

Comprehensive Technical Resource Sheet for the Full Range of InSpec DE Liquid Formats



Features

- Low residue and rapid action
- Bactericidal and Fungicidal
- Validated 6 months 'in-use' sterility for 1L Trigger Spray Sterile formats
- All trigger spray formats presented as protected systems
- Manufactured with Water for Injection
- Multiple bags for cleanroom transfer
- Ideal surface and aseptic transfer disinfectants
- Manufactured in accordance with GMP
- Active substance compliant with Article 95 of the Biocidal Products Regulation (BPR)

Formulation

InSpec DE is a blend of BPR grade denatured ethanol with Water for Injection (WFI).

Active substance concentration: 70 % v/v denatured ethanol.

The formulation is consistent across the range with the same blend for sterile and non-sterile formats.

Instructions for Use

InSpec DE is a ready-to-use product, do not dilute.

Spray Bottles: Hold approximately 15cm to 20cm from area to be treated. Apply to surface to ensure complete coverage for the required contact times.

Screw Top Bottles: Pour into an appropriate container for mopping. Apply to floor to ensure complete coverage for the required contact times.

Material Compatibility

Application of InSpec DE products, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical File.

Standard	Contact Time
EN 1276 Bacteria	5 minutes
EN 13697 Bacteria	5 minutes
EN 13697 Fungi	15 minutes
EN 1650 Fungi	15 minutes

Safe Handling and Storage Information

Always read the label and Safety Data Sheet (SDS) before use.

Store upright in original closed containers away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the SDS.

Formulation Batch Release Specifications

The formulation is tested for the following specifications for batch release:

Specification	Release Parameters
SG	0.880 - 0.888
Concentration	68 - 72 % v/v
Colour	Colourless
Clarity	Clear
Odour	Alcoholic

Manufacturing Process

InSpec DE is manufactured in accordance with GMP in an ISO 5 cleanroom. The solution is filtered through a 0.2-micron filter at point of fill.

Sterility

The sterile formats of InSpec DE are gamma irradiated to a validated process (20-50kGy for 5L products, 25-45kGy for all other formats) to give a sterility assurance level SAL of 10⁻⁶.

Sterile InSpec DE products are tested for sterility and endotoxin for batch release.

The trigger spray formats have a validated 6-months 'in-use' sterility. This is delivered through a protected system of using "bag-in-bottle" technology and a membrane-filter trigger or by using a collapsible bag and a non-venting trigger.

For screw cap formats, use the entire contents in one session/4-hours to ensure sterility.

Products are double-bagged for the cleanroom transfer process.

Endotoxin

All sterile formats of InSpec DE are tested for endotoxin, with a release specification of < 0.25 EU/ml.

Certificates

Each batch of InSpec DE is provided with a Certificate of Analysis (COA) confirming batch release specifications and providing batch manufacturing information. The COAs for Sterile InSpec DE products contain information regarding the irradiation of the batch and the concentration, sterility and endotoxin test results.



Formats Available

The following formats of InSpec DE are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
Sterile Formats					
InSpec DE 1L	DEWFI10-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-bagged LDPE
InSpec DE 1L Dose	DEWFIDOSE-1LS	Screw Cap	6 x 1L Bottles	HDPE	Double-bagged LDPE
InSpec DE 5L	DEWFI10-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-bagged LDPE
InSpec DE 500ml	DEWFI1-500MLS	Trigger	8 x 500ml Bottles	HDPE	Double-bagged LDPE
InSpec DE 5L Bag	DEWFIBAG-5LS	Trigger	2 x 5L Bags	PE, PET Nylon	Double-bagged LDPE
Non-Sterile Formats					
InSpec DE 1L Non-Sterile	NSDEWFI-1L	Trigger	6 x 1L Bottles	PP and co-extruded resin	Single-bagged LDPE
InSpec DE 5L Non-Sterile	NSDEWFI-5L	Screw Cap	2 x 5L Bottles	HDPE	Single-bagged LDPE

Formats Available

Product	Code	Case Dimensions	Commodity Code	Cases per pallet Euro/UK	Dangerous Goods*
Sterile Formats					
InSpec DE 1L	DEWFI10-1LS	27cm x 19cm x 33cm 6.4Kg	22072000	64/60	UN 1170 Limited Quantity
InSpec DE 1L Dose	DEWFIDOSE-1LS	27cm x 19cm x 33cm 6.4Kg	22072000	64/60	UN 1170 Limited Quantity
InSpec DE 5L	DEWFI10-5LS	29cm x 20.5cm x 31cm 9.5Kg	22072000	52/51	UN 1170
InSpec DE 500ml	DEWFI1-500MLS	23.5cm x 23.5cm x 24.5cm 4.3Kg	22072000	60/80	UN 1170 Limited Quantity
InSpec DE 5L Bag	DEWFIBAG-5LS	35.5cm x 32.5cm x 35cm 9.5Kg	22072000	18/18	UN 1170
Non-Sterile Formats					
InSpec DE 1L Non-Sterile	NSDEWFI-1L	27cm x 19cm x 33cm 6.4Kg	22072000	64/60	UN 1170 Limited Quantity
InSpec DE 5L Non-Sterile	NSDEWFI-5L	29cm x 20.5cm x 31cm 9.5Kg	22072000	52/51	UN 1170

*Limited quantity applies to inner packaging of 1L or less for products classed as UN 1170