schülke

Active oxygen-based instrument disinfectant for manual cleaning and disinfection with a multi-enzyme formula.

# gigasept® pearls

## Our Plus:

- full microbiological effectiveness
- outstanding cleaning performance via its multi-enzyme formula in combination with a neutral pH (non-protein-fixing) and powerful surfactants
- excellent material compatibility even with sensitive materials such as flexible endoscopes
- more user safety - thanks to its the innovative pearl structure - dust-free (no risk of inhalation)
- surprisingly pleasant smell

## Application areas

Universal cleaning and disinfection of thermostable and thermolabile medical instruments of all types. Particularly suitable for flexible endoscopes and sensitive materials such as silicone, polycarbonate, polysulfone and acrylic glass. Beneath the manual reprocessing gigasept® pearls are also suited to use in ultrasonic baths.

## Instructions for use

The instrument disinfection granules are diluted with cold water to the desired concentration for use.
**Dosage:** 1.0 % – 2.0 %, depending on microbiological activity. Prepare the solution with the enclosed measuring spoon.
**Example for use:** 10 litres of a 2 % working solution is equivalent to 9.8 litres of water and 200 g (200 g = 300 ml) gigasept® pearls. Further information about the dosage of the product can be found in the dosage table on the next page.
Add water and sprinkle in the appropriate amount of granules. Stir several times for the first 15 minutes. After this activation time, the working solution is ready for use. Minor undissolved residues form an active deposit of activity, but do not impair the effectiveness of the solution.
Immerse endoscopes and instruments to be reprocessed into the working solution. Ensure complete coverage, including hollow instruments, and allow to act. After instrument reprocessing, rinse/flush thoroughly with water of at least drinking water quality, preferably deionised water, in order to completely remove residues of the working solution.
Please refer to the reprocessing recommendations by the instrument manufacturer. Do not mix with other cleaning products or disinfectants.
National regulations may require that cleaning and disinfection are carried out in two separate process steps.
**Standing time:** Replace working solutions every working day and if contamination is clearly visible.

## Microbiological efficacy

| Efficacy | Concentration | Contact time |
|---|---|---|
| **bactericidal, levurocidal**<br>*acc. to VAH*<br>*EN 13727, EN 14561*<br>*EN 13624, EN 14562* | 2 %<br>1 % | 5 min.<br>10 min. |
| **tuberculocidal**<br>*acc. to VAH* | 2 %<br>1 % | 5 min.<br>15 min. |
| **tuberculocidal**<br>*EN 14348, EN 14563* | 2 %<br>1 % | 5 min.<br>10 min. |
| **virucidal**<br>*in accordance with DVV/ RKI Guideline 2015* | 2 %<br>1 % | 10 min.<br>30 min. |
| **virucidal**<br>*EN 14476* | 2 %<br>1 % | 10 min.<br>60 min. |
| **sporicidal**<br>*Bacillus subtillis EN 13704* | 2 %<br>1 % | 15 min.<br>30 min. |
| **sporicidal**<br>*Clostridium difficile EN 13704* | 2 %<br>1 % | 5 min.<br>30 min. |
| **fungicidal**<br>*EN 13624* | **2 %**<br>2 %<br>1 % | **30 min.**<br>*15 min.<br>*60 min. |

* clean conditions

All concentrations (without *) are stated with high organic load
Statements also apply for use in the ultrasonic bath

CE 0297

# gigasept® pearls

## Product data

**Composition:**
100 g of the granules contains the following active ingredients: 43.0 g Sodium percarbonate, 22.0 g Tetraacetylethylenediamine.
**Labelling according to Regulation (EC) No 648/2004:**
> 30 % oxygen-based bleaching agents, < 5 % non-ionic surfactants, < 5 % phosphates, < 5 % EDTA and salts thereof, enzymes, perfumes.

### Chemical-physical data

| | |
|---|---|
| Color | light blue |
| Flash point | Not applicable |
| Form | granular |
| pH | approx. 8 / 20 g/l / 20 °C / in water |
| Viscosity, dynamic | Not applicable |

## Special advice

**Always read the label and product information before use.**
Not suitable for instruments made of copper and chrome- or nickel-plated instruments that have previous mechanical damage.
With the addition of specific adjuvants, the pH of gigasept® pearls is buffered within a neutral range. This prevents protein coagulation (binding of proteins on surfaces) and also provides optimal material compatibility.
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 doesn't affect the product quality.

## Information for order

| Item | Delivery form | Item no. |
|---|---|---|
| gigasept® pearls 1.5 kg bucket | 4 / Carton | 70000179 |
| gigasept® pearls 6 kg bucket | 1 / Carton | 70000178 |

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

## Dosage table

| litre solution | concentration of the working solution | |
|---|---|---|
| | 1 % | 2 % |
| 1 litre | 10 g (≙ 15 ml) | 20 g (≙ 30 ml) |
| 2 litre | 20 g (≙ 30 ml) | 40 g (≙ 60 ml) |
| 3 litre | 30 g (≙ 45 ml) | 60 g (≙ 90 ml) |
| 5 litre | 50 g (≙ 75 ml) | 100 g (≙ 150 ml) |
| 10 litre | 100 g (≙ 150 ml) | 200 g (≙ 300 ml) |
| 30 litre | 300 g (≙ 450 ml) | 600 g (≙ 900 ml) |

measuring beaker: 100 g granulate ≙ 150 ml
1 heaped measuring spoon ≙ 40 g granulate ≙ 60 ml

## 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:
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EMAS GEPRÜFTES UMWELTMANAGEMENT REG.-NR. D-150-00003

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.

Air Liquide HEALTHCARE

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