



## PRODUCT SPECIFICATION

### IMS 5L RFU STERILE

#### PRODUCT INFORMATION

##### PRODUCT DESCRIPTION

Sterile cleanroom 5L RFU containing 70% denatured alcohol and 30% water for injection.

This product was designed for use in the cleanroom transfer process and the disinfection of hard surfaces.

##### MANUFACTURING

The product is filled and capped in ISO 14644-1 Class 5 (in use) unidirectional airflow cabinets. Packaging is performed within an ISO 14644-1 Class 7 (in use) cleanroom.

The disinfectant is filtered through a 0.2 micron filter at the point of fill.

##### DISINFECTANT SPECIFICATION

70 v/v % IMS (Denatured alcohol Ethanol and Propan-2-ol) and Water for Injection (WFI) grade water.

Unless otherwise stated all Micronclean product labelling for IMS disinfectant products will refer to v/v % as this is the most accurate way of measuring alcohol and water solutions:

	v/v %	CAS No	% Tolerance	Notes
Ethanol (ethyl alcohol)	66.5	64-17-5	+/- 2.0%	@20°C
Propan-2-ol	3.5	67-63-0	+/- 2.0%	@20°C

##### PACKAGING

Primary packaging: natural HDPE bottle with tamper evident screw cap.

Secondary packaging: double bagged in polythene pouches.

## CleanGuard 2

##### STERILISATION DETAILS (if applicable)

Gamma Irradiation (minimum 25kGy).

##### QUALITY ASSURANCE

Product supplied under BS EN ISO 9001 registered systems.

##### SHELF LIFE

2 years from date of manufacture.

##### STORAGE CONDITIONS

Store in cool, well ventilated area. Keep trigger spray tightly closed. Keep away from sources of ignition.

##### HAZARD STATEMENT

Safety Information can be found on the Safety Data Sheet.

## PRODUCT INFORMATION

### DISINFECTANT PERFORMANCE

SURFACE TESTS						
Protocol	Organism	Code	Condition	Log reduction to pass	Log reduction @ 5 mins	Outcome
BS EN 13697:2015	P. aeruginosa	DSM 939	Clean	Log 4.0	> 6.57	Bactericidal
	E. coli	NCTC 10418	Clean	Log 4.0	> 6.23	Bactericidal
	S. aureus	NCTC 10788	Clean	Log 4.0	> 6.44	Bactericidal
	E. hirae	DSM 3320	Clean	Log 4.0	> 4.41	Bactericidal
Protocol	Organism	Code	Condition	Log reduction to pass	Log reduction @ 15 mins	Outcome
BS EN 13697:2015	C. albicans	DSM 1386	Clean	Log 3.0	> 6.29	Yesticidal

SUSPENSION TESTS						
Protocol	Organism	Code	Condition	Log reduction to pass	Log reduction @ 5 mins	Outcome
BS EN 1276:2015	P. aeruginosa	DSM 939	Clean	Log 5.0	> 5.26	Bactericidal
	E. coli	NCTC 10418	Clean	Log 5.0	> 5.54	Bactericidal
	S. aureus	NCTC 10788	Clean	Log 5.0	> 5.17	Bactericidal
	E. hirae	DSM 3320	Clean	Log 5.0	> 5.17	Bactericidal
Protocol	Organism	Code	Condition	Log reduction to pass	Log reduction @ 15 mins	Outcome
BS EN 1650:2015	C. albicans	DSM 1386	Clean	Log 4.0	> 4.26	Yesticidal

**Please note:** Data shown above are just typical values.

### ORDERING/PACKING INFORMATION

Sterile Code	Description	Size	Pack Qty	Case Qty	Case Dimensions	Weight
ZSAL65005	CleanGuard 2 5L RFU IMS 70/30 WFI Sterile	5L	Each	2 x 5L	445 x 395 x 315mm	15.2 Kg

The above product table does not show the regional product codes for clarity. However, to ensure that product labels with the correct languages are ordered and dispatched please contact us.