VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

DEC-AHOL® Products

USP Isopropyl Alcohol formulated with USP Water for Injection

DEC-AHOL WFI® Formula 70%, DEC-AHOL® Aerosol WFI® Formula 70%, DEC-AHOL® 61%, DEC-AHOL® 91%, DEC-AHOL® 99%

Product Description: DEC-AHOL WFI® Formula 70%

After years of development, Veltek Associates, Inc., has been able to produce **DEC-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 **DEC-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.

DEC-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. **DEC-AHOL WFI Formula** can be used for decontamination on numerous surfaces within any cleanroom operation while ensuring a low remaining residue and endotoxin levels.

DEC-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 **DEC-AHOL WFI Formula** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. All shipments are delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report.

DEC-AHOL WFI Formula is available in multiple container sizes including an 11 oz aerosol, 16 oz trigger spray, 16 oz squeeze bottle, 32 oz trigger spray, 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®. **DEC-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 **DEC-AHOL WFI Formula**: the 11 oz aerosol spray can**, DEC-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 endotoxin free Water for Injection
- Assayed according to current USP compendium
- Manufactured within a closed system where endotoxin levels are controlled
- Raw components are air washed with 0.2 micron filtered air
- 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-E

DEC-AHOL WFI® Formula– 70% USP Isopropyl Alcohol and 30% USP Water for Injection	
Certificate of Analysis	**Result**
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
- 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
- Available in an individually packaged saturated wipe: see ALCOH-WIPE®
- Available in a bulk packaged saturated wipe: see Process2Wipe®

Uses

DEC-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.

DEC-AHOL WFI Formula: Parametric Release

In addition to a lot sterility tested **DEC-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-E, receives a lower dose of irradiation compared to **DEC-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-E

ABCD Cleanroom Introduction System®

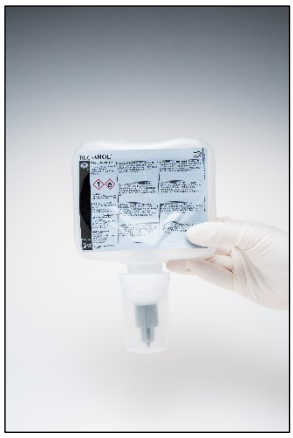
The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. 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 **DEC-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-E

DEC-50 with
DECWFI-SP-70-E

DEC-50 Aerosol Dispenser

The DEC-50 Dispenser is an additional dispensing system for **DEC-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-E.

Ordering Information

DEC-AHOL WFI Formula– 70% USP Isopropyl Alcohol and 30% USP Water for Injection		
Part number	**Description**	**Qty/cs**
DECWFI-SP-70-E	DEC-AHOL Aerosol WFI Formula, 11 oz Aerosol Spray/Mist, Sterile	24
DECWFI-SP-70-B-E	DEC-AHOL Aerosol WFI Formula, 11 oz Aerosol “Inverta” Spray/Mist, Sterile	24
DECWFI-ST-70-E	DEC-AHOL Aerosol WFI Formula, 11 oz Aerosol Stream, Sterile	24
DECWFI-SQ-16Z-E	DEC-AHOL WFI® Formula, 16 oz Squeeze, Attached Nozzle, Individually Bagged, Sterile	12
DECWFI-SQ-03-E	DEC-AHOL WFI Formula, 16 oz Squeeze, Attached Nozzle, Bulk Packaged, Sterile	12
DECWFI-TR-04-E	DEC-AHOL WFI Formula, 16 oz Attached Trigger, Sterile	12
DECTR-08-E	DEC-AHOL WFI Formula, 16 oz Attached Trigger, Sterile, Parametric Release	12
DECWFI-TR-05-E	DEC-AHOL WFI Formula, 32 oz Attached Trigger , Attached, Sterile	12
DECWFI-BOT-02-E	DEC-AHOL WFI Formula, 32 oz bottle for ASEPTI-CLEANSE®, Sterile	12
DECWFI-BOT-01-E	DEC-AHOL WFI Formula, 32 oz bottle for ASEPTI-CLEANSE, Non-Sterile	12
DECWFI-B-70-E	DEC-AHOL WFI Formula, 1 Gallon, Sterile	4
DECWFI-B-70-NS-E	DEC-AHOL WFI Formula, 1 Gallon, Non-Sterile	4
DECWFI-B-5G-70-E	DEC-AHOL WFI Formula, 5 Gallon Drum, 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-E

