



# Contec® Sterile 70% Denatured Ethanol

**Contec® Sterile 70% Denatured Ethanol is adapted for use in critical clean environments and recommended for regular, effective, rapid removal of surface residues and contaminants on:**

Hard surfaces of cleanrooms, isolators, laminar flow cabinets, Restrictive Access Barrier System (RABS), filling lines

*'The sanitation of clean areas is particularly important. They should be cleaned thoroughly in accordance with a written programme.'*\*

Gloved hands

Products and equipment before transfer into controlled environments

*'The transfer of materials into and out of the unit is one of the greatest potential sources of contamination.'*\*

*As standard disinfection procedure, a combination of spraying and wiping should be employed at least once in the transfer process.*\*\*



70% v/v Denatured Ethanol blended with Purified Water  
Conforms to the European Pharmacopoeia

FEATURES	BENEFITS
Ready to use with a 2 year shelf life	<ul style="list-style-type: none"> <li>Eliminates mixing, filtration, processing and QC expense of in-house production. Allows easy inventory management</li> </ul>
Filled in a Grade C (ISO Class 7) Cleanroom, 0.2 micron filtered and gamma irradiated not less than 25 kGy using validated processes	<ul style="list-style-type: none"> <li>Ensures denatured ethanol, container and packaging are free from particulate contamination and are sterile</li> </ul> <p><i>'Disinfectants and detergents used in grades A and B areas should be sterile prior to use'</i>.*</p>
Endotoxin level less than 0.25 EU/ml and residue-free	<ul style="list-style-type: none"> <li>Suitable for use during critical manufacturing processes</li> </ul>
Denatured with only isopropanol and no other additives	<ul style="list-style-type: none"> <li>Extremely low residue on evaporation, comparable with EP ethanol</li> </ul>
Does not contain denatonium benzoate or MEK	<ul style="list-style-type: none"> <li>Suitable for use in critical applications</li> </ul>
Each bottle is labelled with the batch no. and expiration date. Certificates of analysis, irradiation and sterility (EP method) with each batch	<ul style="list-style-type: none"> <li>Assures complete product traceability and provides assurance of product quality</li> </ul>
Filled bottles are enclosed in two sealed, protective linear-tear bags	<ul style="list-style-type: none"> <li>Enables serial transfer into critical areas and easy opening when wearing cleanroom gloves</li> </ul>
Co-extruded flexible inner bag and solid outer bottle with modified trigger create an 'airless' system	<ul style="list-style-type: none"> <li>Prevents bottle contents becoming contaminated during use. No requirement to discard unused product during shelf life.</li> </ul>
Ergonomic bottles designed in optimised sizes, with lock-caps and no pressurized propellants	<ul style="list-style-type: none"> <li>Convenient, comfortable, easy to use, cost effective, secure, economical waste disposal</li> </ul>
Spray or jet options dispensing larger size droplets of fast drying isopropanol	<ul style="list-style-type: none"> <li>Facilitates process standardisation and optimised production efficiency</li> </ul>

## Ordering Information

Part No.	Description	Quantity
SBT170DE	Sterile bottle with trigger, 70% denatured ethanol, 1L	6 x 1L / case
SBC570DE	Sterile bottle with cap, 70% denatured ethanol, 5L	2 x 5L /case

## Product Application

Apply directly to the surface ensuring even coverage.

Physically remove contaminants from the surface using an appropriate cleanroom wipe and a recommended wiping technique for optimum contamination control.

*The use of a wiping stage that follows a spraying stage is recommended because any spores that may have been washed away on a surface on spraying can be picked up and removed with the use of a wipe.\*\**

Contec offers a range of innovative wipes and mopping systems designed for efficient and effective cleaning in controlled environments. See [www.contecinc.com](http://www.contecinc.com) or contact your local sales representative for advice and information about the most suitable products and cleaning techniques for your facility.



## References

**\* Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007:**  
Section II, Part 1, Annex 1: Manufacture of Sterile Medicinal Products:

**\*\*Evaluation of Disinfecting Procedures for Aseptic Transfer in Hospital Pharmacy Departments**  
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