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Sterile, alcohol based ready to use solution for surface disinfection in cleanrooms / PT02

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 1 l- 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 to objects and surfaces and allow to take effect. Clean the surface carefully before use. If necessary, remove excess water from the surface before disinfection. Do not apply more than 25 ml/m². Ensure complete wetting. Used wipes must be disposed of in a sealed container. Disinfect after each production and cleaning process or as required by the standard operating procedure (SOP). For professional use only. perform® sterile alcohol IPA is also suitable for glove disinfection. Surfaces that are particularly sensitive to alcohol, such as acrylic glass, must not be treated. Optionally, perform® sterile alcohol IPA is available with WFI (Water for Injection).

Spraying:

Spray the ready-to-use product onto the surface and leave to act for at least 1 minute at room temperature (20 \pm 2°C).

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 |
|--|---------------|--------------|
| bactericidal EN1276, EN13697 - clean conditions | ready-to-use | 1 min. |
| yeasticidal EN1650, EN13697 - clean conditions | ready-to-use | 1 min. |

Wiping:

| Efficacy | Concentration | Contact time |
|---|---------------|--------------|
| bactericidal EN1276, EN16615 - clean conditions | ready-to-use | 5 min. |
| yeasticidal EN1650, EN16615 - clean conditions | ready-to-use | 5 min. |





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

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 11 bottle | 6 / carton | on request |
| perform® sterile alcohol IPA 500 ml bottle | 10 / 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 (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.

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