DECWFI-SP-70-E

DECWFI-TR-04-E

DECWFI-SQ-16Z-E

VAI's Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DEC-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 60%	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 91%	WHITE	LIGHT BLUE		
DEC-AHOL FORMULA 99%	WHITE	LIGHT BLUE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DEC-HAND STERILE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-HAND NON-STERILE	CLEAR	LIGHT BLUE		
DEC-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DEC-CYCLE	WHITE	LIGHT BLUE		
DEC-CLEAN	WHITE	LIGHT BLUE		
DEC-QUAT 100	WHITE	LIGHT BLUE		
DEC-QUAT 200C	WHITE	LIGHT BLUE		
DEC-QUAT 200V	WHITE	LIGHT BLUE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DEC-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DEC-GLASS	WHITE	LIGHT BLUE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

PRODUCT LABELING

DEC-AHOL WFI® Formula

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

(Any specific product label is available upon request.)

DEC-AHOL WFI Formula Family of Products

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.

DEC-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)

First Aid

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 a person sip a glass of water if able to swallow. – Move person to fresh air. – Do not induce vomiting unless told be a poison control center or doctor. – Do not give anything to an unconscious person. – Have product container or label with you when calling poison control or doctor, or going for treatment.
In inhaled	– Move person to fresh air. – If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-mouth, if possible. – Call a poison control center or doctor for further 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/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.	

PRECAUTIONARY STATMENTS

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. Was 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.

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. **DEC-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 **DEC-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.

DEC-AHOL is bactericidal. The results of AOAC Efficacy Tests show that **DEC-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.

DEC-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.

DEC-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

Made in USA

First Aid

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 a person sip a glass of water if able to swallow. – Move person to fresh air. – Do not induce vomiting unless told be a poison control center or doctor. – Do not give anything to an unconscious person. – Have product container or label with you when calling poison control or doctor, or going for treatment.
In inhaled	– Move person to fresh air. – If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-mouth, if possible. – Call a poison control center or doctor for further 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/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.	

PRECAUTIONARY STATMENTS

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 of 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 party 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. **DEC-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 **DEC-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.

DEC-AHOL AEROSOL is bactericidal. The results of AOAC Efficacy Tests show that **DEC-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.

DEC-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.

EN TESTING RESULTS SUMMARY

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

Bactericidal Efficacy

Surface Bactericidal Effectiveness Test

Efficacy of DEC-AHOL in the Surface Bactericidal Effectiveness Test – EVALUATION OF BACTERICIDAL ACTIVITY: CARRIER TEST (EN13697:2001)

On the basis of the results obtained, in compliance with the assay validity criteria, the test item DEC-AHOL AEROSOL WFI FORMULA results BACTERICIDAL at the concentration of 100% after 2 minutes of contact, using a 0.03% final concentration of bovine albumin, in compliance with EN 13697:2001.

The study was conducted in order to assess the efficacy of the test item, in conformity to EU regulatory requirements.

The study was performed **in Compliance with Good Laboratory Practice**

The test Lab declares that the studies described in their report on which this summary was prepared have been conducted under their supervision and in compliance with the following standards of Good Laboratory Practice:

- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – OECD principles of Good Laboratory Practice (as revised in 1997) – Environmental Directorate – Organisation of Economic Co-Operation and Development, Paris 1998.
- Legislative decree n.50 of March the 2nd, 2007. Enforcement of Community Directives 2004/9/CE & 2004/10/CE, concerning the inspection and verification of Good Laboratory Practice and the drawing of the legislative, regulatory and administrative dispositions relative to the application of Good Laboratory Practice rules, to the control of their application on the assays performed on the chemical substances (GU n.86 of April the 13th, 2007).
- United States Food and Drug Administration, Title 21 Code of Federal Regulations Part 58, Federal Register 22 December 1978, and subsequent amendments.
- Certification N. 038/2013 released by the Italian Ministry of Health on November 19th 2013) authorizing Eurofins Biolab S.r.l. to perform analyses in compliance with the principles of good laboratory practices (http://www.eurofins.it).

