



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



VAI[®] WFI Quality Water

USP Grade Bulk Water for Injection

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.

07FEB2024

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VAI WFI Quality Water Family of Products

PRODUCT OVERVIEW

VAI® manufactures a USP grade bulk Water for Injection (WFI) that is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. **VAI WFI Quality Water** is an innovative solution for GMP facilities that demand the use of a sterile WFI quality water in their daily operations but do not have it readily available on site. **VAI WFI Quality Water** is ready-to-use and can be used throughout any facility for chemical formulation, disinfectant dilution, cleaning, rinsing, and lubrication. Lubrication of moving parts, process lines, and conveyors is essential for continuous and effortless manufacturing. **VAI's WFI Quality Water** is produced from a 6 effect distilled water system that is validated, routinely monitored, and passes all USP monograph requirements for "Water for Injection."

VAI WFI Quality Water is filled in ISO 7 cleanroom (Grade B), filtered at 0.2 microns, and subsequently terminally sterilized to 10^{-6} sterility assurance level. Each lot of **VAI WFI Quality Water** is sterility tested according to current USP Compendium, is tested for endotoxins, is completely traceable, and has been completely validated for sterility and shelf life. **VAI WFI Quality Water** is delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium.

VAI WFI Quality Water is available sterile in multiple container sizes including an 11 oz aerosol, a 16 oz trigger spray, a 1 gallon, a 2 gallon, and a 200 liter drum. The 11 oz aerosol spray can precipitates in a broad spray/mist without aspiration of the room's air during use. Non-aspiration ensures that the master reservoir of **VAI WFI Quality Water** remains sterile from the first drop to the last drop. Included with each aerosol can of **VAI WFI Quality** is a nozzle extension that allow operators to use in hard to reach places or on intricate mechanical parts. Each sterile container of **VAI WFI Quality Water** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

VAI WFI Quality Water is not for human or animal injection, diagnostic, or therapeutic use.

Quality and Manufacturing

- Filled in an ISO 7 cleanroom (Grade B)
- 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
- Lot tested for endotoxins
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Produced from a validated 6 effect distilled water system
- Passes all USP monograph requires for "Water for Injection"

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8336 www.sterile.com

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Features and Benefits

- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium
- Available in sterile in multiple container sizes
- Ready-to-use
- Available in 11 oz aerosol that will not aspirate the room's air
- 11 oz aerosol delivered with one unattached nozzle extension for use in hard to reach areas or when lubricating intricate machinery and equipment parts
- For use on a multitude of surfaces
- Lubricates for continuous and effortless manufacturing
- Meets the needs for USP grade WFI when required in cleanroom operations
- Ideal for operations that do not have USP grade WFI readily available

Product Uses

- Cleanroom operations that do not have USP grade WFI readily available
- Chemical formulation and disinfectant dilution
- Lubricating
- Rinsing and cleaning
- Use limitations: not for human or animal injection, diagnostic, or therapeutic use



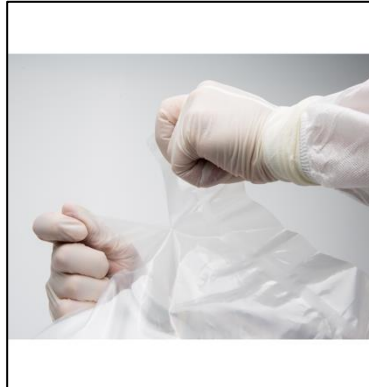
2 Gallon Water
VAI-WFI-2G

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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.



CHEMICAL SPECIFICATIONS

VAI WFI Quality Water – USP Grade Bulk Water for Injection	
Certificate of Analysis	Specifications
Conductivity	$\leq 5\mu\text{S}/\text{cm}$
TOC	<math>< 8.0\text{ mg/L}</math>
LAL Result	<math>< 0.25\text{ EU/ml}</math>
Appearance	Clear Liquid
Ammonia	$\leq 0.2\text{ ppm}$
Residue on Evaporation	Max 0.001%
pH	5.0 – 7.0
Calcium	No Turbidity
Nitrates	<math>< 0.2\text{ ppm}</math>
Expiration Period	2 years

