



VELTEK ASSOCIATES, INC.

# TECHNICAL DATA FILES



## STERI-PEROX<sup>®</sup> 6%

Hydrogen Peroxide and Water for Injection Solution

Sterile Pharmaceutical Cleanroom Formula

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*STERI-PEROX 6%  
Sterile 16 oz. Spray Bottle  
SPER-16Z-6%-E*

## **PRODUCT OVERVIEW**

VAI® manufactures 6% hydrogen peroxide solution, formulated with USP Water for Injection, **STERI-PEROX 6%** is an effective one-step, ready-to-use, oxidizing cleaner. **STERI-PEROX 6%**, penetrates to the surface and is tough on a variety of soils. **STERI-PEROX 6%** 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 6%** is processed to comply with the standards required by the pharmaceutical, biotechnology, healthcare, and medical device industries. **STERI-PEROX 6%** 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.

**STERI-PEROX 6%** is manufactured via aseptic fill, filtered at 0.2 microns into gamma irradiated sterile components in an ISO 5 cleanroom (Grade A). Each lot of **STERI-PEROX 6%** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-PEROX 6%** is delivered each time with lot specific analytical and sterility documentation.

**STERI-PEROX 6%** is available sterile in 16 oz trigger spray and 1 gallon containers. Each sterile container is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®. Gallon bottles are also available non-sterile.

Use Limitations: **STERI-PEROX 6%** is not for medical use, not for human or animal contact, and not for diagnostic or therapeutic use.

## **Quality and Manufacturing**

- Filled in an ISO 5 cleanroom (Grade A)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- 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
- Formulated with USP Water for Injection (<0.25 EU/mL)



## Features and Benefits

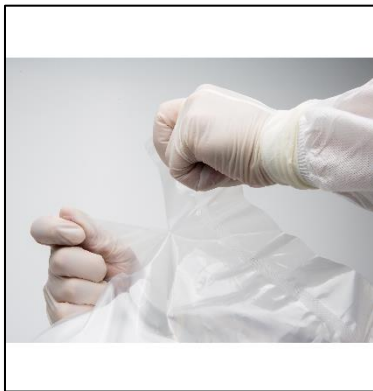
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System<sup>®</sup>
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data tested to current USP compendium
- Specifically formulated as a sterile pharmaceutical cleanroom formula
- Compatible with most surfaces
- Available in ready-to-use solution: 6% concentration
- 16 oz containers come with sterile spray attachments
- Low remaining residue

## Product Uses

- Most environmental, hard, non-porous surfaces
- Manufacturing equipment, packaging equipment, filling equipment
- Glass, plexiglass, stainless steel
- Walls, ceilings
- Compatible with many types of glove materials

## ABCD Cleanroom Introduction System<sup>®</sup>

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.



## CHEMICAL SPECIFICATIONS

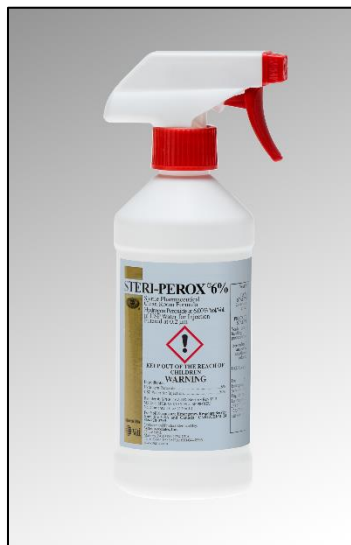
STERI-PEROX 6% – Hydrogen Peroxide and Water for Injection Solution	
Certificate of Analysis	Specification
Assay	6.0 – 6.9%
Acidity	< 5.5 mL
Barium	No Turbidity
Heavy Metals (as Pb)	< 5 ppm
Nonvolatile Residue	< 30 mg
Preservative	< 50 mg
Expiration Period	2 years from manufacture date

## ORDERING INFORMATION

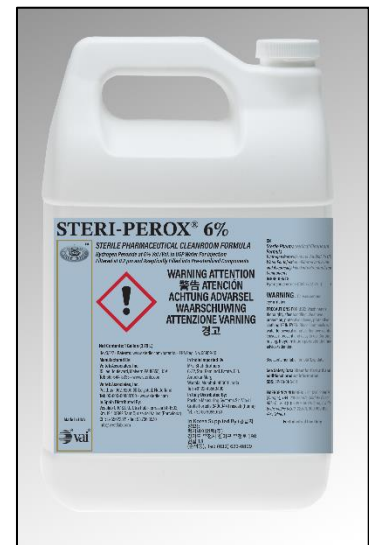
STERI-PEROX 6% – Hydrogen Peroxide and Water for Injection Solution		
Part number	Description	Qty/cs
SPER-01-6%-E	STERI-PEROX 6%, 1 Gallon, Non-Sterile	4
SPER-02-6%-E	STERI-PEROX 6%, 1 Gallon, Sterile	4
SPER-16Z-6%-E	STERI-PEROX 6%, 16 oz, Unattached Trigger, Sterile	12



