

schülke -}

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

perform[®] sterile alcohol IPA

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 1L- spray system
- optional 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 undiluted to objects and surfaces and allow to take effect. Ensure complete wetting. The product dries off quickly. perform[®] sterile alcohol IPA is also suitable for disinfecting gloves. Maximum application rate 50 ml/sq.m. Do not use to treat surfaces that are particularly sensitive to alcohol, such as acrylic glass. perform[®] sterile alcohol IPA is also available with WFI (Water for Injection).

Microbiological efficacy

Efficacy	Concentration	Contact time
bactericidal EN1276, EN13697	ready-to-use	1 min.
yeasticidal EN1650, EN13697	ready-to-use	1 min.
virucidal against enveloped viruses in accordance with DVV (German Registered Association for Combating Viral Diseases)//RKI Guideline	ready-to-use	30 sec.

perform[®] sterile alcohol IPA

Product data

Composition:

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

Chemical-physical data

Color	colourless	
Density	approx. 0,88 g/cm3 / 20 °C	
Flash point	22 °C / Method : DIN 51755 Part 1	
Form	liquid	
рН	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
- remains sterile after opening

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

Information for order

ltem	Delivery form	ltem no.
perform [®] sterile alcohol IPA 1l bottle perform [®] sterile alcohol IPA 500ml bottle	6/Carton 10/Carton	on request on request

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

Application aids

Application aids	ltem no.
perform [®] spray bottle holder	693540
perform [®] spray bottle holder - plate	693541

Related Products

- perform[®] sterile alcohol IPA (WFI)
- 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. schülke Headquarters Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt, Germany Phone +49 40 - 52100 - 0 Fax +49 40 - 52100 - 318 www.schuelke.com info@schuelke.com

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