

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



#### Features

- An exceptional non-oxidising biocide
- Bactericidal and fungicidal
- Validated 6 months 'in-use' sterility for trigger-spray formats
- Trigger spray formats presented as protected systems
- Ready-to-use (RTU) formats manufactured with Water for Injection
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec QT, HA and OX
- RTU and Concentrated formats available
- Manufactured in accordance with GMP
- Active substance compliant with Article 95 of the Biocidal Products Regulation (BPR)

#### Formulation

InSpec AN is an alcohol, chlorine and QUAT-free disinfectant. Ready-to-use formats blended with Water for Injection (WFI).

Active substance concentration, RTU formats: 0.2-0.3% w/w diamine.

Active substance concentration, concentrated formats: 6-7% w/w diamine.

#### Instructions for Use

InSpec AN is designed for spraying, wiping and mopping applications.

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 Cap versions: Pour into an appropriate container for mopping. 100ml concentrate added to 2.4L of water is required for mopping. 200ml concentrate added to 4.8L of water is required for mopping. Apply to surface to ensure complete coverage for the required contact times.

#### Material Compatibility

Application of InSpec AN 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 1650 Fungi	15 Minutes
EN 13697 Fungi	15 Minutes

#### Safe Handling and Storage Information

Always wear gloves and goggles or face protection. 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 Safety Data Sheet (SDS).

#### Manufacturing Process

InSpec AN 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.

#### Formulation Batch Release Specifications

Specification	Release Parameters
<b>RTU Formats</b>	
SG	0.990 - 1.010
Diamine Concentration	0.2 - 0.3% w/w
pH	8.8 - 10.5
Colour	Yellow Tint
Clarity	Clear
Odour	Typical
<b>Concentrate Formats</b>	
SG	1.015 - 1.029
Diamine Concentration	6 - 7% w/w
pH	≥ 10
Colour	Light Yellow
Clarity	Clear
Odour	Typical

#### Sterility

The sterile formats of InSpec AN 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<sup>-6</sup>.

Sterile InSpec AN products are tested for sterility for batch release.

The trigger spray formats have a validated 6-months 'in-use' sterility. The contents are protected using "bag-in-bottle" technology and a membrane-filter 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.



## Certificates

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

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

## Formats Available

The following formats of InSpec AN are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
<b>Sterile Formats</b>					
InSpec AN 900MLS	ANWF120-900MLS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-Bagged LDPE
InSpec AN 900MLS Dose	ANWFIDOSE-900MLS	Screw Cap	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec AN 5L	ANWF120-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
InSpec AN Concentrate 100ml	ANCNC20-100	Screw Cap	50 x 100ml Bottles	HDPE	Double-Bagged LDPE
InSpec AN Concentrate 200ml	ANCNC20-200	Screw Cap	50 x 200ml Bottles	HDPE	Double-Bagged LDPE
<b>Non-Sterile Formats</b>					
InSpec AN 900ML Non-Sterile	NSANWFI-900ML	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-Bagged LDPE
InSpec AN 5L Non-Sterile	NSANWFI-5L	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
InSpec AN Concentrate 100ml Non-Sterile	NSANCONC-100ML	Screw Cap	50 x 100ml Bottles	HDPE	Double-Bagged LDPE
InSpec AN Concentrate 200ml Non-Sterile	NSANCONC-200ML	Screw Cap	50 x 200ml Bottles	HDPE	Double-Bagged LDPE

## Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per Pallet Euro/UK	Dangerous Goods*
<b>Sterile Formats</b>					
InSpec AN 900MLS	ANWF120-900MLS	27cm x 19cm x 33cm 6.4Kg	38089490	64/60	Not classified as hazardous for transport
InSpec AN 900MLS Dose	ANWFI-DOSE-900MLS	27cm x 19cm x 33cm 6.4Kg	38089490	64/60	Not classified as hazardous for transport
InSpec AN 5L	ANWF120-5LS	29cm x 20.5cm x 31cm 10.8Kg	38089490	44/51	Not classified as hazardous for transport
InSpec AN Concentrate 100ml	ANCNC20-100	24cm x 24cm x 24cm 5.9Kg	38089490	60/80	UN 1903 Limited Quantity
InSpec AN Concentrate 200ml	ANCNC20-200	54cm x 25.5cm x 19cm 12.0Kg	38089490	24/24	UN 1903 Limited Quantity
<b>Non-Sterile Formats</b>					
InSpec AN 900ML Non-Sterile	NSANWFI-900ML	27cm x 19cm x 33cm 6.4Kg	38089490	64/60	Not classified as hazardous for transport
InSpec AN 5L Non-Sterile	NSANWFI-5L	29cm x 20.5cm x 31cm 10.8Kg	38089490	44/51	Not classified as hazardous for transport
InSpec AN Concentrate 100ml Non-Sterile	NSANCONC-100ML	24cm x 24cm x 24cm 5.9Kg	38089490	60/80	UN 1903 Limited Quantity
InSpec AN Concentrate 200ml Non-Sterile	NSANCONC-200ML	54cm x 25.5cm x 19cm 12.0Kg	38089490	24/24	UN 1903 Limited Quantity

\*Limited quantity applies to inner packaging of 1L or less for UN 1903