

InSpec™ DE

Description

Sterile Denatured Ethanol 70% v/v with WFI Quality Water

Rapid Action, Low Residue, Fast Drying, Alcohol Disinfectant.

InSpec™ DE is a sterile preparation of 70% Denatured Ethanol (DE) in 30% Water For Injection (WFI) quality water.

These products are supplied sterile, double bagged, gamma irradiated and provided with certificates of analysis, irradiation, sterility and endotoxin level.

InSpec™ DE is available in a 5L screw capped container, a 1L trigger spray or a 500ml trigger spray. The trigger spray bottle is designed to prevent contamination of the product with micro-organisms, which can survive in 70% alcohol. The trigger spray bottle has a validated in-use shelf life.

InSpec™ DE is manufactured in an ISO 6 Cleanroom, filled under an ISO 5 localised air shower in the ISO 6 background. Batch certified covering areas such as sterility, endotoxin and irradiation. Manufactured to GMP under an ISO 9001 quality system.



General Guidance

- ❑ **Use Instructions:** InSpec™ DE is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate bucket for mopping. 100ml concentrate makes up to 5L with water for mopping. Apply to surface to ensure complete coverage. Allow sufficient wet contact time before proceeding.
- ❑ **Appearance:** Clear liquid free from insoluble. Alcohol proportion: 70% +/- 1% v/v. The above data is typical of normal production and should not be taken as a specification.
- ❑ **Storage:** Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is provided in a separate Safety Data Sheet (SDS).
- ❑ **Safe Handling:** Always wear gloves and goggles or face protection. Always read the label and SDS before use.
- ❑ **Material Compatibility:** Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical File.

Benefits

- ❑ Low residue.
- ❑ Rapid action.
- ❑ Irradiation indicator.
- ❑ Manufactured to GMP.
- ❑ Tested according to EN1276, EN1650, EN13697.
- ❑ Defined shelf life.
- ❑ Validated in-use shelf life. Contents protected from “suck back” in 1 Litre trigger spray formats.
- ❑ Multiple bagged.
- ❑ Detailed technical file.
- ❑ Coded batch and manufacture date.

Technical User Information

- ❑ InSpec™ DE is a sterile ready to use disinfectant. This is 70% v/v alcohol solution in WFI quality water.
- ❑ InSpec™ DE is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.
- ❑ The solution is filtered aseptically through a 0.2 micron filter and gamma irradiated to a validated process (at 25kGy) to give a sterility assurance level SAL of 10⁻⁶.
- ❑ InSpec™ DE comes with key certification such as irradiation, sterility, endotoxin and analysis.
- ❑ Trigger spray has a validated 3 month in-use shelf life.
- ❑ For 5L screw cap bottles use the entire contents after opening.

Purchase Information

ID: DEWFIAUS-1LS
Packaging: 6 x 1Ltr Trigger Spray bottles/case