

Sterile TexTra™ 10

Sterile Wipe For Spill Control in ISO 3-5.



Benefits

Sterility

- Pre-sterilized for aseptic and sterile environments
- Eliminates preparation, documentation and validation of autoclaving wipers

Wipers

- Large wiper size and liquid capacity simplify the application and removal of large volumes of cleaning and disinfecting solutions
- Superior wiper strength allows for rigorous wiping with minimal release of particles and fibers
- Extremely low levels of releasable visible fibers consistent with requirements for sterile ISO Class 3-5 environments
- Withstands exposure to common cleaning and disinfecting solutions including bleaches, phenols and quats

Packaging

- Packaging permits alcohol wipedown of exterior bag before introduction of inner bag to sterile environments

Quality Assurance

- Assures quality of individual lots and lot-to-lot traceability



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Description

Sterile TexTra™ 10 is a single-ply, double-knit, 100% continuous-filament polyester wiper that offers high-capacity sorption in a sealed-border wiper designed to prevent particle and fiber release. It is an alternative to two-ply polyester wipers.

Sterile TexTra 10 provides premium performance in such Class 3-5 environments as pharmaceutical aseptic fill areas, biotechnology manufacturing facilities and microbiological laboratories.

Each case of wipers 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
- Absorbency of a two-ply wiper
- Good abrasion resistance
- Gamma irradiated to a Sterility Assurance Level of 10^{-6}

Packaging

- Double-bagged in solvent-safe bags
- Header strip protects wipers that remain in bag after opening

Quality Assurance

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

Applications

- Engineered for high-sorption use in ISO Class 3-5 environments
- Designed for sterile wiping of environmental surfaces and production equipment in aseptic fill areas
- Ideal for applying and removing large volumes of cleaning and disinfecting solutions
- Spill control
- Sorptive work surface

Product

Number	Description	Packaging
TX3224	Sterile TexTra™ 10 9" x 9" nominal (23 cm x 23 cm) polyester wipers with thermally sealed borders	100 wipers/bag (5 inner bags of 20 wipers) 5 bags/case 500 wipers total/case
TX3225	Sterile TexTra™ 10 12" x 12" nominal (31 cm x 31 cm) polyester wipers with thermally sealed borders	100 wipers/bag (5 inner bags of 20 wipers) 5 bags/case 500 wipers total/case

Sterile TexTra™ 10

Performance Characteristics

Property	Typical Value	Test Method*
Basis weight	233 g/m ²	1, TM20
Absorbency		
Sorpative capacity	600 mL/m ²	1, TM20
Sorpative rate	0.3 seconds	1, TM20

Contamination Characteristics

Property	Typical Value	Test Method*
Particles and fibers		
Particles 0.5-5.0 µm	8 x 10 ⁶ particles/m ²	1, 2, TM15
5.0-100 µm	220,000 particles/m ²	1, 2, TM15
Fibers: >100 µm	240 fibers/m ²	1, 2, TM15
Nonvolatile residue		
IPA extractant	0.07 g/m ²	1, TM1
DIW extractant	0.04 g/m ²	1, TM1

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.