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

gigasept® pearls

Our Plus

- full microbiological effectiveness via its synergistic combination of active substances plus active oxygen (concluding virucidal disinfection with 2% in 10 minutes)
- outstanding cleaning performance via its multi-enzyme formula (protease, lipase and amylase) 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)
- innovative packaging system for safe and easy removal
- 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. Furthermore, its special formulation is suitable for use in an ultrasonic bath, as well as manual reprocessing and circulation procedures (semi-automatic). The efficacy can be checked using schülke indicator strips, e.g. for contaminated solution or elevated temperature.

Microbiological efficacy

Efficacy	Concentration	Contact time
bactericidal EN13727, EN14561, in accordance with VAH - dirty conditions	1 % (10 ml/l)	10 min.
bactericidal EN13727, EN14561, in accordance with VAH - dirty conditions	2 % (20 ml/l)	5 min.
tuberculocidal EN14348, EN14563 - dirty conditions	1 % (10 ml/l)	10 min.

Efficacy	Concentration	Contact time
tuberculocidal EN14348, EN14563, in accordance with VAH - dirty conditions	2 % (20 ml/l)	5 min.
levurocidal EN13624, EN14562, in accordance with VAH - dirty conditions	1 % (10 ml/l)	10 min.
levurocidal EN13624, EN14562, in accordance with VAH - dirty conditions	2 % (20 ml/l)	5 min.
fungicidal EN13624 - dirty conditions	2 % (20 ml/l)	30 min.
virucidal EN14476 - dirty conditions	1 % (10 ml/l)	60 min.
virucidal EN14476, in accordance with DVV (German Registered Association for Combating Viral Diseases)/RKI Guideline - dirty conditions	2 % (20 ml/l)	10 min.
Clostridium difficile EN13704 - dirty conditions	1 % (10 ml/l)	30 min.
Clostridium difficile EN13704 - dirty conditions	2 % (20 ml/l)	5 min.
Bacillus subtilis EN13704 - dirty conditions	1 % (10 ml/l)	30 min.
Bacillus subtilis EN13704 - dirty conditions	2 % (20 ml/l)	15 min.





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
Viscosity, dynamic Not applicable

Hazard notes and safety advice





H302	Harmful if swallowed.
H318	Causes serious eye damage.
P280	Wear protective gloves/ protective
	clothing.

P301 + P312 IF SWALLOWED: Call a POISON

CENTER or doctor/ physician if you feel

unwell.

P302 + P352 IF ON SKIN: Wash with plenty of soap

and water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water

for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical

advice/ attention.

Special advice

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 gigasept® pearls. 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 eff ectiveness of the solution. Immediately after use, 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



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.



drinking water quality, preferably deionised water, in order to completely remove residues of the disinfectant solution. Please refer to the reprocessing recommendations by the instrument manufacturer. Do not mix with other cleaning products or disinfectants. Not suitable for instruments made of brass and copper, or chrome- or nickel-plated instruments that have been mechanically pre-damaged. According to recommendations by the German Robert Koch Institute, replace working solutions every working day and if contamination is clearly visible.

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).

Information for order

Item	Delivery form	Item no.
gigasept pearls 6 kg EM	1/bucket(S)	on request
gigasept pearls 1,5 kg EM	1/bucket(S)	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: Customer Care

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