

# Biguaton forte Neu

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



VAH certificate of efficacy

## Product description

**Biguaton forte NEU** is a concentrate based on quarternary ammonium compound and amine for preparation of a working solution for manual disinfection of invasive medical devices in an immersion bath. The product is free of aldehydes and phenols.

## Area 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 endoscopes.

Not suitable for disinfection of skin and hands.

Not tested for food and veterinary area.

Do not use for spraying.

## Advice for users

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.

Application only by qualified personnel.

Rinse the instruments with demineralized water if they are supposed to be sterilized.

In case the product has been accidentally subjected to lower temperatures during transport: Warm the container up to 25°C and swing the closed container gently back and forth in order to dissolve possible precipitates before preparing the working solution.

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

The safety datasheet is available at [www.pliwa.de](http://www.pliwa.de).

## 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). Example for a 3% working solution: Mix 970 ml water (approx. 20°C) + 30 ml concentrate. Chronological order: First provide water, then add concentrate and mix.

2.) Immerse the cleaned, opened, disassembled instruments in the working solution. All surfaces and cavities have to be wetted. Comply exactly with the recommended contact time.

3.) After the contact time has elapsed: Rinse the instruments thoroughly with water (at least drinking water quality, approx. 20°C) 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 of medical devices.

**For efficacy spectrum and information on material compatibility see page 2.**

## 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.



**PLIWA Hygiene GmbH**

Pliwastraße 2  
34323 Malsfeld, Germany  
[www.pliwa.de](http://www.pliwa.de)

Tel. 0049 5661 / 73 17 0  
Fax 0049 5661 / 73 17 10  
[info@pliwa.de](mailto:info@pliwa.de)

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## Efficacy spectrum/concentration/contact times

efficacy (assessed at room temperature)	standard	condition	conc.	contact time
<b>Bacteria</b>				
<i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. hirae</i>	EN 13727	dirty	1 %	5 min
	EN 14561	clean	0,5 %	15 min
			0,1 %	30 min
<b>Mycobacteria/TB</b>				
<i>M. terrae</i> , <i>M. avium</i>	EN 14348	clean	1,5 %	30 min
	EN 14563	clean	2 %	30 min
		dirty	3 %	30 min
<b>Yeasts</b>				
<i>C. albicans</i>	EN 13624	dirty	1 %	5 min
<i>C. albicans</i>	EN 14562	clean	0,5 %	15 min
			0,1 %	30 min
<b>Viruses</b>				
<b>Enveloped viruses</b>				
MVA Modified Vacciniavirus Ankara	EN 14476	dirty	1 %	15 min
<b>Non-enveloped viruses</b>				
Adenovirus	EN14476	dirty	3 %	30 min
			4 %	15 min
Poliovirus		3 %	15 min	
MNV Murine Norovirus		dirty	3 %	60 min
	clean	3 %	30 min	

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".)

## Examples for working solution preparation

Concentration of working solutions	water	concentrate
2.0 %	980 ml	20 ml
3.0 %	970 ml	30 ml
4.0 %	960 ml	40 ml

## Composition

100 g contain the following active substances:  
6.65 g Didecyloxyethylammonium propionate,  
6.20 g N,N-Bis(3-aminoethyl)dodecylamine,  
4.40 g Cocospropylendiamindiguanidinium acetate,  
2.60 g fatty alkyl amine

## Physico-chemical data

Appearance of concentrate: clear, blue to turquoise liquid  
pH-value: 10,0 – 11,0  
rel. density: 0,940 – 0,999 g/cm<sup>3</sup>

## Material compatibility

Plastics	PE, PSU, PVC
Metal	stainless steel
Rubber, flexible materials	silicone
Others	ceramics
Advice	<p>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. Avoid contact of more than 48 hours with polycarbonates (Makrolon). Test material compatibility for polyacrylates and polycarbonates before use.</p> <p>For copper, brass and aluminium a colour change is possible upon prolonged contact time. Natural rubber and EPDM may loose elasticity and change their colour upon prolonged contact time. The product is not suitable for disinfection of devices made from Viton.</p> <p>Test material compatibility for not mentioned materials.</p>

## Storage advice

Store the product between 5°C and 25°C.

Keep only in original container. Protect from direct sunlight. Keep the container in an upright position in a well-ventilated place. Keep container tightly closed. Keep away from food, drink and animal feedingstuffs.



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## 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.



**UN 1903**

## Information for order

Single package	Packaging unit	REF
1 Litre dosing bottle	18 x 1 Litre	10-0001
2 Litres bottle w. handle	10 x 2 Litres	10-0002
5 Litres canister		10-0004
10 Litres canister		10-0005
Application aids for canisters		
dosing pump		50006
drainage tap		50009

## Labelling

Medical device class II b / MD 0108

**CE** 0123

Certificate of efficacy issued by VAH  
(Association of Applied Hygiene, Germany)

## Expert opinions & further information

Biguaton forte Neu 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](mailto: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.

