

### Comprehensive Technical Resource Sheet for the Full Range of InSpec IPA 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
- Product approved under the Biocidal Products Regulation (BPR)

#### Formulation

InSpec IPA is a blend of BPR grade isopropyl alcohol with Water for Injection (WFI).

Active substance concentration: 70 % v/v isopropyl alcohol.

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

#### Instructions for Use

InSpec IPA 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 IPA 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	0.872 - 0.883
Concentration	68 - 72 % v/v
Colour	Colourless
Clarity	Clear
Odour	Alcoholic

#### Manufacturing Process

InSpec IPA 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 IPA are gamma irradiated to a validated process (20-50kGy for 5L products, 25-45kGy for all other sizes) to give a sterility assurance level SAL of 10<sup>-6</sup>.

Sterile InSpec IPA 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.

Double and triple-bagged formats are available for the cleanroom transfer process.

#### Endotoxin

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

#### Certificates

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

The COAs for Sterile InSpec IPA products contain information regarding the irradiation of the batch and the concentration, sterility and endotoxin test results.



## Formats Available

The following formats of InSpec IPA are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
<b>Sterile Formats</b>					
InSpec IPA 1L	IPAWFI1-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-bagged LDPE
InSpec IPA 1L Dose	IPAWFIDOSE-1LS	Screw Cap	6 x 1L Bottles	HDPE	Double-bagged LDPE
InSpec IPA 1L Triple Bagged	IPAWFI3-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Triple-Bagged LDPE
InSpec IPA 5L	IPAWFI1-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-bagged LDPE
InSpec IPA 500ml	IPAWFI-500MLS	Trigger	8 x 500ml Bottles	HDPE	Double-bagged LDPE
InSpec IPA 500ml Flip Top Cap	IPAWFI-500FLP	Flip-Top Cap	8 x 500ml Bottles	HDPE	Double-bagged LDPE
InSpec IPA 5L Bag	IPAWFIBAG-5LS	Trigger	2 x 5L Bags	PE, PET Nylon	Double-bagged LDPE
<b>Non-Sterile Formats</b>					
InSpec IPA 1L Non-Sterile	NSIPAWFI-1L	Trigger	6 x 1L Bottles	PP and co-extruded resin	Single-bagged LDPE
InSpec IPA 5L Non-Sterile	NSIPAWFI-5L	Screw Cap	2 x 5L Bottles	HDPE	Single-bagged LDPE
InSpec IPA 500ml Flip-Top Cap Non-Sterile	NSIPAWFI-1LFLP	Flip-Top Cap	8 x 500ml Bottles	HDPE	Single-bagged LDPE

## Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per pallet Euro/UK	Dangerous Goods
<b>Sterile Formats</b>					
InSpec IPA 1L	IPAWFI1-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 1L Dose	IPAWFIDOSE-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 1L Triple Bagged	IPAWFI3-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 5L	IPAWFI1-5LS	29cm x 20.5cm x 31cm 9.5Kg	29051200	52/51	UN 1219
InSpec IPA 500ml	IPAWFI-500MLS	23.5cm x 23.5cm x 24.5cm 4.3Kg	29051200	60/80	UN 1219 Limited Quantity
InSpec IPA 500ml Flip Top Cap	IPAWFI-500FLP	23.5cm x 23.5cm x 24.5cm 4.8Kg	29051200	60/80	UN 1219 Limited Quantity
InSpec IPA 5L Bag	IPAWFIBAG-5LS	35.5cm x 32.5cm x 35cm 9.5Kg	29051200	18/18	UN 1219
<b>Non-Sterile Formats</b>					
InSpec IPA 1L Non-Sterile	NSIPAWFI-1L	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 5L Non-Sterile	NSIPAWFI-5L	29cm x 20.5cm x 31cm 9.5Kg	29051200	52/51	UN 1219
InSpec IPA 500ml Flip-Top Cap Non-Sterile	NSIPAWFI-1LFLP	23.5cm x 23.5cm x 24.5cm 4.3Kg	29051200	60/80	UN 1219 Limited Quantity

\*Limited quantity applies to inner packaging of 1L or less for products classed as UN 1219