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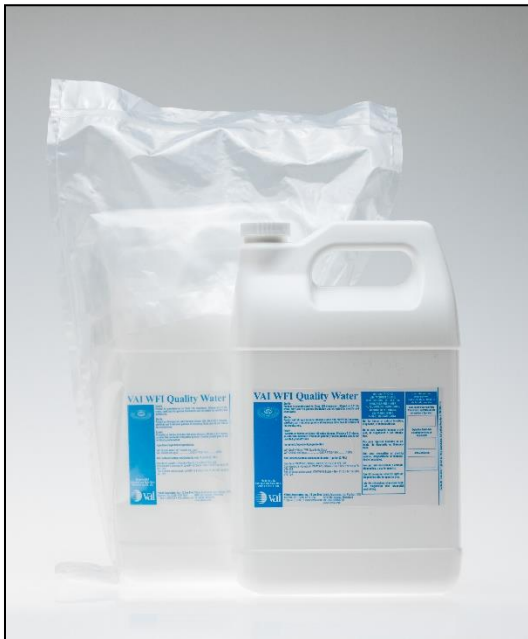
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ORDERING INFORMATION

VAI WFI Quality Water – USP Grade Bulk Water for Injection		
Part Number	Description	Qty/cs.
VAI-WFI-SP-11Z	VAI WFI Quality Water, 11 oz Aerosol Spray/Mist, Unattached Nozzle Extension, Sterile	24
VAI-WFI-16Z	VAI WFI Quality Water, 16 oz, Attached Trigger, Sterile	12
VAI-WFI-1G	VAI WFI Quality Water, 1 Gallon, Sterile	4
VAI-WFI-2G	VAI WFI Quality Water, 2 Gallons, Sterile	2
VAI-WFI-200L	VAI WFI Quality Water, 200L Drum, Single Bagged, Sterile	1
VAI-WFI-200L-2B	VAI WFI Quality Water, 200L Drum, Double Bagged, Sterile	1



VAI-WFI-1G



VAI-WFI-16Z



VAI-WFI-200L

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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	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

