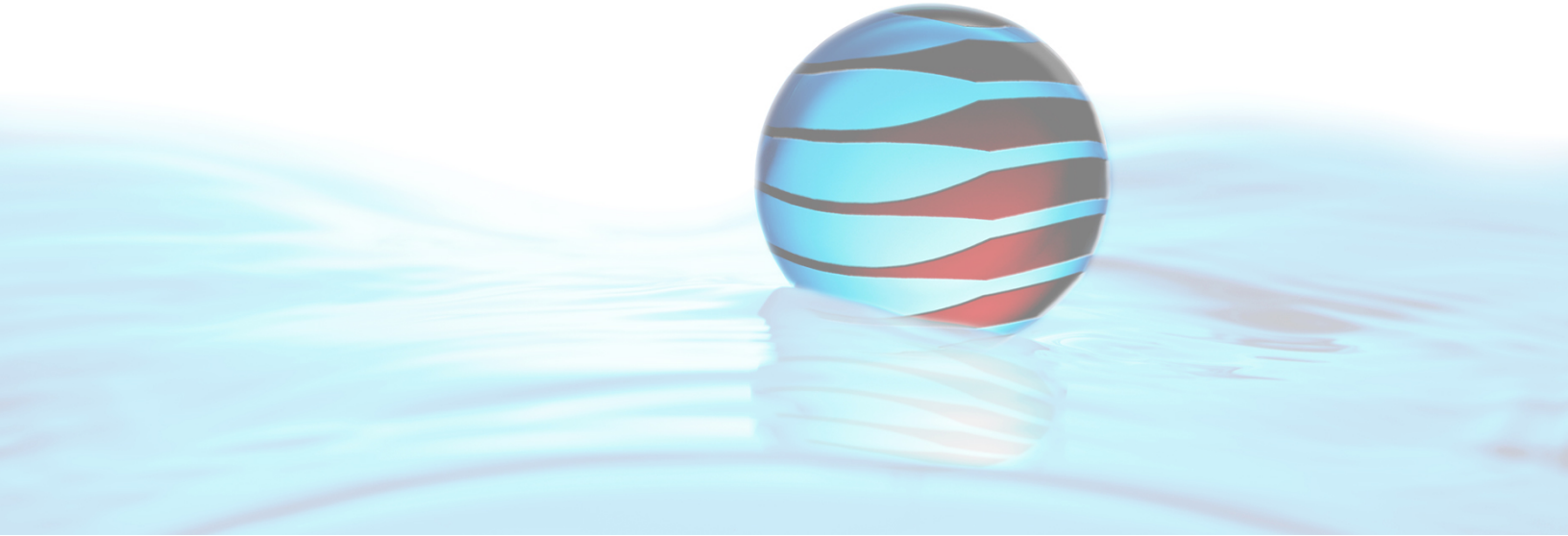
VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

VAI WFI Quality Water®

USP Grade Bulk Water for Injection
Sterile Pharmaceutical Clean Room Formula



Product Description

VAI WFI Quality Water is an innovative solution for GMP facilities that demand the use of a sterile WFI quality water in their daily operations. **VAI's WFI Quality Water** is produced from a 6 effect distilled water system that is validated, routinely monitored, and passes all USP monograph requirements for "Water for Injection." **VAI's WFI Quality Water** can be used throughout any facility for chemical formulation, disinfectant dilution, cleaning, rinsing, and lubrication. Lubrication of moving parts, process lines, and conveyors is essential for continuous and effortless manufacturing.

VAI WFI Quality Water is not for human or animal injection, diagnostic, or therapeutic use.

All concerns of environmental conditions are taken into account during manufacturing of **VAI's WFI Bulk Quality Water**. Prior to filling, all bottles are blown and cleaned with 0.2 micron filtered air, all quality water is filtered at 0.2 microns in an ISO 5 (Former class 100, Grade A/B) operation, and the finished product is subsequently gamma irradiated at 10^{-6} SAL. Available container sizes include 16 oz Trigger Spray, 1 Gallon, 2 Gallons, 200L Drums, and an 11 oz Aerosol Spray Can. Each lot of **VAI's WFI Quality Water** is assayed and sterility tested according to current USP compendium, and tested for endotoxin levels, those of which consistently falls below 0.03 EU/mL. **VAI WFI Quality Water** has been completely validated for sterility and shelf life and is completely traceable from start to finish.

