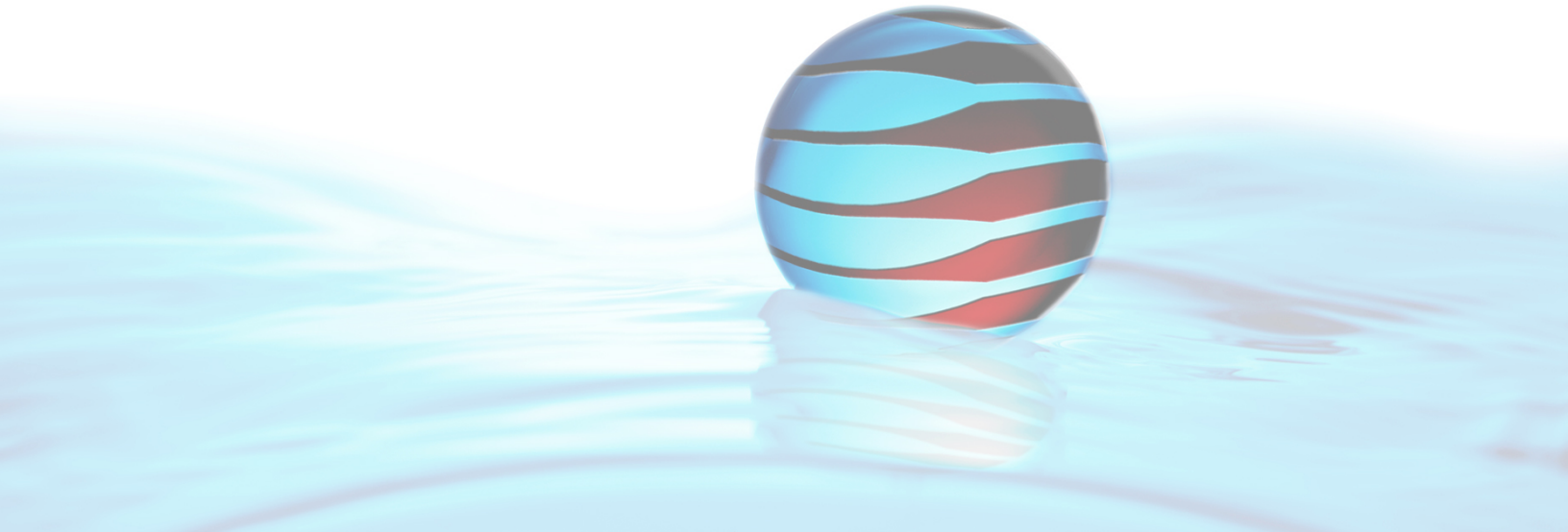
VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STERI-PEROX® 3% & 6%

Hydrogen Peroxide and Water for Injection Solution
Sterile Pharmaceutical Cleanroom Formula



Product Description

Veltek Associates, Inc. manufactures two hydrogen peroxide solutions, **STERI-PEROX®** 3% and 6% that are processed to comply with the standards required by the pharmaceutical, biotechnology, health care, and medical device industries. **STERI-PEROX** is recommended for use in cleanroom cleaning rotations that demand the use of a sterile hydrogen peroxide solution adequate for maintaining a clean and critical environment. As an effective one-step, ready-to-use, oxidizing cleaner, **STERI-PEROX,** penetrates to the surface and is tough on a variety of soils. **STERI-PEROX** reduces exposure concerns for VOC's in cleanroom operations, leaves a low remaining residue, and is designed for most washable, non-porous, hard, inanimate environmental surfaces.

STERI-PEROX is Hydrogen Peroxide formulated to 3% or 6% concentrations using Water for Injection. **STERI-PEROX** is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100). Each lot of **STERI-PEROX** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-PEROX** is delivered each time with lot specific Certificate of Analysis and Certificate of Sterility.

STERI-PEROX 3% and 6% concentrations are available sterile and non-sterile in a 16 oz trigger spray, 32 oz trigger spray, 1 gallon, or a 200L drum sized containers. Each sterile container is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Use Limitations: **STERI-PEROX** is not for medical use, not for human or animal contact, and not for diagnostic or therapeutic use.

