VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STERI-PEROX® 6%

Hydrogen Peroxide and Water for Injection Solution

Sterile Pharmaceutical Cleanroom Formula

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.

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STERI-PEROX 6%
Sterile 16 oz Spray Bottle
SPER-16Z-6%-C

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 with lot specific analytical and sterility data, tested to current USP compendium.

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 (<0.45 EU/mL)

Features and Benefits

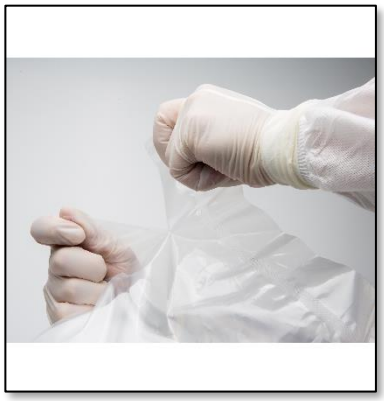
- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data, tested to current USP compendium
- Specifically formulated as a sterile pharmaceutical cleanroom formula
- Compatible with most surfaces
- Available in ready-to-use solution: 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®

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.



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

CHEMICAL SPECIFICATIONS

STERI-PEROX 6% – Hydrogen Peroxide and Water for Injection Solution	
Certificate of Analysis	**Specification**
Assay	6.2 – 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%-C	STERI-PEROX 6%, 1 Gallon, Non-Sterile	4
SPER-02-6%-C	STERI-PEROX 6%, 1 Gallon, Sterile	4
SPER-16Z-6%-C	STERI-PEROX 6%, 16 oz, Unattached Trigger, Sterile	12
SPER-32Z-6%-C	STERI-PEROX 6%, 32 oz, Unattached Trigger, Sterile	12

SPER-02-6%-C

SPER-16Z-6%-C

SPER-01-6%-C

LABELING

VAI's 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	COOL GREY		
DECON-AHOL WFI FORMULA 91%	WHITE	COOL GREY		
DECON-AHOL FORMULA 99%	WHITE	COOL GREY		
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		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	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 6%

Hydrogen Peroxide and Water for Injection Solution

STERI-PEROX® 6%

STERILE PHARMACEUTICAL CLEANROOM FORMULA/ FORMULE STÉRILE POUR SALLE BLANCHE PHARMACEUTIQUE

Hydrogen Peroxide at 6% Vol./Vol. in USP Water For Injection/Peroxyde d'hydrogène à 6% en vol./vol. dans eau USP pour injection • Filtered at 0.2 µm and Aseptically Filled into Pre-sterilized Components/Filtré à 0,2 µm et rempli aseptiquement dans des composants pré-stérilisés

WARNING
ATTENTION

Net Contents/Contenu net:
- ☐ **473 mL** x 12 (5.68 L) **Reorder/Commandez à nouveau # SPER-16Z-6%-C**
- ☐ **946 mL** x 12 (11.4 L) **Reorder/Commandez à nouveau # SPER-32Z-6%-C**
- ☐ **3.79 L** x 4 (15.2 L) **Reorder/Commandez à nouveau # SPER-02-6%-C**

Label/étiquette # SPER-6%-00-C
Rev 09/22A • **Patents/les brevets:** www.sterile.com/patents • EPA Reg. No. 68959-10

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

Made in USA
Fabrique aux Etats-Unis

In Canada, distributed by/Au Canada, distribué par:
Canada Clean Room
20 Cope Dr., Kanata, ON K2M 2V8
www.ccrcanada.com
Tel: 888-595-8070

VWR International
2360 Argentia Road
Mississauga, Ontario L5N 5Z7
1-800-932-5000

Fisher Scientific
112 Colonnade Road
Ottawa, Ontario, Canada K2E 7L6
1-800-234-7437

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. Harmful to aquatic life.

PRECAUTIONARY STATEMENTS: Wash face, hands thoroughly after handling. Avoid release to the environment. 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. Dispose of contents/container to an authorized waste collection point.

