



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



Process2Wipe® IPA70

70% USP Isopropyl Alcohol and 30% Water for Injection
Pre-Saturated 100% Polyester Wipes and
Pre-Saturated Polyester Non-Woven Wipes

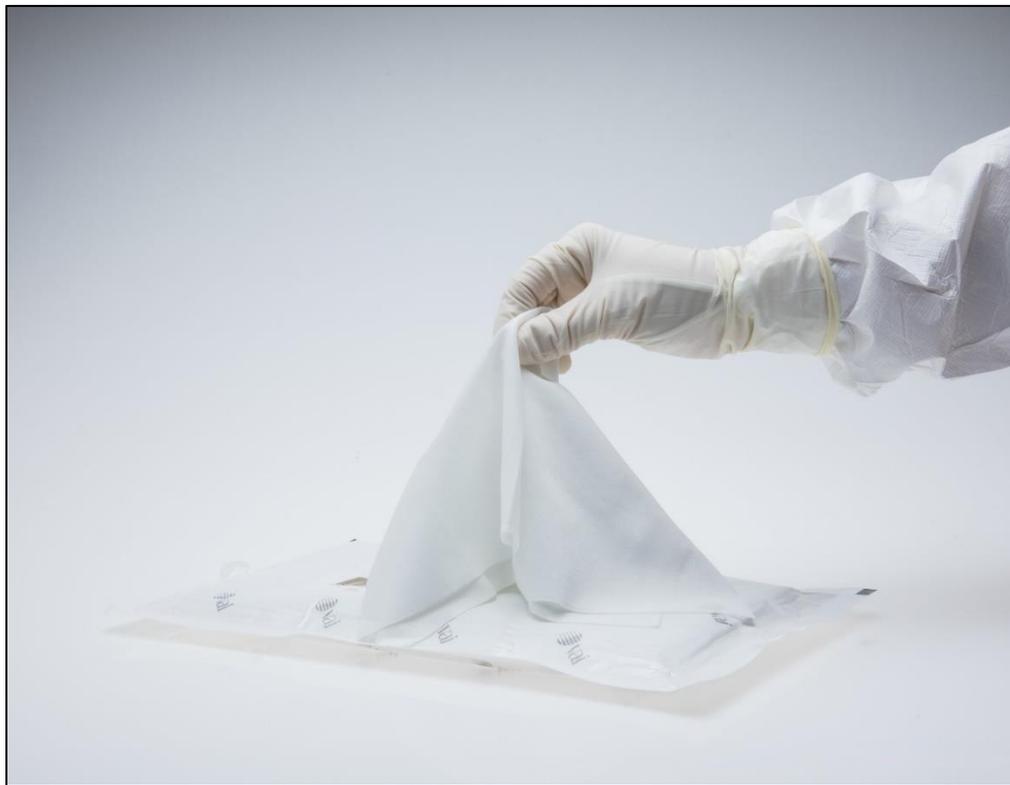
22NOV2022

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VAI Wipes

PRODUCT OVERVIEW

Process2Wipe® IPA70 wipes are ready-to-use and saturated with VAI®'s 70% USP Isopropyl Alcohol (IPA) and 30% USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, lexan, polycarbonate, glass, and any critical surface that requires cleaning. **Process2Wipe** pre-saturated wipes can prevent the overuse of chemicals and reduce costs.

Process2Wipe wipes are laundered and packaged in ISO 4 conditions, closed filled in an ISO 7 cleanroom (Grade B), and subsequently terminally sterilized to 10^{-6} sterility assurance level. Individual lots are completely traceable, sterility tested according to current USP compendium, and validated for sterility and shelf life. **Process2Wipe** wipes are delivered with lot specific analytical, irradiation, conformance, sterility data, and LAL data tested to current USP compendium.

Process2Wipe wipes are available in two sterile configurations: non-woven material or knitted material.

- The non-woven material is 100% polyester, white, clean, and absorbent. It has low shedding characteristics with minimal fiber and particulate release.
- The knitted material is a 100% continuous knit polyester filament that has been specifically designed to be exceptionally clean and absorbent. Particulates, residues, and foreign matter are effectively entrapped in the webbing of the material. The knit construction and pattern has been developed to ensure the greatest product integrity and cleaning performance while offering high resistance to abrasion and picking.

These wipes are cut using FocusEdge cutting technology. This cutting method does not heat the yarn bundles as high as lasers, therefore, eliminating the small plastic balls that form on the end of every yarn strand. Due to the wipe's sealed edges, shedding is minimal during wipe downs or general use, therefore, reducing particulates in controlled environments. After cutting, the wipes are then laundered in ISO 4 conditions to ensure cleanliness.



