VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STERI-PEROX® 3%

Hydrogen Peroxide and Water for Injection Solution

Sterile Pharmaceutical Cleanroom Formula

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STERI-PEROX 3%
Sterile 32 oz Spray Bottle
SPER-32Z-3%

PRODUCT OVERVIEW

VAI® manufactures a 3% hydrogen peroxide solution, formulated with USP Water for Injection. As an effective one-step, ready-to-use, oxidizing cleaner, **STERI-PEROX 3%,** penetrates to the surface and is tough on a variety of soils. **STERI-PEROX 3%** 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 3% is processed to comply with the standards required by the pharmaceutical, biotechnology, healthcare, and medical device industries. **STERI-PEROX 3%** 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 3% 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 3%** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-PEROX 3%** is delivered each time with lot specific analytical and sterility documentation.

STERI-PEROX 3% is available sterile in 16 oz trigger spray, 32 oz trigger spray, 1 gallon, or 200L drum sized 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 3%** 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

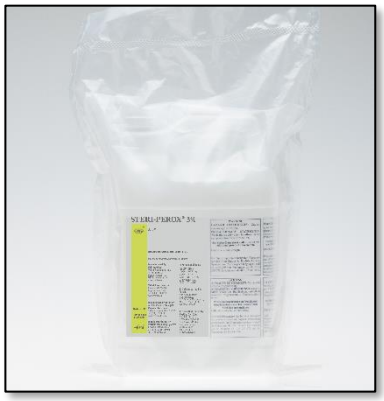
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data tested to current USP compendium
- Specifically formulated as a sterile pharmaceutical cleanroom formula
- Compatible with most surfaces
- Available in ready-to-use solution: 3% concentration
- 16 oz and 32 oz containers come with sterile spray attachments
- Low remaining residue

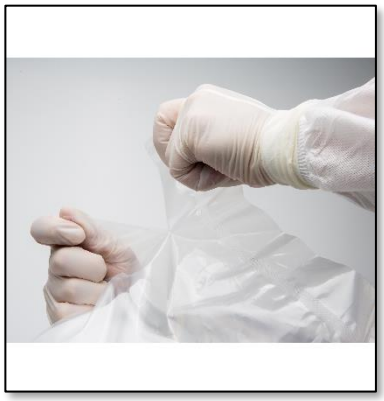
Product Uses

- 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®

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. After the two outer bags are removed, the individual containers are each additionally contained in two easy tear bags.





CHEMICAL SPECIFICATIONS

STERI-PEROX 3% – Hydrogen Peroxide and Water for Injection Solution	
Certificate of Analysis	**Specification**
Assay	2.5 – 3.5%
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 3% – Hydrogen Peroxide and Water for Injection Solution		
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-02-3%

SPER-16Z-3%

SPER-01-3%

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 3%

Hydrogen Peroxide and Water for Injection Solution

STERI-PEROX® 3%

Sterile

Net Contents /Contenu net:

- 16 oz (473 mL) x 12 [1.5 Gallons (5.7 L)]
- 32 oz (946 mL) x 12 [3 Gallons (11.4 L)]
- 1 Gallon (3.79 L) x 4 [4 Gallons (15 L)]

Label #: SPER-3%-00 - Rev1121

Patents/les brevets: www.sterile.com/patents

Manufactured By/ Fabriqué Par:
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19355-1234
USA Tel: 610-644-8335
www.sterile.com

In Korea Supplied By (공급자 정보):
럭키싸이언텍(주)
경기도 부천시
원미구 부천로 198
번길18(춘의동),
Tel: (032) 623-0899

Veltek Associates, Inc.
Postbus 1062, 8200 BB
Lelystad, Nederland
Tel: 00-800-08888700
www.sterile.com

In India Imported By:
Tansha
A-17 Wadala Shriram,
Industrial Estate,
G. D. Ambekar Marg, Wadala,
Mumbai - 400 031, India
Tel: 022-43560400

In Canada, distributed by: Au Canada, distribué par:
Canada Clean Room
20 Cope Dr. Kanata ON. K2M 2V8
Tel: (888) 595-8670
www.ccrcanada.com

In Spain Distributed By:
Vestilab Crc, S.l.u.
Ctra Rubi - Terrassa
BP-1503 Km. 19,4 08192
Sant Quirze del Valles
Barcelona Espana
CIF: B-65622821
Tel: 93.736.35.10
info@vestilab.com

In Italy Distributed By:
Particle Measuring Systems
S.r.l.Via di Grotte Portella
3400044 Frascati (Roma)
Tel. +39 06 90530130

Made in USA
Fabrique aux Etats-Unis

EN
PHARMACEUTICAL CLEANROOM FORMULA
Hydrogen Peroxide at 3.00% w/w in USP Water For Injection Filtered at 0.2 µm

INGREDIENTS:
Hydrogen Peroxide (CAS 7722-84-1).....3%
Other Ingredients: Water

Safety data sheet available on request. See container for lot # / Exp Date

EMERGENCY NUMBER:
1-866-928-0789 (toll free USA)
1-800-579-7421 (toll free Canada)
1-215-207-0061 (Americas)
+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)

SDS: SP-98-01-3 (Americas)
SP-98-01-3-EU (Europe)

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

For Industrial Use Only.

FR
FORMULE POUR SALLE BLANCHE PHARMACEUTIQUE
Peroxyde d'hydrogène à 3,00 % en w/w dans l'eau USP pour injection Filtré à 0,2 µm

INGREDIENTES
Peroxyde d'hydrogène (CAS 7722-84-1).....3%
Autres Ingrédients: L'eau

Fiche de données de sécurité disponible sur demande. Voir le récipient pour le lot #/ date d'expiration

NUMÉRO D'URGENCE:
1-866-928-0789 (sans frais USA)
1-800-579-7421 (Canada sans frais)
1-215-207-0061 (Ameriques)
+44 1235 239670 (L'Europe)
+44 1235 239671 (Moyen-Orient/Afrique)
+31 45 42 59 61 (INRS/ORFILA)
+353 (0)1 809 2166 (Irlande, disponible au public 08.00-22.00).
000 800 100 7479 (Hindi)

SDS: SP-98-01-3-CFR (Ameriques)
SP-98-01-3-FR (Europe)

Voir la fiche de données de sécurité pour les premiers secours et des informations complémentaires sur le produit.

Réservé à un Usage Industriel.

ZH(中文)
制药洁净室配方.
USP 注射用水中的 3.00% w/w 过氧化氢 0.2 µm 过滤器

配料:
过氧化氢
(CAS 7722-84-1).....3%

对水生生物有害
防范说明: 避免释放到环境中。
处置内装物/容器至经授权的废物收集点。

查看容器上的批号和失效日期.
运输法规没有记载货品危害性.

应急咨询电话:
中文(24小时):
+86 532 8 388 9090

SDS: SP-98-01-3-P

有关急救和其他产品的信息, 请参见安全数据表.

仅供产业使用.

KO (한국어)
제약 등급 클린 룸 포뮬러. 과산화수소 USP 주사용수에 3.00 % w/w 0.2 미론으로 여과

성분:
과산화수소
(CAS 7722-84-1).....3%

요청시 안전 데이터 시트 제공.
용기에서 로트 번호 /유효 기간을 확인하십시오.

긴급 전화 번호:
+82 2 3479 8401

SDS: SP-98-01-3-KO

응급 처치 및 추가 제품 정보는 안전 데이터 시트를 참조하십시오.

산업 사용을위한.

DE
PHARMAZEUTISCHE REINRAUM-REZEPTUR
Wasserstoffperoxid von 3,00 % w/w in USP Wasser für Injektionszwecke Filtriert bei 0,2 µm

BESTANDTEILEN:
Wasserstoffperoxid
(CAS 7722-84-1).....3%

Sicherheitsdatenblatt auf Anfrage erhältlich. Siehe Behälter für Los #/ Haltbarkeitsdatum

NOTRUFNUMMER:
+44 1235 239 670 (Europa)
+44 1235 239 671 (Mittlerer Osten/Afrika)

SDS: SP-98-01-3-GR

Erste Hilfe und zusätzliche Produktinformationen finden Sie im Sicherheitsdatenblatt.

Nur für den Industriellen Gebrauch.

ES | SV | IT | NL | DA

Case Label SPER-3%-00 Rev1121

Any specific product label is available upon request.

SPER-10-200L-3% Drum

STERI-PEROX® 3%

Sterile

Label #: SPER-3%-00 • Rev1121
Patents/les brevets: www.sterile.com/patents

Manufactured By/ Fabriqué Par:

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

EN

PHARMACEUTICAL CLEANROOM FORMULA
Hydrogen Peroxide at 3.00% w/w in USP
Water For Injection Filtered at 0.2 µm

INGREDIENTS:

Hydrogen Peroxide
(CAS 7722-84-1)..... 3%

OTHER INGREDIENTS: Water

Safety data sheet available on request
See container for lot # / Exp Date

EMERGENCY NUMBER:

1-866-928-0789 (toll free USA)
1-800-579-7421 (toll free Canada)
1-215-207-0061 (Americas)
+44 1235 239670 (Europe)
+44 1235 239671 (Middle East/Africa)
000 800 100 7479 (Hindi)
+86 532 8 388 9090 (China)
+82 2 3479 8401 (S. Korea)
+353 (0)1 809 2166 (Ireland, available to the public 08.00–22.00)

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

For Industrial Use Only.

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® '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 or visit our website at www.sterile.com. Patents: www.sterile.com/patents