VAI offers an innovative container size for **VAI WFI Quality Water**: the 11 oz aerosol spray can. The aerosol spray can precipitates in a broad, yet fine droplet spray that does not aspirate the room's air. Non-aspiration ensures that the master reservoir of WFI Quality Water remains sterile from the first drop to the last drop. Aerosol spray cans are delivered with a nozzle extension that is ideal for use in harder to reach locations or when lubricating intricate machinery parts.

Quality and Manufacturing

- Gamma irradiated at a 10^{-6} SAL
- Each container is double bagged packaged sterile and available in our ABCD Cleanroom Introduction System ™
- Completely lot traceable and has been validated for sterility and shelf life
- Assayed according to current USP compendium
- Filtered at 0.2 microns
- Delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation and safety material
- Sterility tested according to current USP Compendium

VAI WFI Quality Water – USP Grade Bulk Water For Injection	
Certificate of Analysis	**Result**
TOC:	<8.0 mg/L
Conductivity	</= 5uS/cm
LAL Result:	<0.25 EU/mL
Expiration Period:	2 years

Uses

VAI WFI Quality Water is used for chemical formulation, cleaning, rinsing, and lubricating parts. It is an excellent choice for dilution of disinfectant concentrates to a use-dilution mixture.

Features and Benefits

- Available in the ABCD Introduction System ™
- Multiple convenient container sizes – 16 oz, 1 Gallon, 2 Gallon, 200L, and 11 oz Aerosol
- Ideal for chemical formulation, disinfectant dilution, cleaning, rinsing, or lubrication
- For use on a multitude of surfaces
- Available in sterile or non-sterile versions
- Ready-to-Use
- Meets the needs for USP Water for Injection in cleanroom operations

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.

Ordering Information

VAI WFI Quality Water – USP Grade Bulk Water For Injection		
Part number	**Description**	**Qty/cs**
VAI-WFI-SP-11Z	VAI WFI Quality Water, 11 oz, Aerosol Spray Mist, Unattached Nozzle Extension, RTU, Sterile	24
VAI-WFI-16Z	VAI WFI Quality Water, 16 oz, Trigger Spray, RTU, Sterile	12
VAI-WFI-1G	VAI WFI Quality Water, 1 Gallon, RTU, Sterile	4
VAI-WFI-2G	VAI WFI Quality Water, 2 Gallon, RTU, Sterile	2
VAI-WFI-200L	VAI WFI Quality Water, 200L Drum, Single Bagged, RTU, Sterile	1
VAI-WFI-200L-2B	VAI WFI Quality Water, 200L Drum, Double Bagged, RTU, Sterile	1

VAI's Product Label Colors

15 Lee Boulevard Malvern, PA 19355-1234 USA
Toll Free: 888.478.3745 T: 610.644.8335 www.sterile.com

Veltek Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI 70% Aerosol	Cool Grey	Printed Can Cool Grey		
DECON-AHOL WFI 70% Trigger Spray, 1 & 5 Gallon	White	Cool Grey		
DECON-AHOL WFI 70% Squeeze Bottle	White Semi-Tranparent	Cool Grey		
DECON-AHOL WFI 70% Asepti-Cleanse Bottle	White Semi-Transparent	Cool Grey		
DECON-AHOL WFI 60%	White	White		
DECON-AHOL WFI 91%	White	White		
DECON-AHOL WFI 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		
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		
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		

Rev. 06 June 2012

PRODUCT LABELING

VAI WFI Quality Water®

USP Grade Bulk Water for Injection

Sterile Pharmaceutical Clean Room Formula

Aerosol Spray Can Labeling

Filtered at 0.2 microns
Sterilized via gamma irradiation and lot tested for sterility and endotoxins

Ingredients:
WFI Quality Water …… 100%

VAI WFI Quality Water is not for human or animal injection, diagnostic, or therapeutic use.

Net contents/Contenu net/Contenido neto: 11 oz (325mL)

MSDS #: VEL-028

Container and Product Sterilized and Distributed By:

Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234
Tel: 610-644-8335
Fax: 610-644-8336
www.sterile.com

PRECAUTIONARY STATEMENTS

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 (49°C). Avoid freezing.

Spill/Exposure Emergency Response Service call CARECHEM24: 866-928-0789 (USA and Canada), Arabic call +44-1235-239-671, Chinese call +86-10-5100-3039.

Bottle Labeling

For Disinfectant Formulation ONLY
Product is manufactured in Class 100 clean room, filtered at 0.2 microns, sterilized via gamma irradiation and lot tested for sterility and endotoxins.