100% Polyester Wiper Substrate

Process2Wipe wipes are packaged in opaque, ported, resealable bags which allow for continued use after opening. Each sterile wiper bag is double bag packaged and available in our ABCD Cleanroom Introduction System® for easy introduction into the core or other critical environments.

- **Process2Wipe** 9" x 9" non-woven wipes packaged in peel and reseal style bags with 50 wipes/bag.
- **Process2Wipe** 9" x 9" wipes are packaged in peel and reseal style bags with 20 wipes/bag.
- **Process2Wipe** 12" x 12" wipes are available in peel and reseal style bags with 20 wipes/bag as well as a Zip-Lock style package with 30 wipes/bag.

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel, or any other critical surface that requires cleaning
- To prevent overuse of IPA when compared to using trigger sprayers or gallon pour bottles
- General wiping and contamination control

Quality and Manufacturing

- Laundered and packaged in ISO 4 conditions, closed filled in an ISO 7 cleanroom (Grade B)
- 70% USP Isopropyl Alcohol and 30% USP Water for Injection (<0.45 EU/mL) solution is filtered at 0.2 microns
- Gamma irradiated to 10^{-6} SAL
- Lot sterility tested according to current USP Compendium
- Completely lot traceable
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque bag
- Individually labeled with lot number and expiration
- Reduces VOC emissions
- Low endotoxins
- For use on multiple surfaces
- Wipes folded for easy removal
- Ready-to-use
- Delivered with lot specific analytical, irradiation, conformance, sterility data, and LAL data tested to current USP compendium

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.



Filling Port



Zip Lock Closure



Peel and Reseal Label on the Back of the Bag



VEL12-12X12-S-3023 Peel and Reseal Packaging



VEL12-12X12-S-3030 Zip-Lock Packaging

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234
Tel: 610-644-8335 Fax: 610-644-8335 www.sterile.com
22NOV2022

MATERIAL SPECIFICATIONS

Process2Wipe – Laundered Polyester Wipe – VEL12-12X12-S-3023	
Certificate of Conformance	Values *
Material Description	Laundered Polyester Wipe
Dimensions	12" × 12" (30.50 cm × 30.50 cm)
Sorbancy	>/= 270 mL/m ²
Particles	<4.5 × 10 ⁶ particles/m ²
Material	100% Polyester
Color	White
Classification Compatibility	Laundered and packaged in ISO 4 conditions, closed filled in an ISO 7 cleanroom (Grade B)
Construction	Continuous Filament Knitted Construction
Thickness	0.56 – 0.64 mm
Fibers @ 100 um/m ²	63, 1.0 IEST-RP-CC004.3, SEC 6.1.3/6.2.2

Process2Wipe – Hydroentangled Polyester Non-Woven – VEL12-9X9-S-3032	
Certificate of Conformance	Values *
Material Description	Laundered Polyester Wipe
Dimensions (ave.)	9" × 9" (23.3 cm × 22.4 cm)
Sorbancy	>/125 mL/m ²
Particles	<12 mm/m ² 0.5 micron
Material	100% Polyester
Color	White
Classification Compatibility	Laundered and packaged in ISO 4 conditions, closed filled in an ISO 7 cleanroom (Grade B)
Construction	Non-Woven
Thickness	0.51 mm
Fibers (via Biaxial Shake)	8710/m ² (@ 100 microns)
Basis Weight	2.0 oz/sq yard

* The test results listed above represent typical values obtained and are not product specifications.

CHEMICAL SPECIFICATIONS

Process2Wipe – 70% USP Isopropyl Alcohol and 30% Water for Injection	
Certificate of Analysis	Specifications
Appearance	Clear Colorless
Assay	68.0 – 72.0%
Acidity	</= 1.0 mL
Nonvolatile Residue	<5.0 mg
Specific Gravity @ 20 Degrees C	0.872 – 0.883
Expiration Period	2 years

ORDERING INFORMATION

Process2Wipe – 70% USP Isopropyl Alcohol and 30% Water for Injection		
Part Number	Description	Qty/Case
VEL12-12X12-S-3023	Process2Wipe IPA70 12" × 12", Peel and reseal packaging 20 wipes/bag, 10 bags/case, Sterile	200
VEL12-12X12-S-3030	Process2Wipe IPA70 12" × 12", Zip-Lock style packaging 30 wipes/bag, 10 bags/case, Sterile	300
VEL12-9X9-S-3036	Process2Wipe IPA70 9" × 9", Peel and reseal packaging 20 wipes/bag, 10 bags/case, Sterile	200
VEL12-9X9-S-3032	Process2Wipe IPA70 9" × 9", Non-Woven Peel and reseal packaging 50 wipes/bag, 20 bags/case, Sterile	1000



VEL12-12X12-S-3023

LABELING



Process2Wipe®

70% USP Isopropyl Alcohol and 30% Water for Injection

Any specific product label is available upon request.

