



# **PRODUCT SPECIFICATION**

## IMS 5L RFU STERILE



### 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.

### **PRODUCT FEATURES**

Tamper evident PP vented cap. HDPE 5 Ltr bottle.

### **TECHNICAL INFORMATION**

### MANUFACTURING

The product is filled and capped in a Grade B (in use) cleanroom.

Packaging is performed in a Grade C (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<br>(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: 5 Litre container complete with a screw on air tight cap. Secondary packaging: double bagged in polythene bags. 2 double-bagged bottles in the box.

### 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**

| Non-Sterile Code | Sterile Code | Description             | Size | Pack Qty | Case Qty | Case Dimensions   | Weight  |
|------------------|--------------|-------------------------|------|----------|----------|-------------------|---------|
|                  | ZSAL65005    | IMS 5 Litre RFU Sterile | 5L   | Each     | 2 x 5L   | 290 x 215 x 290mm | 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.

| SO 9001 | SO 9001 | SO 1048 | SO 10401 | S