VAI® WFI Quality Water

USP Grade Bulk Water for Injection

<p>VAI® WFI Quality Water</p> <p>STERILE/STÉRILE Filtered at 0.2 µm and Gamma Irradiated at 10⁴ SAL/ Filtré à 0,2 µm et irradié par rayons gamma à 10⁴ SAL</p> <p>Net Contents/Contenu Net:</p> <ul style="list-style-type: none"> 19 fl. oz. (473 mL) x 12 (1.5 Gallons (5.7 L)) Reorder/Commandez à nouveau # VAI-WFI-16Z 1 Gallon (3.79 L) x 4 (4 Gallons (15.2 L)) Reorder/Commandez à nouveau # VAI-WFI-1G 2 Gallons (7.6 L) x 2 (4 Gallons (15.2 L)) Reorder/Commandez à nouveau # VAI-WFI-2G <p>Label/Étiquette # VAI-WFI-00 - Sterile/Stérile Rev 02/23 - Patents/les brevets: www.sterile.com/patents</p> <p>Manufactured By/Fabriqué Par: Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355-1234, USA Tel: 610-644-8335 www.sterile.com</p> <p>Veltek Associates, Inc. Postbus 092, 5200 RB Lelystad, Nederland Tel: 00-600-00886700 www.sterile.com</p> <p>In Canada, distributed by/Au Canada, distribué par: Canada Clean Room 20 Cope Dr. Karara ON K2M 2V8 Tel: (888) 556-8070 www.ccr.ca/Canada.com</p> <p>Fisher Scientific 112 Colonnade Road Ottawa, Ontario, Canada K2E 7L6 Tel: 1-800-234-7437</p> <p>VNI International 2360 Argentea Road Mississauga, Ontario L5N 5Z7 Tel: 1-800-332-5000</p> <p>In Italy Distributed By: Particle Measuring Systems S.r.l./S.p.A. di Grotte Portofa 34000/44 Fracassi (Rovigo) Tel: +39 06 99530330</p> <p>In Spain Distributed By: VelteLab Crc. S.L.A. Ctra Rubí - Terrassa BP 9503 Km. 33.4 08192 Sant Sadurn del Valles Barcelona España CIF: B-45622081 Tel: 93.736.36.30 info@velteab.com</p> <p>In India Imported By: Tanisha A-17, Madala Shiram, Industrial Estate, G. D. Ambekar Marg, Wadala, Mumbai - 400 033, India Tel: 022-45560400</p> <p>In Korea Supplied By/공급자 정보: 경기도 부천시 원미구 부천로 15975 김복(주) (주), Tel: (032) 623-0899</p> <p>EN/STÉRILE Filtré à 0,2µm and Gamma irradiated at 10⁴ SAL Ingredients: 100% WFI Quality Water See container for lot & Expiration Date/lot irradiation indicator Not for human or animal injection, diagnostic, or therapeutic use. See Safety Data Sheet for first aid and additional product information. SSS: VEl-140 (Americas), VEl-140-EU (Europe) EMERGENCY NUMBER: 1-866-628-0789 (toll free USA), 1-800-579-7421 (toll free Canada), 1-235-239-670 (Europe), +44 1235 239 671 (Middle East/India), +353 (0) 809 2166 (Ireland, available to the public 06.00 - 22.00), 000 800 100 7479 (Hindi) For Industrial Use Only</p> <p>FR/STÉRILE Filtré à 0,2 µm et irradié par rayons gamma à 10⁴ SAL COMPOSANTS: 100% Eau de qualité WFI Voir le récipient pour le lot et/ou date d'expiration/indicateur de irradiation usage Pas pour injection humaine ou animale, de diagnostic ou thérapeutique. Voir la fiche de données de sécurité pour les premiers secours et des informations complémentaires sur le produit. SSS: VEl-140-CFR (Amérique), VEl-140-FR (Europe) NUMÉRO D'URGENCE: 1-866-628-0789 (sans frais USA), 1-800-579-7421 (Canada sans frais), 1-235-239-670 (Europe), +44 1235 239 671 (Moyen-Orient/Afrique), +353 (0) 809 2166 (Irlande, disponible au public 06:00-22:00), 000 800 100 7479 (Hindi) Réservé à un Usage Industriel</p> <p>ES/ESTÉRIL Filtrado a 0,2 µm e irradiado con rayos gamma a 10⁴ SAL COMPONENTES: 100% agua de calidad WFI Ver recipiente para el lote y/ fecha de caducidad/indicador de irradiación uso No es para inyección humana o animal, de diagnóstico o uso terapéutico. Consulte la Hoja de datos de seguridad para obtener información sobre primeros auxilios e información adicional sobre el producto. SSS: VEl-140-SP (América), VEl-140-SP (Europa) NÚMERO DE EMERGENCIA: 1-866-628-0789 (sin costo USA), 1-800-579-7421 (sin costo Canadá), 1-235-239-670 (Europa), +353-084-8163 (Irlanda) +44 1235 239 671 (Europa), +44 1235 239 671 (Oriente Medio/Africa) Reservado para uso Industrial</p> <p>ZH/中文 无菌 经 0.2 µm 过滤器 和 γ 射线辐照灭菌, SAL 达 10⁴ 配料: 100% WFI 纯水 请查看容器上的产品批次号/有效期/红色辐照指示 不适用于人/动物注射液, 诊断或治疗用途。 有关急救和其他产品的信息, 请参考安全数据表。 SSS: VEl-140-P 应急咨询电话: 中文(24小时): 86 532 8388 9090。 仅供参考使用。</p> <p>IT Filtrato a 0,2 µm e irradiato con raggi gamma a 10⁴ SAL INGREDIENTI: 100% acqua di qualità WFI Vedere il contenitore per il lotto e/ Data di scadenza/indicatore di irraggiamento uso Non per iniezione umana o animale, diagnostica, o uso terapeutico. Consultare la scheda di dati di sicurezza per informazioni aggiuntive sul prodotto e per le informazioni di primo soccorso. SSS: VEl-140-IT NUMERO DI EMERGENZA: +44 1235 239 670 (Europa), +44 1235 239 671 (Medio Oriente/Africa), Riservato a Uso Industriale</p> <p>DE Gefiltert mit 0,2 µm und Gamma- bestrahlt mit 10⁴ SAL BESTANDTEILE: 100% Wasser von WFI-Qualität Siehe Behälter für Lot #/ Haltbarkeitsdauer/ rote Bestrahlungsanzeige Nicht für Injektionen, diagnostische oder therapeutische Zwecke bei Menschen oder Tieren. Erste Hilfe und zusätzliche Produktinformationen finden Sie im Sicherheitsdatenblatt. SSS: VEl-140-DE NOTRUFNUMMER: +44 1235 239 670 (Europa), +44 1235 239 671 (Mittel- und Ostafrika) Nur für den Industriellen Gebrauch</p> <p>SV Steriliserat vid 0,2µm och gammabestrålad vid 10⁴ SAL INGREDIENSER: 100% vatten av WFI-kvalitet Se behållare för lot- och hållbarhetsdata/irradieringsindikator Inte för injektioner eller djurs injektion, diagnostik eller terapeutisk användning. Läs säkerhetsdatabladet för första hjälpen-instruktioner och ytterligare produktinformation. SSS: VEl-140-SV NÖDNUMMER: +44 1235 239 670 (Europa), +44 1235 239 671 (Mellanöstern/Afrika). Endast för industriell bruk</p> <p>DA Steriliseret ved 0,2 µm og gammabestrålet ved 10⁴ SAL INGREDIENSER: 100% WFI kvalitetsvand Se beholder til vare #/Hållbarhets/ rødt bestrålingsindikator Ikke til mennesker eller dyr injection, diagnostik eller terapeutisk brug. Se sikkerhedsdatabladet for førstehjælp og yderligere produktinformation. SSS: VEl-140-DA ALARMNUMMER: +44 1235 239 670 (Europa), +44 1235 239 671 (Melleøsten/Afrika). Kun til industriel brug</p> <p>NO Steriliseret over 0,2 µm og gasteriliseret med gammastraling til 10⁴ SAL INGREDIENSER: 100% sterilt vann for injeksjonsvæddet Se beholder for vare #/Hållbarhets/ rødt bestrålingsindikator Ikke for menneskelig eller dyrelig injeksjon, diagnostisk eller terapeutisk bruk. Se sikkerhetsdatabladet for førstehjelp og ytterligere produktinformasjon. SSS: VEl-140-NO NØDNUMMER: +44 1235 239 670 (Europa), +44 1235 239 671 (Først Midtøsten/Afrika). Kun for industriell bruk</p> <p>KO (한국어) 멸균 0.2µm에서 필터링 및 10⁴ SAL에서 감마 조사 성분: 100% WFI 품질의 물 용기에서 로트번호/유효기간/적색 표시를 확인하십시오 사람이거나 동물에게 주사, 진단 또는 치료용으로 사용하지는 않습니다. 응급 조치 및 추가 제품 정보는 안전 데이터 시트를 SSS: VEl-149-KO 긴급 연락 번호: +82 2 3479 8401. 산업 사용용만</p>	
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Case Label VAI-WFI-00 Rev 02/23