Ingredients:
WFI Quality Water …… 100%

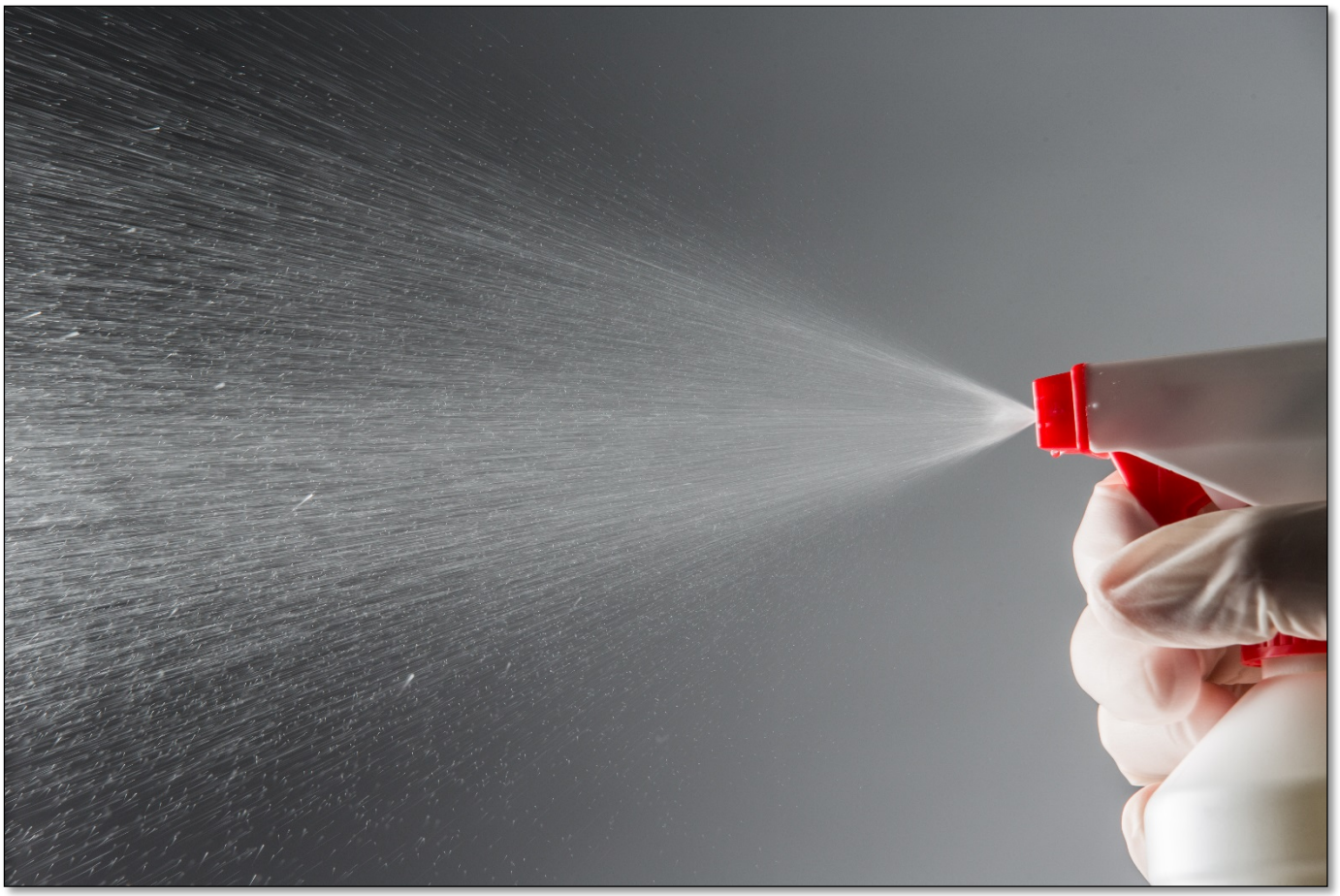
VAI WFI Quality Water is not for human or animal injection, diagnostic, or therapeutic use.

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335

Fax: 610-644-8336



VAI WFI Quality Water

USP Grade Bulk Water for Injection

Lot Specific Sterile Documentation

(received with each shipment)

Certificate of Analysis
Certificate of Sterility
Certificate of Irradiation

(Please contact VAI for a sample of this documentation)

SCMD

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 unidose 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