There were no circumstances that may affect the quality or integrity of the study. No deviations occurred during the study.

The bactericidal effectiveness was verified through the following test:

- **Phase 2/step 2 bactericidal activity. Carrier test** in which four bacterial strains, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536 and *Pseudomonas aeruginosa* ATCC15442, were exposed to the test item in the following conditions:
  - Test concentrations: 100% (neat) – 50% - 25%
  - Contact times: 2 – 15 minutes
  - Temperature test: 20°C±1°C
  - Interfering substance: bovine albumin solution with a 0.03% final concentration (simulating clean conditions).

The test was performed on steel carriers.

DEC-AHOL			
Microorganism Test	**Contact Times and Concentrations Tested**		
	100%	**50%**	**25%**
	2 minutes		
***Staphylococcus aureus* ATCC 6538**	>6.51	3.41	0.98
***Pseudomonas aeruginosa* ATCC 15442**	>7.00	3.84	1.75
***Escherichia coli* ATCC 10536**	>6.61	3.87	1.63
***Enterococcus hirae* ATCC 10541**	>6.91	3.80	1.00

*The test item is considered bactericidal when ME≥4 Log at least following 5 minutes of contact.

Bactericidal Suspension Test

Efficacy DEC-AHOL bactericidal suspension test. EN1276:2009

On the basis of the results obtained, in compliance with the assay validity criteria, the test item DEC-AHOL causes a reduction >5Log with the test concentration: neat, i.e. 80% of the product (maximum concentration testable) equivalent to 57.12% of active ingredient concentration, using a 0.03% final concentration of bovine albumin, in compliance with EN 1276:2009.

A series of assays were conducted on the test item **DEC-AHOL** in order to determine its suspension bactericidal activity for the specific use of the product

A study was conducted in order to assess the suspension bactericidal efficacy of the test item, in conformity to EU regulatory requirements.

The study was performed **in Compliance with Good Laboratory Practice**

The test Lab declares that the studies described in their report on which this summary was prepared have been conducted under their supervision and in compliance with the following standards of Good Laboratory Practice:

- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – OECD principles of Good Laboratory Practice (as revised in 1997) – Environmental Directorate – Organisation of Economic Co-Operation and Development, Paris 1998.
- Legislative decree n.50 of March the 2nd, 2007. Enforcement of Community Directives 2004/9/CE & 2004/10/CE, concerning the inspection and verification of Good Laboratory Practice and the drawing of the legislative, regulatory and administrative dispositions relative to the application of Good Laboratory Practice rules, to the control of their application on the assays performed on the chemical substances (GU n.86 of April the 13th, 2007).
- United States Food and Drug Administration, Title 21 Code of Federal Regulations Part 58, Federal Register 22 December 1978, and subsequent amendments.
- Decree of the Italian Ministry of Health October the 12th 2010, certification N. 121/2010 and Provisional Certification (October the 12th 2012) authorizing the test Lab to perform analyses in compliance with the principles of good laboratory practices.

There were no circumstances that may affect the quality or integrity of the study. No deviations occurred during the study.

The bactericidal effectiveness was verified through the following tests:

- **Phase 2/step 1: bactericidal activity in suspension. Dilution – neutralization method** in which 4 different bacterial strains, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442, *Escherichia coli* ATCC 10536, *Enterococcus hirae* ATCC 10541, were exposed to the test item at the following conditions:
  - Concentration: neat, i.e. 80% of the product (maximum concentration testable) because the test sample is diluted with 1 ml of interfering substance and 1 ml of microbial suspension); it is equivalent to 57.12% of active ingredient concentration, isopropyl alcohol, as per Certificate of Analysis of the analyzed batch)
  - Contact times: 2 – 5 - 10 minutes
  - Temperature: 20 1°C
  - Interfering substance: a bovine albumin solution with 0.03% final Concentration (simulating clean conditions)

