

### Comprehensive Technical Resource Sheet for the Full Range of InSpec DE Wipes Formats.



#### Features

- Low residue and rapid action
- Manufactured with Water for Injection
- Multiple bags for cleanroom transfer
- Ideal surface and aseptic transfer disinfectant
- Manufactured to 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 all sterile and non-sterile formats.

#### Instructions for Use

Remove from outer bags. For efficient wiping, wipe in one direction using parallel, overlapping strokes starting from the cleanest area and wiping towards the least clean area. Use a clean wiper surface for each wiping stroke. Apply to surface to ensure complete coverage for the required contact times. Dispose of contaminated wipes after single use.

#### 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.

#### Microbiological Minimum Efficacy Contact Times

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 wipes are 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 Wipes are gamma irradiated to a validated process (25-45kGy) to give a sterility assurance level SAL of 10<sup>-6</sup>.

Sterile InSpec DE wipe products are tested for sterility for batch release.

Use the entire contents in one session/ 4-hours to ensure sterility.

Multiple outer bag formats are available for the cleanroom transfer process.

#### Certificates

Each batch of InSpec DE Wipes is provided with a Certificate of Analysis (COA) confirming batch release specifications and providing batch manufacturing information.

The COAs for Sterile InSpec DE Wipe products contain information regarding the irradiation of the batch and the concentration and sterility test results.



## Formats Available

The following formats of InSpec DE Wipes are available:

Product	Code	Wipe Material	Number of Wipes	Bags and Material	Pouch Material	Number of pouches per case
<b>Sterile Formats</b>						
InSpec DE Pouch Wipes	DEWFIPCH15S	55% cellulose 45% polyester	15	Double-bagged LDPE	LDPE and PET Laminate	25
InSpec DE Pouch Wipes	DEWFIPCH50S	55% cellulose 45% polyester	50	Double-bagged LDPE	LDPE and PET Laminate	16
InSpec DE Tub Wipes	DEWFI12TB200S	Blend of cellulosic and synthetic fibres	200	Double-bagged LDPE	HDPE	12
<b>Non-Sterile Formats</b>						
InSpec DE Pouch Non-Sterile	NSDEWFIPCH15	55% cellulose 45% polyester	15	Double-bagged LDPE	LDPE and PET Laminate	25
InSpec DE Pouch Non-Sterile	NSDEWFIPCH50	55% cellulose 45% polyester	50	Double-bagged LDPE	LDPE and PET Laminate	16

## Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per Pallet Euro/UK	Dangerous Goods*
<b>Sterile Formats</b>					
InSpec DE Pouch Wipes	DEWFIPCH15S	37.5cm x 27cm x 19cm 5.8Kg	22072000	32/50	UN 1170 Limited Quantity
InSpec DE Pouch Wipes	DEWFIPCH50S	37cm x 25.2cm x 26cm 9.6Kg	22072000	32/40	UN 1170 Limited Quantity
InSpec DE Tub Wipes	DEWFI12TB200S	45.5cm x 35cm x 28cm 9.2Kg	22072000	16/24	UN 1170 Limited Quantity
<b>Non-Sterile Formats</b>					
InSpec DE Pouch Wipes Non-Sterile	NSDEWFIPCH15	37.5cm x 27cm x 19cm 5.8Kg	22072000	32/50	UN 1170 Limited Quantity
InSpec DE Pouch Wipes Non-Sterile	NSDEWFIPCH50	37cm x 25.2cm x 26cm 9.6Kg	22072000	32/40	UN 1170 Limited Quantity

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



## Wipe Material Specifications

Feature	Pouch Wipes	Tub Wipes
Product Codes	DEWFIPCH15S DEWFIPCH50S NSDEWFIPCH15 NSDEWFIPCH50	DEWFI12TB200S
Composition	55% cellulose 45% polyester	Blend of cellulosic and synthetic fibres
Basis Weight	68 gsm	23 gsm
Finish	-	-
Thickness	0.3 mm	125 microns
Absorption Capacity	288 mL/m <sup>2</sup>	390 %
Absorption Time	0.8 s	2.2 s
APC (Air Particle Count)	5.74 x 10 <sup>3</sup> counts/m <sup>2</sup> /cfm	-
LPC (Liquid Particle Count)	82.42 x 10 <sup>6</sup> counts/m <sup>2</sup>	-
Organics, FTIR	No Silicon, Oil, Amide or DOP detected	-
Fibre, Particles > 100µm	-	-
Non-volatile Residue NVR, in DI water	0.091 mg/g	-
Non-volatile Residue NVR, in IPA	0.431 mg/g	-
Ion Content - Chloride (Cl)	0.0012 mg/g	-
Ion Content - Sodium (Na)	No detection	-
Ion Content - Potassium (K)	No detection	-
Ion Content - Magnesium (Mg)	0.0500 mg/g	-
Ion Content - Calcium (Ca)	0.0660 mg/g	-