

Instrument disinfection

PHAGO'PREN AF

Concentrate based on quarternary ammonium compounds and amine for preparation of a working solution for manual disinfection of invasive medical devices in an immersion bath

Product description

PHAGO'PREN AF is a concentrate based on quarternary ammonium compounds and amine for preparation of a working solution for manual disinfection of invasive medical devices in an immersion bath.

Areas of application

Suitable for dental and surgical instruments as well as rotating precision instruments. Examples:

- mirrors
- forceps
- probes
- root canal instruments
- polishers
- reamers

Not suitable for final disinfection.

Not suitable for endoscopes.

Not suitable for disinfection of skin and hands.

Not tested for food and veterinary area.

Do not use for spraying.

Advice for users

Application only by qualified personnel.

Do not mix with other products. Clean immersion bath and application aids thoroughly prior to the first application of the product, after application of other products and at the end of the working day.

Do not pour concentrate that has been removed back into the original container.

Report serious incidents related to this product to the manufacturer and the respective authority.

Application

Put on protective clothing, eye protection, face mask and protective gloves before each disinfection! Do not allow debris to dry on the instruments. Thoroughly clean the opened and disassembled instruments.

Disinfection in immersion bath:

1.) Prepare working solution in the desired concentration with water (approx. 20°C, at least drinking water quality).

Example for a 0.25% working solution: Provide 997.5 ml water, add 2.5 ml concentrate and mix.

2.) Immerse the cleaned, opened, disassembled instruments in the working solution. All surfaces and cavities have to be wetted.

3.) After the contact time has elapsed: Rinse the instruments thoroughly with water (at least drinking water quality*) and dry them.

4.) Check instruments for cleanliness and integrity.

Comply with the instrument manufacturer's recommendations for reprocessing as well as with national requirements for reprocessing.

*use demineralized water in case the instruments are supposed to be sterilized.

See page 2 for efficacy spectrum and information on material compatibility.

Shelf life and expiry date

Shelf life of working solution: 1 day.

Renew immediately in case of visible contamination.

See product label for expiry date. Do not use the product after the expiry date.



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page

1/2

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Detailed spectrum of efficacy

Disinfection by immersion: Efficacy under dirty conditions (tested at room temperature)	test standard	conc.	contact time
Bacteria			
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> , <i>E. coli</i>	EN 13727	0.25 %	1 min
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i>	EN 14561	0.1 %	15 min
Yeasts			
<i>C. albicans</i>	EN 13624	0.25 %	1 min
	EN 14562	0.25 %	5 min
Viruses			
Enveloped viruses			
Vaccinia Virus strain Elstree	EN 14476	0.25 %	15 min
Non-enveloped viruses			
SV40 Polyomavirus	EN 14476	1.0 %	30 min

Examples for the preparation of working solutions

concentration of working solution	water	concentrate
0.25 %	997.5 ml	2.5 ml
1.0 %	990 ml	10 ml

Product composition

Active ingredients in 100 g:
19.05 g N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamine,
5.60 g N,N-Didecyl-N-methyl-poly(oxyethyl)-
ammoniumpropionate,
2.10 g Didecyltrimethylammonium chloride
9.97 g 2-propanol

Physico-chemical data

appearance of concentrate: clear, yellowish liquid
pH-value: 11.0 – 12.0
density: 0.940 – 0.999 g/cm³

Material compatibility

Metals	stainless steel
plastics	Polyvinylchloride, Polysulfone, PE
Further materials	Ceramics
Advice:	Upon compliance to the intended use as well as the indicated contact time and concentration, no material damage is to be expected with the above mentioned materials. With copper, aluminium and brass color changes may occur upon prolonged contact. With natural and synthetic rubber as well as silicone color changes, deformation and loss of elasticity may occur. Test material compatibility for polyacrylates, polycarbonates as well as not mentioned materials.

Storage advice

Storage between 5-25°C. Only store in original container. Protect from direct sunlight. Store in an upright position. Store in a well-ventilated place. Keep away from food, drink and animal feedingstuffs.

Labelling

CE 0123 MD IIb

Labelling according to Regulation (EC) No. 1272/2008 (CLP)

For information on labelling according to Regulation (EC) No 1272/2008 (CLP) see safety datasheet and label.

Expert opinions and further information

PHAGO'PREN AF has been assessed by independent laboratories.

For further details on expert opinions, more information on the product or individual questions contact us by e-mail (info@pliwa.de) or telephone (+49 (0)5661-7317-0).

PLIWA Hygiene GmbH has a manufacturing authorisation as per §13 German medicines act as well as a GMP- and an EN ISO 13485 certificate.

Ordering information (label in English language)

Single package	Packaging unit	REF
1 L dosing bottle	18 x 1 L (box)	12-0061-E
1 L cylindrical bottle	10 x 1 L (box)	12-0061-1-E
5 L canister		12-0064-E

Dosing aids for canisters	
Dosing pump	50006
Drainage tap	50009

For further information on the reprocessing of medical devices, recommendations are available online on the homepage of the Robert Koch-institute (Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) on the "Hygiene requirements for the reprocessing of medical devices".)

