

SterileWipe™ LP 10

Knitted polyester wiper with sealed borders for critical sterile environments



Description

SterileWipe™ LP 10 is a 100% continuous-filament polyester wiper with thermally sealed borders that have been designed to control particle and fiber contamination. Each package is gamma irradiated to 10⁻⁶ Sterility Assurance Level.

SterileWipe™ LP 10 is used to clean critical sterile environments such as pharmaceutical aseptic fill areas, biotechnology manufacturing facilities, microbiological laboratories, sterile suites and prep rooms.

Features

- Gamma irradiated to 10⁻⁶ Sterility Assurance Level, according to AAMI Guidelines
- Lot-specific information on each shipment simplifies record keeping:
 - Certificate of Processing confirming radiation dosage
 - Certification of Compliance
 - Expiration date marked on each package
- Cleanroom-laundered 100% polyester knit with thermally sealed borders
- Independent quality control audits for sterility assurance

Benefits

- Withstands exposure to common cleaning and disinfecting solutions including bleaches, phenols and quaternary ammonium compounds
- Extremely low levels of releasable particles and fibers consistent with requirements for sterile Class 100 cleanroom environments
- Packaging permits alcohol wipedown of exterior bag before introduction of the inner bag into sterile suites
- Superior strength allows for rigorous wiping with minimal release of fibers and particles
- Wiper glides smoothly over surfaces
- Assures quality of individual lots and lot-to-lot traceability

Applications

- Developed to clean sterile environments without compromising the sterile nature of those environments
- Designed for cleaning and polishing equipment and environmental surfaces during and following the production flow
- Ideal for applying cleaning, sterilizing and disinfecting solutions

Products

TX Number	Description	Packaging
TX3212	SterileWipe™ LP 10 12" x 12" nominal (31 cm x 31 cm) polyester knit wipers with sealed edges	100 wipers/bag 5 inner bags of 20 wipers; 5 bags/case

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SterileWipe™ LP 10

TX3212

Performance Characteristics

Property	Typical Value	Test Method*
Basis weight	131 g/m ²	1, TM2
Absorbency		
Sorptive capacity	300 mL/m ²	1, TM3
Sorptive rate	5.1 seconds	1, TM3

Contamination Characteristics

Property	Typical Value	Test Method*
Particles and fibers		
Particles 0.5-5.0 µm	5 x 10 ⁶ particles/m ²	1, 2, TM15
5.0-100 µm	220,000 particles/m ²	1, 2, TM15
Fibers: >100 µm	120 fibers/m ²	1, 2, TM15
Nonvolatile residue		
IPA extractant	0.06 g/m ²	1, TM1
DIW extractant	0.02 g/m ²	1, TM1
Ions		
Sodium	0.25 ppm	1, TM18
Potassium	0.08 ppm	1, TM18
Chloride	0.05 ppm	1, TM18

Note: The data in this table represent typical analyses of these wipers at the time of publication. These are not specifications.
ITW Texwipe continually refines both its processes and its products.

*Test Methods

- 1 – “Evaluating Wiping Materials Used in Cleanroom and Other Controlled Environments,” IEST-RP-CC 004.3, Institute for Environmental Sciences and Technology, Rolling Meadows, IL 2004; www.iest.org.
- 2 – “Standard Method for Size-Differentiated Counting of Particles and Fibers Released from Clean Room Wipers Using Optical and Scanning Electron Microscopy,” E2090-00, ASTM International, West Conshohocken, PA, 2000; www.astm.org.
- TM – Refers to ITW Texwipe Test Method — available upon request, contact ITW Texwipe Customer Service at www.texwipe.com for a copy.

ITW Texwipe is the only wiper company to be ISO 9001:2000, 13485:2003, 14001:2004 and OHSAS 18001:1999 registered.

Sterile AlphaSat® 10 with WFI

SterileWipe™ LP 10 wipers pre-wetted with 70% IPA and 30% WFI



Applications

- Developed to clean sterile environments without compromising the sterile nature of those environments
- Designed for cleaning production equipment and environmental surfaces in a sterile environment during and following the production flow
- Ideal for wiping gloved hands

Description

Sterile AlphaSat® 10 with WFI incorporates SterileWipe™ LP 10 sealed-border wipers pre-wetted with 70% USP Isopropyl Alcohol (IPA) and 30% Water for Injection (WFI) in a resealable flatpack package. SterileWipe™ LP 10 is a 100% continuous-filament polyester wiper with thermally sealed borders that have been designed to control particle and fiber contamination. Each case of wipers is triple-bagged and gamma irradiated to a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11137-1994.

Sterile AlphaSat® 10 with WFI is used to clean critical sterile environments in pharmaceutical aseptic processing areas, biotechnology manufacturing facilities, microbiological laboratories, and prep rooms.

