

TECHNICAL DATA SHEET

# DENATURED ETHANOL Sterile

**Cleanroom Solutions** 



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**Denatured Ethanol** 

### TECHNICAL SHEET DATA





Products					
Number	Description	Sterile	Packaging	Case	
Sterile Denatured Ethanol					
TX3265	70% Denatured Ethanol, sterile		32 fluid ounces (946 mL) trigger spray	12 bottles / case	
TX3267	70% Denatured Ethanol, sterile		16 fluid ounces (473 mL) trigger spray	12 bottles / case	





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**Denatured Ethanol** 

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### **Description**

Sterile, ready-to-use 70% denatured ethanol (EtOH) solution designed especially for cleanroom use. Filtered through 0.2 micron filter, individually double-bagged and gamma-irradiated to ensure sterility. Made using USP components and packaged in an ISO Class 5 cleanroom.

USP-grade ethanol is denatured with USP-grade isopropyl alcohol according to the US Code of Federal Regulations 27 CFR 21.37 Formula No. 3-C.

Texwipe does not use methanol to make denatured ethanol.

### **Applications**

- Surface cleaning and residue removal
- Use on gloved hands in sterile suites
- Wipe down for pass through to controlled environments
- Ideally suited for use with sterile cleanroom wipers

### **Industries**

Aerospace	Animal Laboratory	Biologics
Cleanroom Design/Build	Compounding Pharmacies	Data Storage
Facilities Maintenance	Industrial	Laboratory
Medical Device	Microelectronics	Pharmaceutical
Printing/Graphics	Semiconductor	USP <797> / USP <800>

Find more information on Ethanol products here.

### **Features & Benefits**

- Filled in an ISO Class 5 environment; 0.2 μm filtered
- Individually double bagged and gamma irradiated to a Sterility Assurance Level of 10<sup>-6</sup> according to AAMI guidelines
- Evaporates leaving low residue
- Trigger sprayer bottles are fully assembled and ready-to-use
- Trigger sprayers offer stream delivery or coarse spray
- Meets USP <797> and USP <800> requirements
- Individually lot coded for ease of traceability and quality control
- Each lot tested for endotoxins

### **Sterility Assurance**

- Gamma irradiated to a Sterility Assurance Level of 10<sup>-6</sup> according to AAMI Guidelines
- Sterile Validation Documentation **available upon request**
- Certificates of Compliance, Analysis and Processing/ Irradiation available at www.texwipe.com/certifications

### **Cleanroom Environment** Sterile

- ISO Class 3 − 8
- Class 1 − 100.000
- EU Grade A D

### **Shelf Life**

• 2 years from date of manufacture





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Product Characteristics				
Property	Description			
Ethanol Quality	Meets the requirements of USP-grade Ethanol			
Water Quality	Meets the requirements of USP-grade purified water			
Isopropyl Alcohol (IPA) Quality	Meets the requirements of USP-grade IPA			
Appearance	Clear, colorless liquid			
Odor	Characteristic alcohol			
% Ethanol Content	68% – 72%			
% IPA Content	3.4% – 3.6%			
Specific Gravity	0.869 - 0.882			
Acidity	Not more than 1.0 mL of 0.02 N Sodium Hydroxide			
Limit of Non-Volatile Residue (NVR)	Does not exceed 2.5 mg in 50 mL (0.01%)			

Note: The data in this table represent typical analyses.

Test Methods: Available upon request. Contact Texwipe Customer Service at www.texwipe.com or info@texwipe.com for a copy.

## **Storage Conditions**

Store at ambient conditions, defined as temperatures between 59°F (15°C) and 86°F (30°C). Since there is a flammable liquid present, please follow all Federal, State, Provincial, local, and internal guidelines.

Texwipe holds ISO 9001:2015 registration.

All Texwipe products conform to GHS classification for labeling. Country-specific GHS information is included on the inside pages of both product labels. Shipping classification based on weight of inner package.





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