

PHAGO'DENT ROTO

Ready to use drill disinfection solution

VAH certificate of efficacy

Product description

PHAGO'DENT ROTO is a ready to use drill disinfection solution. It contains potassium hydroxide, alcohols and amines as well as corrosion inhibitors for material protection. The extensive spectrum of efficacy and the very good material compatibility offer a safety level for the applicant during the reprocessing and application of rotating precision instruments. PHAGO'DENT ROTO is free of aldehydes and phenols.

Area of application

PHAGO'DENT ROTO is applied for the manual disinfection of rotating invasive medical devices (e.g. drills, mills, diamond grinders and other precision instruments) in an immersion bath.

Suitable for e.g.:

- Stainless steel drills
- Diamond drills
- Mills
- Diamond grinders

Not suitable for aluminium parts, elastic polishers, ceramic grinding instruments and root canal instruments.

Do not use for squirting or spraying. Do not use for disinfection of skin and hands.

Material compatibility

Metals	Stainless steel
Plastics	PE, PSU, PVC
Rubber	Silicon, EPDM, natural rubber
Ceramic	Porcelain
Advice:	Upon compliance to the intended use and the indicated contact time, no material damage is to be expected with the above mentioned materials. Avoid contact with aluminium and linoleum. Test material compatibility for polycarbonate, polyacrylate, brass and copper before use.

Application

Put on protective clothing, protective gloves and safety glasses prior to disinfection! Do not allow debris to dry on the instruments.

Disinfection procedure:

- 1) Pour undiluted drill disinfection solution into the drill bath.
- 2) Immerse instruments. Instruments must be completely covered by the solution.
- 3) Rinse instruments very thoroughly with water (at least drinking water quality, ca. 20 °C) after 5 minutes of contact time and dry thoroughly.

In case of persistent debris: Brush off debris under running water, repeat the disinfection procedure with 5 min contact time in fresh drill disinfection solution.

Afterwards, check instruments for cleanliness and integrity and sterilize according to their classification.

Shelf life and expiry

Shelf life: Renew daily and in case of visible contamination.

The expiry date of the product is indicated on the label. Do not use the product after the expiry date.

Special advice

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

Do not mix the product with other chemicals. Prior to the first application of the product or after the application of another product the containers have to be cleaned and rinsed thoroughly.

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

Application only by qualified personnel.

Safety datasheet available at www.pliwa.de.



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Spectrum of efficacy

Efficacy under dirty conditions (undiluted, at room temperature)	Standard	Contact time
Bacteria		
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i>	EN 13727	30 s
	EN 14561	1 min
<i>S. aureus</i> , <i>E. hirae</i> , <i>E. coli</i> , <i>P. mirabilis</i> , <i>P. aeruginosa</i>	Standard methods VAH	5 min
Yeasts		
<i>C. albicans</i>	EN 13624	30 s
	EN 14562	1 min
<i>C. albicans</i>	Standard methods VAH	5 min
Fungi		
<i>A. brasiliensis</i>	Standard methods VAH	5 min
Mykobacteria/TB		
<i>M. terrae</i> , <i>M. avium</i>	EN 14348	2 min
	EN 14563	5 min
<i>M. terrae</i> , <i>M. avium</i>	Standard methods VAH	5 min
Viruses		
MVA modified Vacciniavirus Ankara	EN 14476	1 min
Polyomavirus SV40		5 min
Poliovirus		
Adenovirus		
MNV Murine Norovirus		

Expert opinions and additional information

The efficacy of the PLIWA Roto-Pren has been assessed by independent laboratories.

For further details concerning expert opinions, informations on products and answers to specific questions contact us by e-mail (info@pliwa.de) or telephone (0049 5661 73170).

The manufacturer has a manufacturer's authorisation as per §13 German medicines act as well as a GMP- and an EN ISO 13485 certificate.

Identification, certificates

Medical device class II b / MD 0108

CE 0123

Product composition

100 g ready to use solution contain:

15.00 g Isopropanol, 2.97 g potassium hydroxide, 2.10 g N,N-Bis(3-aminopropyl)-dodecylamine (>90%), 1.25 g sodium nitrite, 1.12 g borax decahydrate

Physico-chemical data

Appearance: clear, colourless liquid

pH-value: > 13

density (20 °C): 1,010 – 1,030 g/cm³

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



UN 2920

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

Storage advice

Store between 5 and 25 °C. Keep the container tightly closed in a well-ventilated place. Store product in an upright position. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from sunlight. Keep only in original container.

See safety datasheet for further advice.

Information for order

Single package	Item no.
1 L (bottle)	12-0051
5 L (canister)	12-0053