Features

- Lot-specific information on each case simplifies record keeping:
 - Certificate of Processing confirms radiation dosage
 - Certificate of Compliance
 - Certificate of Analysis
 - Expiration date marked on each package
- Pre-wetted with 0.2 μ m filtered 70% IPA/30% WFI by volume
- Cleanroom-laundered 100% polyester knit with thermally sealed borders
- Triple-bagged for easy entry into sterile environments
- Independent quality control audits for sterility assurance

Benefits

- Eliminates blending, filtration, processing and QC expense of in-house production of IPA solutions
- Optimizes solution usage and eliminates overspray of alcohol
- Reduces IPA spill potential and eliminates the storage and disposal of excess solvents
- Superior wiper strength allows for rigorous wiping with minimal release of fibers and particles
- Wiper glides smoothly over surfaces
- Extremely low levels of releasable visible fibers consistent with requirements for sterile ISO Class 4 (Class 10) and higher cleanroom environments
- Packaging permits alcohol wipedown of exterior bag before introduction of inner bag to sterile suites
- Assures quality of individual lots and lot-to-lot traceability

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Products

TX Number	Description	Packaging
TX3280	Sterile AlphaSat® 10 with WFI 12" x 12" nominal (31 cm x 31 cm) polyester sealed-border wipers pre-wetted with 70% IPA/30% WFI	50 wipers/flatpack; 5 flatpacks/case, triple-bagged

Sterile AlphaSat® 10 with WFI

TX3280

Product Specifications

Property	Description
IPA Quality	Meets the requirements of USP Isopropyl Alcohol
Water Quality	Meets the requirements of USP Water for Injection
Appearance	Clear, colorless liquid
Odor	Characteristic alcohol
% IPA Content	68%–72%
Endotoxin levels	<0.25 EU/mL
Specific Gravity (20°C)	0.872–0.883
Acidity	Not more than 1.0 mL of 0.020 N Sodium Hydroxide
Limit of NVR	Does not exceed 5 mg (0.01%)

Certificates of Analysis provided with every lot.

ITW Texwipe is the only wiper company to be ISO 9001:2000, 13485:2003, 14001:2004 and OHSAS 18001:1999 registered.

Sterile AlphaSat® 10

Sealed-border polyester wipers pre-wetted with 70% IPA in a small resealable package



Benefits

Sterility

- Pre-sterilized for aseptic and sterile environments
- Eliminates preparation, documentation and validation of in-house production of pre-wetted wipers

Wipers

- Superior strength for rigorous wiping without snagging on equipment
- Wiper glides smoothly over surfaces with low abrasion
- Extremely low levels of releasable visible fibers consistent with requirements for sterile ISO Class 3-5

Pre-wetted with 70% IPA

- Optimizes IPA use for effective particulate removal
- Eliminates overspray of alcohol typical of the use with dry wipers
- Safer to store and handle than IPA bottles
- Eliminates IPA spills
- Reduces IPA waste and disposal

Packaging

- Sized appropriately for limited isolator space
- Packaging permits alcohol wipedown of exterior bag before introduction of inner bag to isolator

Quality Assurance

- Assures quality of each lot
- Lot-to-lot traceability

Description

Sterile AlphaSat® 10 features 9" x 9" SterileWipe™ LP 10 sealed-border wipers with 70% USP Isopropyl Alcohol (IPA) in a small resealable flexpack. SterileWipe LP 10 is a 100% continuous-filament polyester wiper with thermally sealed borders. It is engineered to have the lowest level of releasable particles and fibers for critical and sterile environments.

Sterile AlphaSat 10 wipers are designed to clean ISO Class 3-5 cleanroom environments including the interiors of Compounding Aseptic Isolators (CAIs), aseptic isolators in pharmaceutical manufacturing, and Biological Safety Cabinets (BSCs). The small footprint of the 7" x 13" flexpack optimizes the valuable space inside isolators.

Each case of Sterile AlphaSat 10 is gamma irradiated to a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11137.

Features

Wipers

- Cleanroom-laundered 100% polyester knit with thermally sealed borders
- Pre-wetted with 0.2 μ m filtered 70% IPA
- Gamma irradiated to a Sterility Assurance Level of 10^{-6}

Packaging

- Small resealable flexpack package
- Double-bagged for easy entry into aseptic and sterile isolators

Quality Assurance

- Lot-specific information on each case simplifies record keeping:
 - Certificate of Processing confirms radiation dosage
 - Certificate of Compliance
 - Expiration date marked on each package
- Independent quality control audits for sterility assurance

Applications

- Clean interiors of sterile and aseptic isolators
 - Compounding Aseptic Isolators (CAIs)
 - Aseptic isolators in pharmaceutical manufacturing
 - Biological Safety Cabinets (BSCs)
- Contain spills inside isolators
- Wipe gloved hands prior to inserting hands in isolator sleeves and gloves

Products

TX Number	Description	Packaging
TX3285	Sterile AlphaSat® 10 9" x 9" nominal (23 cm x 23 cm) polyester sealed-border wipers pre-wetted with 70% IPA	20 folded wipers/flexpack; 20 flexpacks/case, double-bagged

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Sterile AlphaSat® 10

TX3285

Product Specifications

Property	Description
IPA Quality	Meets the requirements of USP Isopropyl Alcohol
Water Quality	Meets the requirements of USP Purified Water
Appearance	Clear, colorless liquid
Odor	Characteristic alcohol
% IPA Content	68%–72%
Specific Gravity (20°C)	0.872–0.883
Acidity	Not more than 1.0 mL of 0.020 N Sodium Hydroxide
Limit of NVR	Does not exceed 5 mg (0.01%)

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