SPER-02-6%-E



SPER-16Z-6%-E



SPER-01-6%-E

## LABELING

### 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 200	WHITE	WHITE		
STERI-BUFFER 90 & 99	CLEAR	WHITE		
DEC-CYCLE II	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		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	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

# STERI-PEROX 6%

## Hydrogen Peroxide and Water for Injection Solution

### STERI-PEROX® 6%

**STERILE PHARMACEUTICAL CLEANROOM FORMULA**  
Hydrogen Peroxide at 6% Vol./Vol. in USP Water For Injection  
Filtered at 0.2 µm and Aseptically Filled into Pre-sterilized Components

**WARNING ATTENTION  
警告 ATENCIÓN  
ACHTUNG ADVARSEL  
WAARSCHUWING  
ATTENZIONE VARNING  
경고**

Net Contents:  
 473 mL x 12 (5.7 L)  
 3.79 L x 4 (15.2 L)

Case #: SPER 6%-00-E  
Rev 09/22 - Patents: www.sterile.com/patents - EPA Reg. No. 68959-10

**Manufactured By:**  
Veltek Associates, Inc.  
15 Lee Boulevard, Malvern PA 19355, USA  
Tel: 610-644-8335 - www.sterile.com

**In Spain Distributed By:**  
Vestilab CRC S.L.U. Ctra. Rubí-Terrassa BP-1503,  
Km. 19.4 08192 Sant Quirze del Valles (Barcelona)  
CIF: B-65622821 - Tel: 93.736.3530  
info@vestilab.com

**In India Imported By:**  
Tanuha, A-12, Wadala Shiram,  
Industrial Estate, G. D. Ambekar Marg  
Wadala, Mumbai- 400 031 India  
Tel: +91 22-43560400

**In Italy Distributed By:**  
Particle Measuring Systems S.p.A. di Grotte  
Portofino 3400044 Frascati (Roma)  
Tel: +39 06 90530130

**In Korea Supplied By (공급자 정보):**  
럭키사이언텍(주)  
경기도 부천시 원미구 부천로 198번길 18  
(춘의동), Tel: (032) 623-0899

**EN**  
STERILE PHARMACEUTICAL  
CLEANROOM FORMULA  
Hydrogen Peroxide at 6% Vol./Vol. in USP  
Water For Injection - Filtered at 0.2 µm  
and Aseptically Filled into Pre-sterilized  
Components

**INGREDIENTS:**  
Hydrogen peroxide (CAS 7722-84-1) 6.0%

**WARNING:** Causes serious  
eye irritation.

**PRECAUTIONS FOR USE:** Wash hands  
thoroughly after handling. Wear eye  
protection, protective gloves, protective  
clothing. IF IN EYES: Rinse cautiously with  
water for several minutes. Remove contact  
lenses, if present and easy to do. Continue  
rinsing. If eye irritation persists: Get medical  
advice/attention.

See container label for lot# / Exp date

**See Safety Data Sheet for first aid and  
additional product information.**

SDS: SP-98-01-6-EU  
**EMERGENCY NUMBER:** +44 1235 239670  
(Europe), +44 1235 239671 (Middle East/  
Africa) +353 (0) 808 2166 (Ireland, Available  
to the public 08.00-22.00), 000 800 100  
7479 (India)

**For Industrial Use Only**

**ZH(中文)**  
无菌制药洁净室配方。  
含 6% 过氧化氢 (体积浓度) 的  
USP 注射用水溶液 - 经 0.2  
µm 过滤后无菌灌装于预先灭菌  
的组件中

**配料:**  
过氧化氢 (CAS 7722-84-1) 6.0%

**警告:** 造成严重眼刺激。

**防范说明:** 处置后彻底清洗手部。  
戴防护眼镜、戴防护手套。如进入  
眼睛: 用水小心冲洗几分钟。如戴  
隐形眼镜并可方便地取出, 取出除  
形眼镜 继续冲洗。如觉持续眼刺  
激: 就医/就诊。

查看容器上的批号和失效日期。  
运输法规没有记载货品危险性。  
有关急救和其他产品的信息, 请参  
见安全数据表。

SDS: SP-98-01-6-P  
**应急咨询电话: 中文(24小时):**  
0532 8388 9090

**仅供产业使用**

**KO (한국어)**  
살균 제약 클린룸 풀러  
USP 주사용수에 6% Vol./Vol.의  
과산화수소 - 0.2µm에서 여과되고  
사전 멸균된 구성 요소에 무균적으로  
채워집니다

**성분:**  
과산화수소 (CAS 7722-84-1) 6.0%

**경고:** 눈에 심한 자극을 일으킴.

**예방조치:** 취급 후에는 손 (들)을  
철저히 씻으시오. 보안경, 보호장갑,  
보호의 (들) 착용하십시오. 눈에 들어오면  
면분간 물로 조심해서 씻으시오.  
가능하면 콘택트렌즈를 제거하십시오.  
계속 있으시오. 눈에 자극이 지속되면  
의학적인 조치-조언을 구하십시오.

