VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STERI-WATER®

USP Grade Purified Water

Sterile Pharmaceutical Cleanroom Formula

Product Description

VAI manufactures a USP grade purified water that is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. **STERI-WATER** is an excellent choice for chemical formulation, disinfectant dilution, cleaning, lubricating, rinsing, and many other applications within a cleanroom. Lubrication of moving parts, process lines, and conveyors is essential for continuous and effortless manufacturing. **STERI-WATER** is ready-to-use and is ideal for operations that do not have USP purified water readily available on site when it is required for operational procedures.

STERI-WATER is 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 **STERI-WATER** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-WATER** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

STERI-WATER is available sterile or non-sterile in multiple container sizes including a 16 oz trigger spray, a 1 gallon, a 2 gallon, an 8 liter pail, and in a 5 gallon drum. The 16 oz trigger spray of **STERI-WATER** allows operators to use when rinsing or lubricating hard to reach places and intricate mechanical parts. 5 gallon drums are delivered with an attachable faucet that allows users to easily control pouring and prevent overuse. Each sterile container of **STERI-WATER** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

***STERI-WATER** is not for human or animal injection, diagnostic, or therapeutic use.*

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

STERI-WATER – USP Grade Purified Water	
Certificate of Analysis	**Specifications**
TOC:	<8.0 mg/L
Conductivity:	</= 5 uS/cm
Expiration Period:	2 years

Features and Benefits

STWA-5G with Faucet

- 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 lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation
- Specifically formulated as a sterile pharmaceutical cleanroom formula
- Available in sterile or non-sterile in multiple container sizes
- Ready-to-use
- Available in 16 oz trigger spray that is ideal for rinsing and lubricating hard to reach places or intricate mechanical parts
- 16 oz trigger spray has the option of spray or stream
- 5 gallon container delivered with an optional unattached faucet for pour control
- For use on a multitude of surfaces
- Lubricates for continuous and effortless manufacturing
- Meets the needs for USP purified water when required in cleanroom operations
- Ideal for operations that do not have USP purified water readily available

Uses

- Cleanroom operations that do not have USP purified water readily available
- Chemical formulation
- Disinfectant dilution
- Lubricating
- Rinsing
- Cleaning
- Use limitations: not for human or animal injection, diagnostic, or therapeutic use

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

STERI-WATER – USP Grade Purified Water		
Part Number	**Description**	**Qty/cs.**
STWA-16Z	STERI-WATER, 16 oz, Unattached Trigger, Sterile	12
STWA-01	STERI-WATER, 1 Gallon, Non-Sterile	4
STWA-02	STERI-WATER, 1 Gallon, Sterile	4
STWA-2G	STERI-WATER, 2 Gallons, Sterile	2
STWA-8L	STERI-WATER, 8 Liter Pail, Sterile	2
STWA-5G	STERI-WATER, 5 Gallon Drum, Unattached Faucet, Sterile	1

STWA-02

STWA-8L

STWA-16Z

VAI 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		
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		

PRODUCT LABELING

STERI-WATER®
USP Grade Purified Water

(Any specific product label is available upon request.)

STERI-WATER Family of Products

STERI-WATER®

Sterile Purified Water USP

Sterile Pharmaceutical Cleanroom Formula

ACTIVE INGREDIENTS:
Sterile Purified Water, USP (CAS# 7732-18-5) ……. 100%

Sterile

Product is manufactured in Class 100 cleanroom, filtered at 0.2 microns, sterilized via gamma irradiation and lot tested for sterility and endotoxins.

SDS Number: VEL-028

Container and Product Sterilized and Distributed by:

Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234 USA
Tel: 1-610-644-8335
Fax: 1-610-644-8336
www.sterile.com

Veltek Associates, Inc.
Postbus 1062
8200 BB Lelystad, Nederland
Tel: +800-00888700
Fax: 1-610-644-8336
www.sterile.com

Made in USA

USE LIMITATIONS

Not for human or animal injection, diagnostic, or therapeutic use.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Product Validation
- Safety Data Sheet # VEL-028
- Sample lot specific documentation packages including Certificates of Sterility, Certificate of Irradiation, and Certificate of Analysis

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 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