Quality and Manufacturing

- Formulated with USP Water for Injection
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Raw components are air washed with 0.2 micron filtered air
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

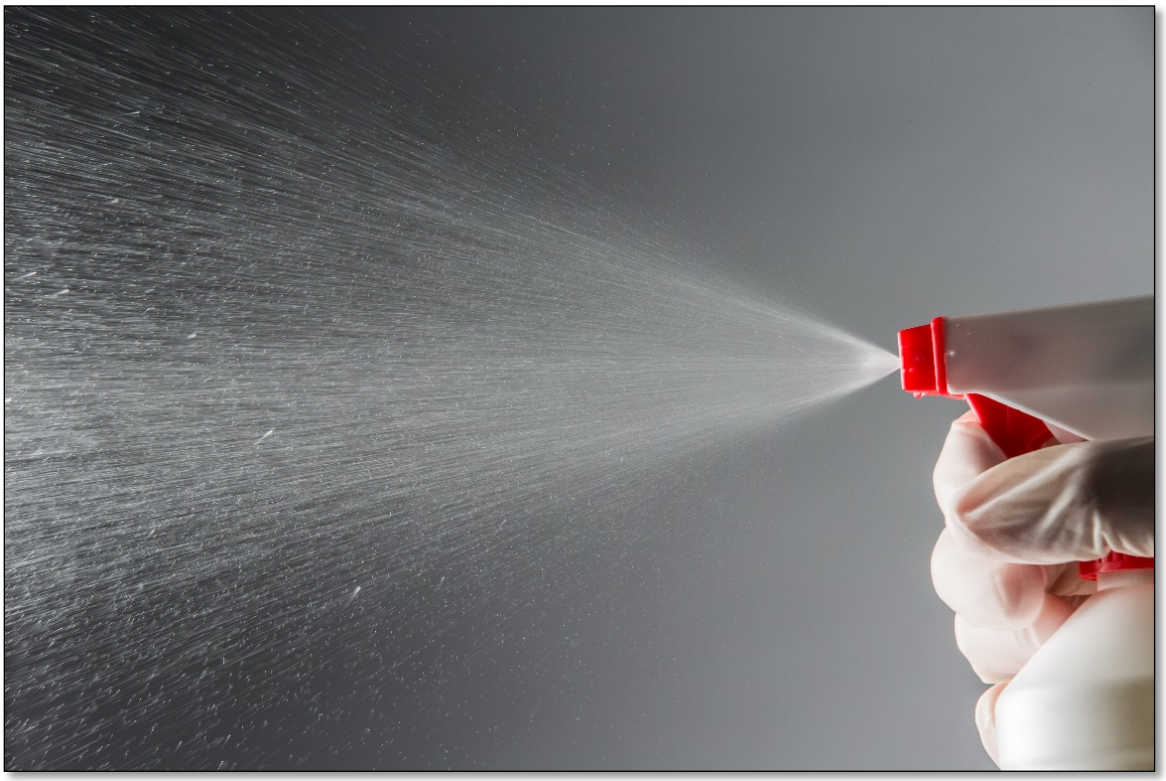
STERI-PEROX– Hydrogen Peroxide Solution and Water for Injection	
Certificate of Analysis	**Specifications**
Assay 3%:	2.5%-3.5%
Assay 6%:	6.0%-6.9%
Acidity:	<2.5 mL
Barium:	No turbidity
Heavy Metals (as Pb):	<5 ppm
Nonvolatile Residue:	<30 mg
Perservative:	<50 mg
Expiration Period:	2 Years

Features and Benefits

- Each sterile container is double bagged packaged
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Compatible with most surfaces
- Available in two ready-to-use solutions: 3% and 6% concentrations
- Available in multiple container sizes either sterile or non-sterile
- Comes in a convenient 16 oz trigger spray that has the option of spray or stream
- 16 oz and 32 oz containers comes with sterile spray attachment
- Low remaining residue
- Available in a saturated wipe: see **STERI-PEROX®** Wipe

Uses

STERI-PEROX® solution is used for the cleaning of glass, plexiglass, walls, ceilings, floors, stainless steel, manufacturing equipment, packaging equipment, filling equipment, and most environmental, hard, non-porous surfaces that require the use of sterile hydrogen peroxide solutions in cleaning rotation cycles. **STERI-PEROX** helps to maintain a critical environment. It is compatible with many types of glove materials.