DEC-AHOL			
Test Organisms	**Contact Times and Concentrations Tested**		
	2 minutes	**5 minutes**	**10 minutes**
	80%		
***Staphylococcus aureus* ATCC 6538**	>5.48	>5.55	>5.55
***Pseudomonas aeruginosa* ATCC 15442**	>5.53	>5.53	>5.53
***Escherichia coli* ATCC 10536**	>5.30	>5.30	>5.30
***Enterococcus hirae* ATCC 10541**	>5.33	>5.42	>5.42

Fungicidal Efficacy

Surface Fungicidal Effectiveness Test

Efficacy of DEC-AHOL in the Surface Fungicidal Effectiveness Test – EVALUATION OF FUNGICIDAL ACTIVITY: CARRIER TEST (EN 13697:2001)

On the basis of the results obtained, in compliance with the assay validity criteria, the test item DEC-AHOL AEROSOL WFI FORMULA results FUNGICIDAL at the concentration of 100% after 15 minutes of contact, using a 0.03% final concentration of bovine albumin, in compliance with EN 13697:2001.

The study was conducted in order to assess the efficacy of the test item, in conformity to EU regulatory requirements.

The study was performed **in Compliance with Good Laboratory Practice**

The test Lab declares that the studies described in their report on which this summary was prepared have been conducted under their supervision and in compliance with the following standards of Good Laboratory Practice:

- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – OECD principles of Good Laboratory Practice (as revised in 1997) – Environmental Directorate – Organisation of Economic Co-Operation and Development, Paris 1998.

- Legislative decree n.50 of March the 2nd, 2007. Enforcement of Community Directives 2004/9/CE & 2004/10/CE, concerning the inspection and verification of Good Laboratory Practice and the drawing of the legislative, regulatory and administrative dispositions relative to the application of Good Laboratory Practice rules, to the control of their application on the assays performed on the chemical substances (GU n.86 of April the 13th, 2007).
- United States Food and Drug Administration, Title 21 Code of Federal Regulations Part 58, Federal Register 22 December 1978, and subsequent amendments.
- Certification N. 038/2013 released by the Italian Ministry of Health on November 19th 2013) authorizing Eurofins Biolab S.r.l. to perform analyses in compliance with the principles of good laboratory practices (http://www.eurofins.it).

There were no circumstances that may affect the quality or integrity of the study. No deviations occurred during the study.

The fungicidal effectiveness was verified by performing the following test:

- **Phase 2/step 2 fungicidal activity. Carrier test** in which two fungi strains, *Candida albicans* ATCC 10231 and *Aspergillus niger* ATCC 16404 were exposed to the test item in the following conditions:
  - Test concentrations: 100% (neat) – 50% - 25%
  - Contact times: 2 – 15 minutes
  - Temperature test: 20°C±1°C
  - Interfering substance: bovine albumin solution with a 0.03% final
  - Concentration (simulating clean conditions)

The test was performed on stainless steel carriers.

DEC-AHOL			
Microorganism Test	**Contact Times and Concentrations Tested**		
	100%	**50%**	**25%**
	2 minutes		
***Candida albicans* ATCC 10231**	>5.95	2.95	2.40
***Aspergillus niger* ATCC 16404**	2.27	1.47	0.87
Microorganism Test	**Contact Times and Concentrations Tested**		
	100%	**50%**	**25%**
	15 minutes		
***Candida albicans* ATCC 10231**	>5.95	>5.95	3.30
***Aspergillus niger* ATCC 16404**	>4.18	2.11	1.42

Fungicidal Suspension Test

Efficacy of DEC-AHOL in the Suspension Fungicidal Effectiveness Test – EVALUATION OF FUNGICIDAL ACTIVITY IN SUSPENSION – DILUTION NEUTRALIZATION METHOD (EN 1650:2008)

On the basis of the results obtained, in compliance with the assay validity criteria, the test item results FUNGICIDAL and YEASTICIDAL with the test conditions using a 0.03% final concentration of bovine albumin, in compliance with EN 1650:2008.

The study was conducted in order to assess the efficacy of the test item, in conformity to EU regulatory requirements.