용기에서 로트 번호 / 유효 기간을  
확인하십시오.

응급 처치 및 추가 제품 정보는 안전  
데이터 시트를 참조하십시오.

SDS: SP-98-01-6-KO  
긴급 전화 번호: +82 2 3479 8401

**산업 사용용위한**

**DE**  
**STERILE FORMEL NACH  
PHARMAZEUTISCHEM  
REINRAUMSTANDARD**  
6% vol/vol hydrogenperoxid / USP-wand III  
injektion - Gefiltert über 0,2 µm an aseptisch  
abgefüllt in vorgesterilisierte Komponenten

**BESTANDTEILEN:**  
Wasserstoffperoxid (CAS 7722-84-1) 6,0%

**ACHTUNG:** Verursacht schwere  
Augenreizung.

**SICHERHEITSHINWEISE:** Nach Gebrauch  
die Hände gründlich waschen. Augenschutz,  
Schutzhandschuhe, Schutzkleidung tragen.  
**BEI KONTAKT MIT DEN AUGEN:** Einige Minuten  
lang behutsam mit Wasser spülen. Eventuell  
vorhandene Kontaktlinsen nach Möglichkeit  
entfernen. Weiter spülen. Bei anhaltender  
Augenreizung: Ärztlichen Rat einholen/  
ärztliche Hilfe hinzuziehen.  
Siehe Behälter für Los #/ Haltbarkeitsdatum  
BaJA Nr. N-52845

**Erste Hilfe und zusätzliche  
Produktinformationen finden Sie im  
Sicherheitsdatenblatt.**  
SDS: SP-98-01-6-GR  
**NOTRUFNUMMER:**  
+44 1235 239 670 (Europa)

**Nur für den Industriellen Gebrauch**

FR IT IN LV  
DA IS

Case Label SPER-6-00-E Rev0922

Any specific product label is available upon request.

# STERI-PEROX® 6%

## Sterile Pharmaceutical Cleanroom Formula

Hydrogen Peroxide at 6% Vol./Vol. in USP Water For Injection  
Filtered at 0.2 µm and Aseptically Filled into Pre-sterilized Components



**WARNING ATTENTION  
警告 ATENCIÓN  
ACHTUNG ADVARSEL  
WAARSCHUWING  
ATTENZIONE VARNING  
경고**

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234  
Tel: 610-644-8335 Fax: 610-644-8335 [www.sterile.com](http://www.sterile.com)

01DEC2022 E

## Product Labeling (Continued)

Case #: SPER-6%-00-E

Rev09/22

Patents: [www.sterile.com/patents](http://www.sterile.com/patents)

### Manufactured By:

Veltek Associates, Inc.

15 Lee Boulevard, Malvern PA 19355, USA

Tel: 610-644-8335 • [www.sterile.com](http://www.sterile.com)

### EN

Sterile Pharmaceutical Cleanroom Formula

Hydrogen Peroxide at 6% Vol./Vol. in USP Water For Injection • Filtered at 0.2 um and Aseptically Filled into Pre-sterilized Components

### INGREDIENTS:

Hydrogen Peroxide (CAS 7722-84-1)..... 6.0%

### WARNING

Causes serious eye irritation.

### PRECAUTIONS FOR USE:

Wash hands thoroughly after handling. Wear eye protection, protective gloves, protective clothing. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

See container label for lot#/Exp date

See Safety Data Sheet for first aid and additional product information.

### EMERGENCY NUMBER:

+44 1235 239670 (Europe)

+44 1235 239671 (Middle East/Africa)

+353 (0)1 809 2166 (Ireland, Available to the public 08.00–22.00)

000 800 100 7479 (Hindi)

+86 532 8 388 9090 (China)

+82 2 3479 8401 (S. Korea)

### For Industrial Use Only

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Tel: 610-644-8335 Fax: 610-644-8335 [www.sterile.com](http://www.sterile.com)

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## ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample Lot Specific Documentation – Product Release Certificate containing analytical and sterility data tested to current USP compendium.



*VAI<sup>®</sup>'s SCMD Product Family*

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 or 7 (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.

For more information call 610-644-8335, email [sales@sterile.com](mailto:sales@sterile.com) or visit our website at [www.sterile.com](http://www.sterile.com). Patents: [www.sterile.com/patents](http://www.sterile.com/patents)

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