Process2Wipe®
IPA70 STERILE

DANGER PELIGRO PERICOLO 위험
危險 GEFAHR FARE GEVAAR FARA

Net Contents/Contenu net: 9" x 9" (23cm x 23cm)
1000 wipes/wingettes (50 pk, 20pk/case)

Label # V022P2WIPW 00 - Rev 04/22
Patent/ Les Brevets: www.sterile.com/patents

EN
STERILE PHARMACEUTICAL CLEANROOM WIPE
70% Isopropyl Alcohol USP formulated with USP/EP WFI grade water
INGREDIENTS: Isopropyl alcohol (CAS # 67-63-0) 70%
Other ingredients: Water

DANGER. Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.

PRECAUTIONARY STATEMENTS: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear eye protection, protective glasses, protective clothing. IN CASE OF FIRE: Use alcohol resistant foam, carbon dioxide (CO2), Dry powder fire fighting. Store in a well-ventilated place. Keep cool. Dispose of contents and container in an authorized waste collection point. Red dot indicates Sterile

See container for lot #/ Expiration Date
R.U.P.C.S 495700
SDS: VEI 038 (America), VEI 038-03 (Europe)

EMERGENCY NUMBER:
1-888-828-0789 (toll free USA), 1-800-576-7120 (toll free Canada), 1-25-207-0100 (America), +44 125 236701 (Europe), +44 125 236701 (Middle east/Africa), +33 031 889 2168 (France). Available to the public 00-800-22-00, 000 800 300 7479 (India).

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

For Industrial Use Only

ZH(中文)
制药洁净室湿巾
使用 USP/EP WFI 品质的水配制的 70% USP 异丙醇
配料: 异丙醇 (CAS # 67-63-0) 70%
危险. 高度易燃液体和蒸气 造成严重眼刺激 可能造成昏昏欲睡或眩晕

使用注意事项: 远离热源、热表面、明火、火花。禁止吸烟 保持容器密闭 只能使用不产生火花的工具 采取防静电放电的措施 避免吸入 蒸气 作业后彻底清洗手部 只能在室外或通风良好之处使用 防护用品、防护用品、防护服 如皮肤(或头发)沾染,立即去除/脱掉所有沾染的衣服。用水清洗皮肤/淋浴 如误吸入,将受累人转移到空气新鲜处,保持呼吸舒适的休息姿势 如进入眼睛;用水小心冲洗几分钟。如戴隐形眼镜并可方便地取出,取出隐形眼镜,继续冲洗 如仍发眼刺激:就医/就诊 如感觉不适,呼叫解毒中心或医生 火灾时:使用泡沫、干粉灭火器、二氧化碳(CO2)、雾状水灭火。存放在通风良好的地方,保持容器密闭 保持低温 存放处须加锁 处置内装物/容器至经授权的废物收集点
危险类别: 41 - UN编码: 315

红点表示无菌
查看容器上的批号和失效日期
SDS: VEI 038

紧急电话号码:
溢出/漏洒应急电话号码 中文(24小时): +852 6388 9390

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

DE
STERILE PHARMAZEUTISCHES FEUERWEICHTUCH
70% USP-Isopropylalkohol formuliert mit Wasser von WFI-Qualität gemäß USP/EP
BESTANDTEILE:
Isopropylal (CAS # 67-63-0) 70%
GEFAHR. Flüssigkeit und Dampf leicht entzündbar. Verursacht schwere Augenreizung. Kann Schläfrigkeit und Benommenheit verursachen.

SICHERHEITSHINWEISE: Von Hitze, heißen Oberflächen, Funken, offenen Flammen sowie anderen Zündquellen fernhalten. Nicht rauchen. Bei Unfallschicht nicht essen, trinken oder rauchen. Augenschutz, Gesichtsschutz tragen. Bei KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Unter Verchluss aufrethaltung. Inhalt behälter autorisierter Abfallsammlungszentren.

Bitte ganz zugängliche
Sicherheitsblätter für Lot #/ Haltbarkeitsdatum
SDS: VEI 038-03

EMPFEHLUNGEN ZUR ANWENDUNG:
Alkoholresistente Schaum, Kohlendioxid (CO2), Pulverlöscher mit Wasser
+44 125 236701 (Europa)
+44 125 236701 (Mittlerer Osten/Afrika)

Weitere Informationen zum Produkt sind dem Sicherheitsdatenblatt.
Nur für den industriellen Gebrauch

FR
LINGETTE STERILE PHARMACEUTIQUE POUR SALLES BLANCHES
Alcool isopropylique 70% USP formulé avec de l'eau de qualité USP/EP WFI
INGREDIENTS: alcool isopropylique (CAS # 67-63-0) 70%
Autres ingrédients: Eau

DANGER. Liquide et vapeurs très inflammables. Provoque une sévère irritation des yeux. Peut provoquer somnolence ou vertiges.

