	<u>Description</u>	<u>Ground or Air</u>
DSTER-WFI-B-70	70% 1 Gallon Sterile	UN1170
DSTER-WFI-04	70% 16 oz. Trigger Spray Sterile	UN1170
DSTER-WFI-70-5G	70% 5 Gallon Sterile	UN1170

DOT SHIPPING NAME: Ethanol HAZARD CLASS: 3 ID NUMBER: UN1170

Shipping Instructions:

UN1170:

Ground: Ethanol , LTD. QTY. UN1170
Ocean: Ethanol , 3.2, UN1170, LTD. QTY.
Air: Ethanol , 3.0, UN1170, PG II

XV. Regulations:

PLEASE CONSULT YOUR STATE AND LOCAL AUTHORITY FOR INGREDIENTS LISTED AS PERTAINING TO REPORTING REQUIREMENTS FOR HAZARDOUS SUBSTANCE LIST.

No special regulation other than transportation and disposal (see section VII and section IX). Conform to Federal, State and Local Regulations for disposal. Follow usage instructions on container.

XVI. Other Information:

NA-Not Applicable, NE-Not Established, NSR-No Special Requirement, D-Not determined for this product

The Information herein is given in good faith. No warranty, expressed or implied is made. Any use of these data and information must be determined by the user to be in accordance with applicable Federal, State and Local Laws and Regulations. The information contained in this form is confidential and is submitted solely for your organization's internal use.

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STER-AHOL®

WFI FORMULA

Sterile Pharmaceutical Clean Room Formula

70% Denatured Ethanol made with USP Water for Injection

Lot Specific Sterile Documentation

(received with each shipment)

Certificate of Analysis

Certificate of Sterility

Certificate of Irradiation

LAL Test Report

(Please contact VAI for a sample of this documentation)

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