See container label for lot #/Exp date

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

SDS: SP-98-01-6

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

For Industrial Use Only

FR
FORMULE STÉRILE POUR SALLE BLANCHE PHARMACEUTIQUE
Peroxyde d'hydrogène à 6% en vol./vol. dans eau USP pour injection • Filtré à 0,2 µm et rempli aseptiquement dans des composants pré-stérilisés

COMPOSANTS:
Peroxyde d'hydrogène (CAS 7722-84-1) 6.0%

ATTENTION Provoque une sévère irritation des yeux. Nocif pour les organismes aquatiques.

CONSEILS DE PRUDENCE: Se laver les mains soigneusement après manipulation. Éviter le rejet dans l'environnement. Porter un équipement de protection des yeux, des gants de protection, des vêtements de protection. **EN CAS DE CONTACT AVEC LES YEUX:** rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. **Si l'irritation oculaire persiste:** consulter un médecin. Éliminer le contenu/récipient dans une installation de collecte des déchets autorisée.

Voir le récipient pour le lot #/ date d'expiration

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

SDS: SP-98-01-6-CFR

NUMÉRO D'URGENCE:
1-866-928-0789 (sans frais USA)
1-800-579-7421 (Canada sans frais)
1-215-207-0061 (Ameriques)

Réservé à un Usage Industriel

Case Label SPER-6-00-C Rev0922A

Any specific product label is available upon request.

SPER-32Z-6%-C

Product Labeling (Continued)

STERI-PEROX® 6%

Sterile Pharmaceutical Cleanroom Formula/

Formule stérile pour salle blanche pharmaceutique

Hydrogen Peroxide at 6% Vol./Vol. in USP Water For Injection/
Peroxyde d'hydrogène à 6% en vol./vol. dans eau USP pour injection •
Filtered at 0.2 µm and Aseptically Filled into Pre-sterilized Components/
Filtré à 0,2 µm et rempli aseptiquement dans des composants pré-stérilisés

WARNING ATTENTION

Case/Cas #: SPER-6%-00-C Rev0922A Patents/les brevets: www.sterile.com/patents

Manufactured By/Fabriqué Par:

Veltek Associates, Inc.
15 Lee Boulevard, Malvern PA 19355, USA
Tel: 610-644-8335 • 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. Harmful to aquatic life.

PRECAUTIONARY STATEMENTS:

Wash face, hands thoroughly after handling. Avoid release to the environment. 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. Dispose of contents/container to an authorized waste collection point.

See container label for lot#/Exp date

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

EMERGENCY NUMBER:

1-866-928-0789 (toll free USA)

1-800-579-7421 (toll free Canada)

1-215-207-0061 (Americas)

For Industrial Use Only

TESTING SUMMARY

STERI-PEROX® 6% Efficacy Summary

STERI-PEROX 6% has been tested to certified AOAC efficacy standards. The product has achieved passing results supporting sporicidal claims. Based on the AOAC certified testing presented below, **STERI-PEROX 6%** is effective as a sterilant at 6 hours.

AOAC 810.2100 & 810.2200 **Acceptance Criteria: No visible growth observed in any carrier as well as in a separate independent confirmation for each organism.**					
Conditions: Organic Soil Load – N/A **Contact Time: 6 hours** **Performed to GLP standards**	**Test Organism**	**Carrier Population**	**Sample Lot**	**# Carriers**	**# Positive**
	Bacillus subtilis **ATCC 19659** heat shocked spore suspension	1.02×10^5 CFU/Dacron Suture 1.71×10^5 CFU/Porcelain Penicylinder	A	60 and 30	0 and 0
			B	60 and 30	0 and 0
			C	60 and 30	0 and 0
	Clostridium sporogenes **ATCC 3584** heat shocked spore suspension	2.59×10^5 CFU/ Dacron Suture 7.7×10^5 CFU/ Porcelain Penicylinder	A	60 and 30	0 and 0
			B	60 and 30	0 and 0
			C	60 and 30	0 and 0

TESTING SUMMARY (Continued)

STERI-PEROX® 6%

STERI-PEROX 6% has been tested to certified European (EN) efficacy standards. **STERI-PEROX 6%** has achieved passing results supporting claims including bactericidal, yeasticidal, fungicidal, and sporicidal.
Based on the EN certified testing presented below, **STERI-PEROX 6%** is effective as a bactericide and yeasticide at 10 minutes, a fungicide at 20 minutes, and a sporicide at 60 minutes.