CONSEILS DE PRUDENCE: tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'inflammation. Ne pas fumer. Éviter soigneusement le plein air ou être en contact avec un feu. En cas d'urgence, ne pas manger, boire ou fumer. Porter des lunettes de protection, des vêtements de protection. EN CAS D'IRRITATION: Rincer de la mouche résistante à l'alcool, du dioxyde de carbone (CO2), Pouvoir sèche pour l'extinction. Stocker dans un endroit bien ventilé. Tenir le récipient fermé et le transporter dans une installation de collecte des déchets autorisée.

Point rouge indique Stérile
Voir le conteneur pour le lot #/ date d'expiration
SDS: VEI 038-03 (Amérique), VEI 038-03 (Europe)
SDS: VEI 038-03 (Europe), VEI 038-03 (Europe)

NUMERO D'URGENCE:
1-888-828-0789 (sans frais USA), 1-800-576-7120 (Canada sans frais), 1-25-207-0100 (Amérique), +44 125 236701 (Europe), +44 125 236701 (Moyen-Orient/Afrique), +33 031 889 2168 (France) (disponible au public) 00-800-22-00, 000 800 300 7479 (Inde).

Consulter la fiche de sécurité pour d'autres informations sur le produit.
Réservé à un usage industriel

KO(한국어)
제약 클린룸 닦음
USP/EP WFI 품질의 물로 조성된 70% USP 이소프로필 알코올 성분 이소프로판올 (CAS # 67-63-0) 70%

위험. 고인화성 액체 및 증기. 눈을 자극할 수 있음. 졸음 또는 혼란을 일으킬 수 있음.

예방조치문구 (예방): 열·스파크·화염·고열로부터 멀리하십시오 - 금연. 욕지 또는 화기가 될 되는 곳에서만 취급하십시오. 보안경, 보호장갑, 보호의 및 (필) 착용하십시오 (취급): 눈에 물이 들어면 및 분간 물로 조심해서 씻으십시오. 가능한 모든 콘택트렌즈를 제거하십시오. 계속 씻으십시오. (보관): 잠금장치가 있는 저장장에 저장하십시오. (폐기): 하거나 폐기를 수거 지정 내용물과 용기를 폐기하십시오.

별간색 점은 멸균 상태를 나타냅니다. 용기에서 로트 번호 /유출 기간을 확인하십시오.
SDS VEI 038-03

유출/노출 긴급 대응 서비스:
+82-2479 9408 (24시간, 한국어).

응급 처치 및 추가 정보: 멸균 안전 데이터 시트를 참조하십시오

산업용으로만 사용하십시오

Case Label



**Sterile Pharmaceutical Cleanroom Wipe
70% Isopropyl Alcohol USP Formulated with USP/EP WFI Grade Water**



DANGER

INGREDIENTS

Isopropanol (CAS 67-63-0)..... 70%

Other Ingredients: Water

DANGER

Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.

PRECAUTIONARY STATEMENTS

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear eye protection, protective glasses, protective clothing. In case of fire: Use alcohol resistant foam, carbon dioxide (CO₂), Dry powder to extinguish. Store in a well-ventilated place. Keep cool. Dispose of contents and container to an authorized waste collection point. Red dot indicates Sterile

See container for lot #/Expiration Date

IRL PCS #96790

SDS: VEL-038

Emergency Number

1-866-928-0789 (toll free USA), 1-800-579-7421 (toll free Canada), 1-215-207-0061 (Americas), +52-55-5004-8763 (Mexico).

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

For Industrial Use Only

Patents: www.sterile.com/patents

Manufactured By

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

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, irradiation, conformance, sterility, and LAL data tested to current USP compendium



VAI®'s Wiper Family

Veltek Associates, Inc. *Disposable Products Manufacturing Division's* (DPMD) capabilities include sterile disposable garments, sterile disposable face masks, dry wipers, sterile wipers, custom cleanroom documentation, sterile synthetic writing substrate, and a HEPA filtered cleanroom printer. DPMD has responded and met demands of professionals in the industry since 1985. Our manufacturing capabilities assure that we will be able to meet all requests and fulfill all of our customer's needs. All DPMD products are processed and packaged in cleanroom facilities from beginning to end and subsequently gamma irradiated or aseptically filled in order assure sterility. For more information call 610-644-8335, email sales@sterile.com or visit our website at www.sterile.com. Patents: www.sterile.com/patents

Veltek Associates, Inc.

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