



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STERI-BUFFER® 90 & 99

Sterile Phosphate Buffer pH 7.2 ± 0.2

90 and 99 mL Fill Levels Formulated with USP Water for Injection



Product Description

VAI manufactures two sterile, disposable, sodium phosphate buffer solutions, **STERI-BUFFER 90 & 99**, that are assayed to current USP Standards (Bufferfield's Buffer) and buffered to a pH of 7.2 ± 0.2 . **STERI-BUFFER** Products are processed to comply with the standards required by pharmaceutical, biotechnology, and medical device industries. **STERI-BUFFER** Products have been developed for use as a buffer solution and diluent in lab testing such a bioburden testing, pharmaceutical microbial limits testing, and AET testing and as a rinsing agent. **STERI-BUFFER** Products are available in either a 90 mL or 99 mL fill level.

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

STERI-BUFFER Products are available in either a 90 mL or 99 mL fill level in an easy open and close, wide mouth bottle, with an interlock screw cap. The wide mouth bottle design allows for easy pouring and the interlock screw cap assures closure after opening. Containers of **STERI-BUFFER** Products are clear and scaled with graduations on all four sides for measuring purposes. Once the product has been filled and capped, a "no tamper strip" is placed on the cap, extending to the bottle, causing it to break when opened. Each sterile container of **STERI-BUFFER** is bagged two per bag and packaged with two additional case liners for easy transport to the core.

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-BUFFER 90 & 99 – Sterile Phosphate Buffer pH 7.2 ± 0.2

Certificate of Analysis	Specifications
Appearance:	Clear
pH (stock solution):	7.0 – 7.4
Odor:	Odorless
Expiration Period:	2 years

Features and Benefits

- Each sterile container is bagged two per bag in easy tear bags and packaged in two case liners for easy transport to the core
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation
- Available in two fill levels, 90 mL or 99 mL to fit your operation's needs
- Assayed to current USP Standards (Butterfield's Buffer)
- Buffered to a pH of 7.2 ± 0.2
- Bottle's wide mouth design allows for easy pouring
- Bottle is easy to open and close and comes with an interlock screw cap for assured closure after opening
- Each bottle has a "no tamper strip" that breaks once the bottle has been opened
- Container is scaled with graduations on all four sides
- Ideal for use as a rinsing agent or buffer solution in laboratory testing
- Disposable
- Odorless

Uses

- Rinsing agent
- Buffer solution in laboratory testing including bioburden testing, pharmaceutical microbial limits testing, and AET testing

Ordering Information

STERI-BUFFER 90 & 99 – Sterile Phosphate Buffer pH 7.2 ± 0.2		
Part Number	Description	Qty/cs.
SB100-90	STERI-BUFFER, 90 mL Fill Level, Sterile	72
SB100-99	STERI-BUFFER, 99 mL Fill Level, Sterile	72



SB100-90



SB100-99

Veltek Associates, Inc.

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

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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		
HYP0-CHL0R 0.25%	WHITE	WHITE		
HYP0-CHL0R 0.52%	WHITE	WHITE		
HYP0-CHL0R 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-BUFFER® 90 & 99 Sterile Phosphate Buffer pH 7.2 ± 0.2

(Any specific product label is available upon request.)



STERI-BUFFER Family

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STERI-BUFFER® 90 & 99

Sterile Disposable Phosphate Buffered (pH 7.2 ± 0.2)

90 mL Fill Level
STERI-BUFFER 90
Sterile Disposable Phosphate Buffered
(pH 7.2 +/- 0.2)

CONTAINS:

USP Water for Injection
Monobasic potassium phosphate (0.004%) and sodium hydroxide for pH adjustments

Net Contents: 90 mL
SDS Number: 2002-SB9099-01
Reorder Number: SB100-90
Quan/Case: 72 x 90 ml

Irradiation Indicator

99 mL Fill Level
STERI-BUFFER 99
Sterile Disposable Phosphate Buffered
(pH 7.2 +/- 0.2)

CONTAINS:

USP Water for Injection
Monobasic potassium phosphate (0.004%) and sodium hydroxide for pH adjustments

Net Contents: 99 mL
SDS Number: 2002-SB9099-01
Reorder Number: SB100-99
Quan/Case: 72 x 99 ml

Irradiation Indicator**Container and Product Sterilized and Distributed by:**

Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234 USA
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Veltek Associates, Inc.
Postbus 1062
8200 BB Lelystad, Nederland
Tel: +800-00888700
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Lot Number and Expiration Date

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada call CARECHEM24 at 866-928-0789. For Spill/Exposure Emergency Response Service from Europe call 44 1235 239 670. For Arabic call 44 1235 239 671.

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Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
 - **STERI-BUFFER 90** SDS # 2002-SB9099-01
 - **STERI-BUFFER 99** SDS # 2002-SB9099-01
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility, Certificate of Irradiation, and Certificate of Analysis



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

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