STERI-PEROX 3% & 6% 16 oz Trigger Spray

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-PEROX – Hydrogen Peroxide Solution 3% & 6%		
Part Number	**Description**	**Qty/cs.**
SPER-01-3%	STERI-PEROX® 3%, 1 Gallon, Non-Sterile	4
SPER-02-3%	STERI-PEROX 3%, 1 Gallon, Sterile	4
SPER-16Z-3%	STERI-PEROX 3%, 16 oz, Unattached Trigger, Sterile	12
SPER-32Z-3%	STERI-PEROX 3%, 32 oz Unattached Trigger, Sterile	12
SPER-10-200L-3%	STERI-PEROX 3%, 200L Drum, Sterile	1
SPER-01-6%	STERI-PEROX 6%, 1 Gallon, Non-Sterile	4
SPER-02-6%	STERI-PEROX 6%, 1 Gallon, Sterile	4
SPER-16Z-6%	STERI-PEROX 6%, 16 oz, Unattached Trigger Sterile	12
SPER-10-200L-6%	STERI-PEROX 6%, 200L Drum, Sterile	1

SPER-01-6%

SPER-02-3%

SPER-16Z-6%

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

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-PEROX® 3% & 6%

Hydrogen Peroxide and Water for Injection

(Any specific product label is available upon request.)

STERI-PEROX 3% and 6% Family of Products

STERI-PEROX® 3% and 6% Case Label

Sterile Pharmaceutical Cleanroom Formula

For Industrial Use Only

Hydrogen Peroxide at 3.00% Vol/Vol. in USP Water for Injection

Hydrogen Peroxide at 6.00% Vol/Vol. in USP Water for Injection

KEEP OUT OF THE REACH OF CHILDREN
WARNING

Ingredients 3%:
Hydrogen Peroxide 3.0%
USP Water for Injection.....97.0%
Total 100.0%

SDS#: SPER-98-01-3 • Rev 18Apr16
Case Label#: SPER-3%-00

Ingredients 6%:
Hydrogen Peroxide 6.0%
USP Water for Injection.....94.0%
Total 100.0%

SDS#: SPER-98-01-6 • Rev 18Apr16
Case Label#: SPER-6%-00

For Spill/Exposure Emergency Response Service from the USA and Canada: CARECHEM 24 866-928-0789

Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19355-1234 USA
Tel: 001-610-644-8335
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Warning

HAZARD STATEMENTS: Causes serious eye irritation.
PRECAUTIONARY STATEMENTS: Wash thoroughly after handling. Wear eye protection/ face protection.

See Safety Data Sheet and/or leaflet for additional product information.

USE: Use at full strength.

For Spill/Exposure Response Service from Europe in English, French, and Spanish (and 23 European Languages) call +44 1235 239 670. For Arabic call +44 1235 239 671. For Chinese call +86 10 5100 3039.

Precautionary Statements

Product can cause moderate to severe irritation of eyes, skin and mucous membranes. Product can cause irritation of the gastrointestinal tract and respiratory tract. Contact with eyes may cause eye damage. Contact with skin may cause stinging, pain, or irritation. Ingestion/inhalation of large amounts may be harmful. Do not get this material in contact with skin or eyes. Do not inhale vapors or mists of this product. Keep container closed. Do not reuse the empty container.

First Aid

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists, get medical attention. **Skin:** For skin contact flush with large amounts of water. Immediately take off all contaminated clothing. Wash contaminated clothing before reuse. If irritation persists, get medical attention. **Ingestion:** If the material is swallowed, get immediate medical attention or advice – Do not induce vomiting. **Inhalation:** If inhaled, immediately remove the affected person to fresh air. If the affected person is not breathing, have a qualified individual apply artificial respiration. Call a physician immediately.

Have the product or container label with you when you call a poison control center or doctor or going for treatment. For Emergency Response call 1CARECHEM24.

Storage

Storage: Store away from incompatible materials. To maintain product quality, do not store in head or direct sunlight.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
    - STERI-PEROX 3% SDS# SP-98-01-3
    - STERI-PEROX 6% SDS# SP-98-01-6
- In-Use Validation
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility and Certificates 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