Any specific product label is available upon request.



16 oz Attached Trigger Spray
VAI-WFI-16Z



Product Labeling (Continued)

VAI® WFI Quality Water

Filtered at 0.2 microns, sterilized via gamma irradiation and lot tested for sterility and endotoxins

Ingredients:

WFI Quality Water 100%

Container and Product Sterilized and Distributed by:

Veltek Associates, Inc.

15 Lee Blvd.

Malvern, PA 19355-1234 USA

Tel: 1-610-644-8335

Fax: 1-610-644-8336

www.sterile.com

Made in USA

USE LIMITATIONS

Not for human or animal injection, diagnostic, or therapeutic use.

Net Contents: 16 oz (473 mL)

Reorder Number: VAI-WFI-SP-11Z

HAZARD & PRECAUTIONARY STATEMENTS

The contents of this can are under pressure. Keep away from flame or intense heat. Do not puncture or burn empty can. Do not store in direct sunlight or temperature above 120°F (49°C). Avoid freezing.

Spill/Exposure Emergency Response Service call CARECHEM24: 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)

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Product Labeling (Continued)

VAI® WFI Quality Water

Filtered at 0.2 microns, sterilized via gamma irradiation and lot tested for sterility and endotoxins

Ingredients:

WFI Quality Water 100%

Net Contents: 11 oz (325 mL)

Reorder Number: VAI-WFI-SP-11Z

Container and Product Sterilized and Distributed by:

Veltek Associates, Inc.

15 Lee Blvd.

Malvern, PA 19355-1234 USA

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ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet (SDS)
- Sample Lot Specific Documentation – Delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium



VAI's SCMD Family of Products

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 unit dose 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