



## gigasept® pearls

Active oxygen-based disinfectant for manual cleaning and disinfection of medical devices.

### Our Plus:

- fast and broad microbiological efficacy through a synergistic combination of active substances with active oxygen (virucidal disinfection with 2 % in 10 minutes)
- outstanding cleaning performance due to a multi-enzyme formula (protease, lipase and amylase) in combination with a neutral pH (non-protein-fixing) and potent surfactants
- very good material compatibility even with sensitive materials such as flexible endoscopes
- more user safety – thanks to the special pearl structure – dustfree (no risk of inhalation)
- pleasant, fresh smell

### Application areas

For manual prophylactic or final disinfection and cleaning of non-invasive and invasive instruments (thermostable, thermolabile) as well as medical devices that can be reprocessed using an immersion bath. Very suitable for the reprocessing of flexible endoscopes and sensitive materials such as silicone, polycarbonate, polysulfone and acrylic glass. The pH of gigasept® pearls can be buffered into a neutral range by adding special additives. This prevents protein coagulation (fixation of proteins to surfaces) and also achieves optimal material compatibility. In addition to manual reprocessing, gigasept® pearls are also suitable for use in ultrasonic baths.

### Instructions for use

gigasept® pearls are dissolved in cold water (10 °C - 25 °C, at least drinking water quality) and diluted to the desired application concentration.

**Dosage:** 1.0 % - 2.0 %, depending on microbiological efficacy. The solution is prepared using the enclosed dosing aid. Clean

off any visible contamination from instruments / medical devices before disinfection and then rinse, preferably with demineralised water.

**Application example:** 10 litres of a 2 % working solution corresponds to 9.8 litres of water and 200 g (200 g = 300 ml) of gigasept® pearls.

Add water and stir several times during the first 15 minutes after sprinkling in the appropriate amount of gigasept® pearls. After this activation time, the working solution is ready to use. Minor, undissolved residue does not affect the efficacy of the working solution, but is an additional activity deposit. Place instruments / medical devices in the working solution immediately after use. Ensure complete wetting, especially of hollow instruments / medical devices, and allow it to take effect. After reprocessing, rinse the instruments / medical devices thoroughly, preferably with demineralised water, to completely remove residue of the working solution.

The reprocessing recommendations of the respective instrument / medical device manufacturers must be complied with. Do not mix with cleaners or other disinfectants. National regulations may require that cleaning and disinfection are carried out in two separate process steps.

**Standing time:** Renew the working solution every work day and if there is visible contamination.

### Microbiological efficacy

Efficacy	Concentration	Contact time
<b>bactericidal</b> EN 13727, EN 14561, in accordance with VAH - dirty conditions	2 % (20 g/l) 1 % (10 g/l)	5 min. 10 min.
<b>yeastocidal</b> EN 13624, EN 14562, in accordance with VAH - dirty conditions	2 % (20 g/l) 1 % (10 g/l)	5 min. 10 min.
<b>mycobactericidal</b> EN 14348, EN 14563, in accordance with VAH - dirty conditions	2 % (20 g/l)	10 min.



<b>tuberculocidal</b> EN 14348, EN 14563 - dirty conditions	2 % (20 g/l) 1 % (10 g/l)	5 min. 10 min.
<b>tuberculocidal</b> in accordance with VAH - dirty conditions	2 % (20 g/l) 1 % (10 g/l)	5 min. 15 min.
<b>virucidal</b> in accordance with DVV (German Registered Association for Combating Viral Diseases)/RKI Guideline	2 % (20 g/l) 1 % (10 g/l)	10 min. 30 min.
<b>virucidal</b> EN 14476, EN 17111 - dirty conditions	2 % (20 g/l) 1 % (10 g/l)	10 min. 60 min.
<b>sporicidal</b> EN 17126 - dirty conditions	1 % (10 g/l)	10 min.
<b>sporicidal C. difficile</b> EN 17126 - dirty conditions	1 % (10 g/l)	5 min.
<b>fungicidal</b> EN 13624, EN 14562 - dirty conditions	2 % (20 g/l)	30 min.
<b>fungicidal</b> EN 13624, EN 14562 - clean conditions	2 % (20 g/l) 1 % (10 g/l)	15 min. 60 min.



## Product data

### Composition:

100 g of gigasept® pearls contain the following active substances: 43.0 g sodium percarbonate, 22.0 g tetraacetylenediamine.

### Labelling according to Regulation (EC) No. 648/2004:

> 30 % oxygen-based bleach, < 5 % non-ionic surfactants, < 5 % phosphates, < 5 % EDTA, enzymes, perfumes.

### Chemical-physical data

Color	light blue
Flash point	not applicable
Form	granular
pH	ca. 8 / 20 g/l / 20 °C / in water
Viscosity, dynamic	not applicable

## Special advice

### Always read the label and product information before use.

gigasept® pearls are intended for use by professional personnel in the medical field, e. g. in clinics, private practices. All serious incidents related to the device shall be reported by the user / patient to the manufacturer and to the competent authority of the state in which the user / patient is established. Do not use on instruments / medical devices with copper or brass surfaces or damaged chrome-plated and nickel-plated surfaces. Do not use for final disinfection of critical instruments / medical devices.

Carryover of small amounts of application solution from the precleaning is not expected to involve interactions with cleaning agents and disinfection agents from automated endoscope reprocessing (e. g. glutaraldehyde and peracetic acid base).

Slight color variations of the gigasept® pearls do not affect the product quality. The working solution can be disposed of via wastewater. Always close containers tightly and store in a dry and cool place, protected from light. Protect package contents from moisture.

## Information for order

Item	Delivery form	Item no.
gigasept® pearls 1,5 kg EM	4 / carton	on request
gigasept® pearls 6 kg EM	1 / carton	on request

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

## Environmental information

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

## Expert opinion and information

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

For individual questions:

Application Department

Phone: +49 40 52100-666

E-mail: [info@schuelke.com](mailto:info@schuelke.com)



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](http://www.schuelke.com)  
[info@schuelke.com](mailto:info@schuelke.com)