

# PLIWA Biguaton Spezial

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



## Product description

**PLIWA Biguaton Spezial** is a concentrate based on quarternary ammonium compound and amine for preparation of a working solution for manual disinfection of invasive medical devices like dental impressions in an immersion bath. The product is free of aldehydes and phenol.

For hygienic reasons, dental impressions should be disinfected in the dental practice before sending the impression to the dental laboratory in order to avoid infections. The disinfection procedure should be repeated by the dental laboratory before starting to work with the dental impressions.

## Area of application:

For disinfection of dental impressions made from silicones, polyether and hydrocolloids (alginates).

## Advice for users

Application only by qualified personnel.

Do not mix with other products. **Avoid contact with stypitic medication.**

Comply exactly with the recommended contact time.

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.

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

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!

### Disinfection in an immersion bath:

- 1) Prepare a 6% working solution: Mix 940 ml water (approx. 20°C, drinking water quality) and 60 ml concentrate. Chronological order: First provide water, then add concentrate.
- 2) Place the dental impression including the tray in the working solution directly after the impression was taken. Move the impression tray back and forth in order to avoid air bubbles.
- 3) After the contact time has elapsed: Rinse dental impression including the impression tray under running water (approx. 20°C, drinking water quality).

Comply with the instrument manufacturer's recommendations for reprocessing as well as with national requirements for reprocessing of dental impressions and impression trays.

**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.

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".)



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## Efficacy spectrum/concentration/contact times

Efficacy under dirty conditions (assessed at room temperature)	standard	concentration	contact time
<b>Bacteria</b>			
<i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i>	EN 13727	6 %	15 min
	EN 14561		
<b>Yeasts</b>			
<i>C. albicans</i>	EN 13624	6 %	15 min
	EN 14562		
<b>Enveloped viruses</b>			
MVA Modified Vacciniavirus Ankara	EN 14476	6 %	15 min

## Material compatibility

impression material	silicone, polyether (polysulfone), hydrocolloids (alginates)
plastics	PE, PSU, PVC
Metals	stainless steel
rubber, flexible plastics	silicone
others	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. Avoid contact of more than 48 hours with polycarbonates (Makrolon). Test material compatibility for polyacrylates and polycarbonates before use. For copper, brass and aluminium a colour change is possible upon prolonged contact time. Natural rubber and EPDM may lose elasticity and change their colour upon prolonged contact time. Test material compatibility for not mentioned materials.

## Storage advice

Store product between 5 and 25°C. Protect from direct sunlight. Keep the container in an upright position in a well-ventilated place. Keep container tightly closed. Keep only in original container. Keep away from food, drink and animal feedingstuffs.

## Composition

Active ingredients in 100 g of concentrate:  
3.15 g Didecyloxyethylmethylammonium propionate,  
2.50 g N,N-Bis(3-aminopropyl)dodecylamine  
2.00 g Cocosporylendiamindiguanidinium acetate

## Physico-chemical data

Appearance of concentrate: clear, blue liquid  
pH value: 7.2 – 8.0  
rel. density: 0.990 – 0.999 g/cm<sup>3</sup>

## 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

## Labelling

Medical device class II b / MD 0108

CE 0123

## Expert opinions & further information

PLIWA Biguaton Spezial 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.

## Information for order

single package	packaging unit	REF
1 Litre dosing bottle	18 x 1 Litre	10-884
2 Litres bottle w. handle	10 x 2 Litres	10-880
5 Litres canister		10-881
10 Litres canister		10-882

## application aids for canisters

dosing pump	50006
drainage tap	50009