EN 1276:2009 **Acceptance Criteria: Demonstrate at least a 5 $\log_{10}$ reduction in viable bacterial counts.**				
Conditions: Clean 0.3 g/l bovine albumin **Test Temperature: 20°C ±1°C** **Performed to European efficacy standards**	**Test Organisms**	**Contact Times and Concentrations Tested**		
		Neat (80%)	**50%**	**33%**
		10 Minutes		
	***Staphylococcus aureus* ATCC 6538**	>5.33	<4.26	<4.26
	***Pseudomonas aeruginosa* ATCC 15442**	>5.38	4.85	<4.31
	***Escherichia coli* ATCC 10536**	>5.42	5.04	<4.35
	***Enterococcus hirae* ATCC 10541**	>5.52	<4.45	<4.45

TESTING SUMMARY (Continued)

EN 1650:2008 Acceptance Criteria: Demonstrate at least a 4 log_{10} reduction in viable yeast counts.				
Conditions: Clean 0.3 g/l bovine albumin **Test Temperature: 20°C +1°C** **Performed to European efficacy standards**	**Test Organisms**	**Contact Times and Concentrations Tested**		
		Neat (80%)	**50%**	**33%**
		10 Minutes		
	***Candida albicans* ATCC 10231**	>4.41	<3.04	<3.04

EN 1650:2019 Acceptance Criteria: Demonstrate at least a 4 log_{10} reduction in fungal counts				
Conditions: Clean 0.3 g/l bovine albumin **Test Temperature: 20°C ±1°C** **Performed to European efficacy standards**	**Test Organisms**	**Contact Times and Concentrations Tested**		
		Neat (80%)	**50%**	**25%**
		20 minutes		
	***Aspergillus brasiliensis* ATCC 16404**	>4	<3.31	<3.31

EN 13704:2018 Acceptance Criteria: Demonstrate at least a 3 log_{10} reduction in viable bacterial counts.				
Conditions: Clean 0.3 g/l bovine albumin **Test Temperature: 20°C ±1°C** **Performed to European efficacy standards**	**Test Organisms**	**Contact Times and Concentrations Tested**		
		Neat (80%)	**50%**	**10%**
		60 Minutes		
	***Bacillus subtilis* ATCC 6633**	>3	2.85	<2.05

TESTING SUMMARY (Continued)

EN 13697:2001 Acceptance Criteria: Demonstrate at least a 4 log_{10} reduction in viable bacterial counts.				
Conditions: Clean 0.3 g/l bovine albumin **Test Temperature: 20°C +1°C** **Performed to European efficacy standards**	**Test Organisms**	**Contact Times and Concentrations Tested**		
		Neat (100%)	**50%**	**33%**
	5 Minutes			
	***Staphylococcus aureus* ATCC 6538**	4.02	2.53	2.25
	***Pseudomonas aeruginosa* ATCC 15442**	>6.00	3.41	2.83
	***Escherichia coli* ATCC 10536**	>5.93	3.43	2.92
	***Enterococcus hirae* ATCC 10541**	4.07	1.81	1.46
	10 Minutes			
	***Staphylococcus aureus* ATCC 6538**	>6.49	3.71	2.44
	***Pseudomonas aeruginosa* ATCC 15442**	>6.00	>6.00	3.51
	***Escherichia coli* ATCC 10536**	>5.93	>5.93	3.62
	***Enterococcus hirae* ATCC 10541**	>6.65	3.19	2.08

ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample Lot Specific Documentation – Delivered with lot specific 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