

Sterile Vertex® Cleanroom Wipers with 70% Ethanol

TECHNICAL DATA SHEET



Ethyl Alcohol (Ethanol)

Applications

- ► Cleaning equipment and environmental surfaces
- Final wipedown after disinfection
- ► Removal of culture residue from contact plates

Amebocyte Lysate (LAL) endotoxin testing

Wiping gloved hands

Description

TX3044P cleanroom wipers, Sterile Vertex with 70% Denatured Ethanol, are made in the USA from a uniquely designed polyester fabric with a very soft feel.

Fabric highlights:

- 100% continuous-filament, polyester knit fabric
- Pre-wetted with 70% denatured ethanol
- 12" x 12" (31cm x 31cm)
- Made in USA

Ethanol

Ethanol is an effective cleaning agent, while being less toxic and irritating to the eyes than IPA.

Ethanol has a better safety profile than IPA. The OSHA Permissible Exposure Limit (PEL) is 2.5 times that of IPA, meaning operator exposure can be longer and with higher concentration solutions. It also offers decreased eye irritation as compared to IPA.

1. PEL for 8 hours: EtOH - 1000 ppm, IPA - 400 ppm 2. 24 hour exposure: EtOH - 500 mg, IPA - 100 mg

of not more than 20 EU/device

Vertex®

Benefits

Texwipe's revolutionary Vertex® process manufactures cleanroom wipers in a fully automated ISO Class 3 micro-environment. Sterile Vertex is packaged in an easy-to-use resealable slider bag with a security seal and small footprint. Quarterly Agar Overlay and LAL testing assures that wipers do not contribute cytotoxic leachables and are nonpyrogenic.

Features

| ► 70% Ethyl Alcohol | ► Ethanol is less toxic and irritating to eyes than IPA |
|---|--|
| ► 100% polyester knit with a soft feel | ▶ Ideal for use with delicate surfaces or applications |
| ► Gamma irradiated in accordance with ANSI/AAMI/ISO 11137 | ▶ Meets Sterility Assurance Level of 10 ⁻⁶ |
| Certificates of Processing and Compliance attached to each case | Confirms radiation dose met specified dose at time of receiving |
| Quarterly microbial testing by Agarose Overlay and Limulus | Meets FDA Guideline for medical device bacterial endotoxin limit |

Products

| Number | Description | Packaging |
|--|-------------|----------------------------|
| TX3044P Sterile Vertex® 12" x 12" nominal (31 cm x 31 cm) sealed-edge wipers pre-wetted with 70% USP-Grade Denatured Ethyl Alcohol and USP Purified Water, triple-bagged | | 25 wipers/bag, 5 bags/case |

North America: 1210 South Park Drive, Kernersville, NC 27284 ● Tel 336.996.7046 ● Fax 336.996.2297

Europe/Middle East: Saffierlaan 5, 2132 VZ Hoofddorp, The Netherlands ● Tel +31 88 1307 400 ● Fax +31 88 1307 499

Asia/Pacific: ITW Singapore (Pte) Ltd., 500 Chai Chee Lane, Singapore 469024 ● Tel +65 6468 9433 ● Fax +65 6468 6772



Sterile Vertex® Cleanroom Wipers Pre-wetted with 70% Ethanol

HNICAL ΤA SHEET TX3044P

Vertex® Dry Wipers

Performance and Contamination Characteristics

| Property | Typical Value | Test Method* |
|--|--------------------------|------------------|
| Absorbency Sorptive capacity Sorptive rate | 450 mL/m² 0.3 seconds | 1,TM20 1,TM20 |

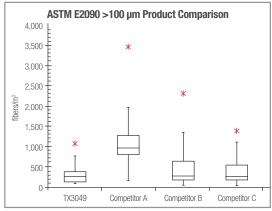
Note: The data in these tables represent typical analyses of these wipers at the time of publication. These are not specifications.

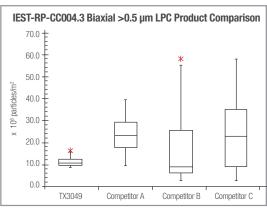
*Test Methods

- IEST-RP-CC004.3, 2004; www.iest.org.
- ASTM E2090-06, 2006; E2090-06, ASTM International; www.astm.org.
- TM Texwipe Test Method available upon request. Visit www.texwipe.com or contact Texwipe Customer Service at + 1-336-996-7046.

| Property | Typical Value | Test Method* |
|--|--|----------------------------------|
| гторенц | Typical value | 1691 MEHION |
| LPC ≥0.5 µm | 9.5 x 10 ⁶ particles/m ² | 1,TM22 |
| Particles and fibers Particles 0.5–5.0 µm 5.0–100 µm Fibers >100 µm | 3.0 x 10 ⁶ particles/m ² 66,000 particles/m ² 200 fibers/m ² | 1,2,TM22 1,2,TM22 1,2,TM22 |
| Nonvolatile residue IPA extractant DIW extractant | 0.02 g/m ² 0.01 g/m ² | 1,TM1 1,TM1 |

Wiper Consistency Data

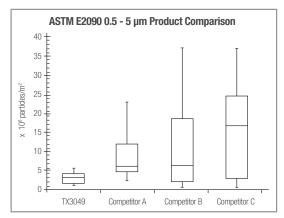


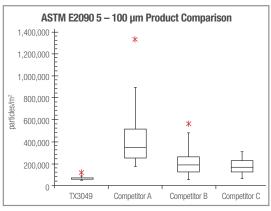


The components of a Consistency Chart are:

- ► Line represents the median or middle value of a ranked data set.
- ► Box represents the range of values in which fifty percent of the data lie.
- ► Whisker the line at each end of the box, expresses a range of values in which twenty-five percent of the data set lie.
- Outlier indicates points that are significantly different than the rest of the data set.

Lower medians, smaller boxes and shorter whiskers together indicate cleaner and more consistent wipers.





Texwipe Regulatory Certificates