The study was performed **in Compliance with Good Laboratory Practice**

The test Lab declares that the studies described in their report on which this summary was prepared have been conducted under their supervision and in compliance with the following standards of Good Laboratory Practice:

- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – OECD principles of Good Laboratory Practice (as revised in 1997) – Environmental Directorate – Organisation of Economic Co- Operation and Development, Paris 1998.
- Legislative decree n.50 of March the 2nd, 2007. Enforcement of Community Directives 2004/9/CE & 2004/10/CE, concerning the inspection and verification of Good Laboratory Practice and the drawing of the legislative, regulatory and administrative dispositions relative to the application of Good Laboratory Practice rules, to the control of their application on the assays performed on the chemical substances (GU n.86 of April the 13th,2007).
- United States Food and Drug Administration, Title 21 Code of Federal Regulations Part 58, Federal Register 22 December 1978, and subsequent amendments.
- Certification N. 038/2013 released by the Italian Ministry of Health on November 19th 2013) authorizing Eurofins Biolab S.r.l. to perform analyses in compliance with the principles of good laboratory practices (http://www.eurofins.it).

There were no circumstances that may affect the quality or integrity of the study. No deviations occurred during the study.

The fungicidal effectiveness was verified by performing the following tests:

- **Phase 2/step 1: fungicidal activity in suspension. Dilution – neutralization method** in which 2 different mycetes, *Candida albicans* ATCC 10231 and *Aspergillus niger* ATCC 16404, were exposed to the test item at the following conditions:
  - Final concentration tested: 80% of ready to use product (due to addition of challenge suspension)
  - Contact time: 2, 5, 10 minutes
  - Temperature: 20 ± 1°C
  - Interfering substance: a bovine albumin solution with a 0.03% final concentration (simulating clean conditions).

DEC-AHOL			
Microorganism Test	**Contact Times and Concentrations Tested**		
	2 minutes	**5 minutes**	**10 minutes**
	80% concentration		
***Candida albicans* ATCC 10231**	>4.43	>4.43	>4.43
***Aspergillus niger* ATCC 16404**	3.73	4.28	>4.44

The test item is considered fungicidal according to EN 1650 when it causes for each fungi strain a reduction of vitality of at least 4 Log at 20°C after 15 minutes contact.

The test item is considered yeasticidal according to EN 1650 when it causes for *Candida albicans* a reduction of vitality of at least 4 Log at 20°C after 15 minutes contact.

This product should be used as it is supplied; ready to use.

EFFICACY TEST SUMMARY

DEC-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**
*Pseudomonas aerug*inosa ATCC #15442	2.78 × 10^6 CFU/Carrier	A, B, and C	60	0/60
Salmonella enterica ATCC #10708	1.81 × 10^5 CFU/Carrier	A, B, and C	60	0/60
Staphylococcus aureus ATCC #6538	2.66 × 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 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**
Staphylococcus aureus ATCC #6538	4.17 × 10^6	A, B, and C	<2 × 10^1	>99.9
Klebsiella pneumonia ATCC #4352	1.07 × 10^6	A, B, and C	<2 × 10^1	>99.9

DEC-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).

AOAC Use Dilution Test Germicidal Spray Method				
Organism	**Carrier Population**	**Sample Lot** (All >60 days old)	**# Carriers**	**# Positive**
Pseudomonas aeruginosa ATCC #15442	7.5 × 10^6 CFU/Carrier	A, B, and C	60	0/60
Salmonella enterica ATCC #10708	8.9 × 10^4 CFU/Carrier	A, B, and C	60	0/60
Staphylococcus aureus ATCC #6538	4.6 × 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**
Staphylococcus aureus ATCC #6538	1.78 × 10^6	A, B, and C	<2 × 10^1	>99.9
Klebsiella pneumonia ATCC #4352	8.32 × 10^6	A, B, and C	<2 × 10^1	>99.9

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheets:
    - **DEC-AHOL Aerosol WFI Formula** 70% - SDS# VEL-104-AEROSOL
    - **DEC-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.

Patents: www.sterile.com/patents