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Ready-to-use high level disinfectant based on peracetic acid for the disinfection of flexible endoscopes and medical instruments. gigasept<sup>®</sup> PAA is a medical device class IIb.

## gigasept® PAA

#### **Our Plus**

- Aldehyde-free
- Ready to use
- Effective against bacteria, fungi, viruses, spores
- No activation necessary

#### **Application areas**

Manual or semi-automated disinfection/processing of precleaned flexible endoscopes, ophtalmological equipment, surgical instruments made of stainless steel and heat sensitive medical devices.

#### Instructions for use

## Use disinfectants safely. Always read the label and product information before use. For professional use only. Read SDS before use.

gigasept<sup>®</sup> PAA is a ready to use product. gigasept<sup>®</sup> PAA is active immediately and stable over 7 days or 50 cycles of disinfection. The peracetic acid (PAA) concentration in solution can be tested using Schülke PAA test strips. In case of visible contamination, the bath should be renewed. Always ensure the pre-cleaning of the endoscope and medical instruments and a complete wetting of the surfaces. Immerse hollow objects in such a way that air escapes completely from the lumen.

After the necessary contact time rinse carefully with sterile or filtered water before re-use. Do not exceed the recommended contact time.

A located ventilation over the bath is recommended. Cover the bath of gigasept<sup>®</sup> PAA as often as possible.

Do not dilute gigasept<sup>®</sup> PAA. Do not mix with other products (cleaner, disinfectants, etc.), particularly with aldehydes or derivates of halogens (e.g. glutaral, sodium hypochlorite, etc.). Do not use after expiry date.

#### **Microbiological efficacy**

Efficacy	Concentration	Contact time
<b>bactericidal</b> EN13727, EN14561 - clean conditions	ready-to-use 20 °C	5 min.
mycobactericidal EN14348, EN14563 - clean conditions	ready-to-use 20 °C	5 min.
yeasticidal EN13624, EN14562 - clean conditions	ready-to-use 20 °C	5 min.
fungicidal EN13624, EN14562 - clean conditions	ready-to-use 20 °C	5 min.
virucidal EN14476, EN17111 - clean conditions	ready-to-use 20 °C	5 min.
sporicidal EN17126 - clean conditions	ready-to-use 20 °C	5 min.
Clostridium difficile EN17126 - clean conditions	ready-to-use 20 °C	5 min.





## **Product data**

Composition: 100 g solution contains the following active substances: 0,12 g Peracetic acid [CAS n°79-21-0].

#### **Chemical-physical data**

Color	colourless	
Density	ca. 1,02 g/cm3 / 20 °C	
Flash point	> 100 °C	
Form	liquid	
рН	ca. 3,5 / 20 °C	
Viscosity, dynamic	not determined	

## **Special advice**

#### Safety:

#### WARNING - irritant product- always refer to the product label and the Safety Data Sheet before use.

gigasept® PAA is not classified as a dangerous formulation by ingestion (Test OECD 401) or irritation to skin (OECD 404). gigasept® PAA does not generate toxic vapour - the average exposure limit of the ingredients is respected.

gigasept® PAA is not sensitising (Test OECD 406). Gloves must be worn when handling disinfectants not intended for the skin.

Any serious incident that has occurred in relation to this device should be reported to Bioxal and your competent authority. **Compatibility:** 

gigasept® PAA can be used in semi-automated endoscope reprocessors that are compatible with peracetic acid. Please check the compatibility of endoscope and reprocessors with paracetic acid.

Incompatible materials: iron, toolsteel, aluminium, platinium, nickel -/ chromeplated or non ferrous metal alloys parts (e.g. cooper and brass).

Compatible materials: (limited to the maximum contact time; obligatory rinse after contact) polycarbonate, polyurethane, silicone, polysulfone, polyamide, polyester, polystyrene. Storage and disposal:

Store and use only in a well ventilated place. Store at ambient temperature in the original canister. Always close canister tightly after removal of product. Canister with venting cap. Do not keep the venting cap sealed. Store in upright position only. Protect from heat and sunlight. Do not store with alkaline products. Never return used product into the original canister. Do not reuse empty container. Dispose of the product including packaging as hazardous waste in compliance with local and national regulations.

### Information for order

ltem	Delivery form	ltem no.
gigasept PAA 5 I KA	1/Canister	on request

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



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.

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## Manufacturer

BIOXAL ZI Sud Secteur A Route des Varennes 71100 Chalon sur Saône FRANCE

Application aids	
Application aids	

y for 5 + 10 l	135810
st-strips gelabelt 900PPM 50 ST DS	70003351

Item no.

## **Environmental information**

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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