# schülke ->



Sterile, alcohol based ready to use solution for surface disinfection in cleanrooms.

# perform<sup>®</sup> sterile alcohol IPA (WFI)

### **Our Plus:**

- fast, effective and residue free
- sterile (X-Ray irradiated) and microbial filtrated (0.2 μm)
- suitable for cleanrooms grade A/B, ISO class 5/6
- ready to use in a handy, sterile 500 ml- and 1 l- spray system
- with WFI (Water for Injection)
- colour and perfume free
- efficacy tested according to European norms (EN)

### **Application areas**

Disinfection of surfaces and equipment / devices in cleanrooms, in particular for class A and B cleanroom areas, according to:

- Annex 1 of EU Guide to Good Manufacturing practice: Manufacture of sterile medicinal products, March 2009.
- FDA Guidance for Industry: Sterile drug products produced by aseptic processing - current Good Manufacturing practice; U.S. Department of Health and Human Services, Food and Drug Administration, September 2004.

### Instructions for use

Apply perform® sterile alcohol IPA WFI undiluted to objects and surfaces and allow to take effect. Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Do not apply more than 25 ml/m². Make sure to wet surfaces completely. Used wipes must be disposed in a closed container. Disinfection after each production and cleaning process or when required according to standard operating procedure (SOP). For professional use only. Application for PT 02: Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B). Effective against bacteria and yeasts.

### Spraying:

Spray ready-to-use product on the surface and allow to take effect at room temperature  $(20 \pm 2^{\circ}C)$  for at least 1 minute.

#### Wipina:

Spray or pour ready-to-use product onto the surface and then wipe with a cloth or wipe the surface with a cloth that has first been pre-soaked by spraying or pouring. Leave to act for at least 5 minutes at room temperature  $(20 \pm 2^{\circ}\text{C})$ .

### Microbiological efficacy

### Spraying:

Efficacy	Concentration	Contact time
<b>bactericidal</b> EN1276, EN13697 - clean conditions	ready-to-use	1 min.
yeasticidal EN1650, EN13697 - clean conditions	ready-to-use	1 min.

## Wiping:

Efficacy	Concentration	Contact time
<b>bactericidal</b> EN1276, EN16615 - clean conditions	ready-to-use	5 min.
yeasticidal EN1650, EN16615 - clean conditions	ready-to-use	5 min.



# perform® sterile alcohol IPA (WFI)

### **Product data**

## Composition:

100 g solution contains the following active substances: 63,1 g Propan-2-ol (equates 70 % (v/v)).

#### Chemical-physical data

Density colourless

Color approx. 0,88 g/cm3 / 20  $^{\circ}$ C Flash point 22  $^{\circ}$ C / Method : DIN 51755 Part 1

Form liquid pH Not applicable

Viscosity, dynamic > 2,5 mPa\*s / 20 °C / Raw material

### **Special advice**

Use disinfectants safely. Always read the label and product information before use.

The sterile 500 ml- and 1 l- spray system offers the following advantages:

- · convenient size for handling and storage
- ergonomically shaped spray pump for ease of use, does not slip out of the gloved hand
- · remains sterile after opening

The bottles are sterile (with irradiation indicator) and double-wrapped individually. perform® sterile alcohol IPA comprises alcohol of pharmaceutical quality in accordance with the Ph. Eur. EU-0023656-0001 1-1

### Information for order

Item	Delivery form	Item no.
perform® sterile alcohol IPA WFI 500 ml bottle	10 / carton	on request
perform® sterile alcohol IPA WFI 1I bottle	6 / carton	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

### **Accessories**

Item	Item no.
perform® spray bottle holder	693540
perform® spray bottle holder - plate	693541

# **Related products**

- perform® sterile alcohol IPA
- perform® sterile dry wipes
- perform® sterile mix dry wipes
- perform® sterile premium dry wipes







Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

# **Environmental information**

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining our high quality standards.

## **Expert opinion and information**

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com

For individual questions: Application Department Phone: +49 40 52100-666 E-Mail: info@schuelke.com

schülke Headquarters