VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STEEL-BRIGHT®

Stainless Steel Polish and Cleaner
Sterile 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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Product Description

VAI manufactures a sterile stainless steel polish and cleaner that is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, lab animal, and healthcare industries. **STEEL-BRIGHT®** has been developed for use in cleaning rotation cycles that demand a sterile stainless steel polish and cleaner to remove residue, spots, and stains in aseptic manufacturing areas and cleanroom operations. With sterile **STEEL-BRIGHT**, stainless steel can be restored to a residue free finish that will not rainbow or accumulate to a heavy build up. Surfaces will remain cleaner longer because there is no residue film to attract the soil. The gloss of the stainless steel is renewed and retained with wiping and buffing with no lasting powdery residue. **STEEL-BRIGHT** can also be used on chrome, brass, aluminum, and copper.

STEEL-BRIGHT is filled in ISO 7 cleanroom (Grade B), filtered, and subsequently terminally sterilized to 10^{-6} sterility assurance level. Each lot of **STEEL-BRIGHT** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STEEL-BRIGHT** is delivered each time with a lot specific Certificate of Conformance, Certificate of Sterility, and Certificate of Irradiation.

STEEL-BRIGHT is available in an 8 oz aerosol. This high quality, carbon dioxide propelled, aerosol spray can precipitate in a broad spray/mist without aspiration of the room's air during use. Non-aspiration ensures that the master reservoir of **STEEL-BRIGHT** remains sterile from the first drop to the last drop. Each sterile container of **STEEL-BRIGHT** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Quality and Manufacturing

- Filled in an ISO 7 cleanroom (Grade B)
- Filtered
- 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

STEEL-BRIGHT – Stainless Steel Polish and Cleaner	
Test	**Specifications**
Specific Gravity	0.8463 – 1.0463
Color:	Milky-White Foamy Emulsion
Odor:	Mild Petroleum Distillate with Lemon Scent
Irradiation Specified Dose (kGy)	Min: 25.0, Max: 50.0
Expiration Period:	3 years

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, conformance, and sterility data, tested to current USP compendium
- Available in an 8 oz aerosol that will not aspirate the room's air
- Specifically formulated as a sterile cleanroom formula
- Professional strength stainless steel cleaner
- Emulsion based cleaner that will not rainbow or accumulate to a heavy build up
- Brightens and polishes without leaving a powdery residue
- Pleasantly lemon scented
- Contains no acids or abrasives
- Available in a saturated wipe, see: **STEEL-BRIGHT®** Wipe

Uses

- Remove chemical residues and spotting and staining caused by water and oils on stainless steel
- Brighten and polish stainless steel
- Can also be used on chrome, brass, aluminum, and copper

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.

Ordering Information

STEEL-BRIGHT – Stainless Steel Polish and Cleaner		
Part Number	**Description**	**Qty/cs.**
SB-02	STEEL-BRIGHT, 8 oz Aerosol Spray/Mist, Sterile	24

SB-02


SB-02

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		
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

STEEL-BRIGHT®

Stainless Steel Polish and Cleaner

(Any specific product label is available upon request.)

STEEL-BRIGHT

STEEL-BRIGHT®

Sterile Cleanroom Formula

INGREDIENTS:
Distillates (petroleum), hydrotreated light parafinnic……..(CAS No.) 64742-47-8…….40-50%
White mineral oil……..(CAS No.) 8042-47-5……...5-<10%
Carbon dioxide…….(CAS No.) 124-38-9……<1.5%
D-Limonene…….(CAS No.) 5989-27-5…...0.25-0.45%

WARNING

Net Contents: 7.41 oz (210 g)
Reorder Number: SB-02
SDS#: SB-01112
Sterile

Made in USA

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

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8200 BB Lelystad, Nederland
Tel: +800-00888700
Fax: 1-610-644-8336
www.sterile.com

US and Foreign Patents, www.sterile.com/patents

In Canada, distributed by:
Canada Clean Room (CCR)
www.ccrcanada.com
Toll free # 888-595-8070

In Spain Distributed By:
Vestilab CRC S.L.U
Ctra Rubi-Terrassa BP-1503, Km. 19.4
08192 Sant Qurize del Valles (Barcelona)
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

Lubricant

Flammable aerosol. Causes skin irritation. May cause an allergic skin reaction. May cause drowsiness or dizziness. Toxic to aquatic life with long lasting effects. May displace oxygen and cause rapid suffocation.

PRECAUTIONS FOR USE:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Avoid breathing vapors. Wear eye protection, protective gloves, protective clothing. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. Contains D-Limonene(5989-27-5). May produce an allergic reaction.

FIRST AID

EYES: Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing, if eye irritation persists: Get medical advice/attention.

SKIN: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.

INGESTION: Do NOT induce vomiting. Do not give an unconscious person anything to drink. Rinse mouth. Obtain immediate medical attention.

INHILATION: Remove person to fresh air and keep comfortable for breathing. If symptoms persist, obtain medical attention.

Recommendations for Use

Use only as directed. Use in well ventilated area. Shake before using. Spray small amount to wet surface, clean with cloth. Polish with another clean, dry cloth. Do not use on pots, pans, or eating utensils.

Emergency Number:

For USA toll free: +1-866-928-0789 (24 hours). For Canada toll free: +1-800-579-742. For Americas: +1-215-207-0061. For Mexico: +52 55 5004 8763. For Europe: +44 1235 239 670 (for English and 23 European Languages) (24 hours) or +44 1235 239 671 (Arabic) (24 hours) . For Ireland: +353 (0)1 809 2166 (Available to the public 08.00-22.00). For Middle East/Africa: +44 1235 239 671 (24 hours). For China: 0532 8388 9090 or +86 512 8090 3042 (alternative). For Korea: +82 2 3479 8401 (24 hour, Korean). For Australia toll free: +61 2 8014 4558. For Hindi: 000 800 100 7479 (24 hours).

SDS: SB-01112

For Industrial Use Only.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Product Validation
- In-use Validation Report
- Safety Data Sheet # SB-01112
- Sample lot specific documentation packages including sterility, irradiation, and analytical data

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. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents