Germo® S.P.A.
Sede Legale Stabilimento e Uffici: 20032 CORMANO (Milano) Via Giotto, 19/21
Telefono +39-0266301938 r.a. - Telefax +39-0266301939
E-mail: info@germodis.com www.germo.it
Capitale Sociale € 156.000,00 interamente versato - R.E.A. 497966 Cod. Fisc. e Part. IVA 00772350153 - Iscr. 125750 R.I. Canc. Trib. MI

LINEA GERMOCID - TECHNICAL DATASHEET

GERMOCID POLVERE

GERMOCID POLVERE is a Class IIb Medical Device conforming to Directive 93/42/EEC.

The powder formulation based on Sodium Percarbonate and Tetraacetylethylenediamine is activated after dissolving the dose of use in warm water; the blue liquid obtained will be transparent in fifteen minutes, time necessary to develop the active ingredient (Peracetic acid). The powder, once dissolved, leaves no residue on the bottom and has no surface foam. GERMOCID POLVERE can be used as a decontaminant, disinfectant, sporicidal, cold sterilizer of invasive medical devices in hospitals, medical and dental surgeries. GERMOCID POLVERE is also a practical sterilant for cold disinfection of heat-sensitive materials such as: endoscopes, optical fibers, transducers, etc. It can also be used with washing machine for endoscopes. The solution can be disposed of as non-hazardous waste. Peracetic acid, formed by the reaction between Sodium Percarbonate and Tetraacetylethylenediamine, even with the interference of organic elements (e.g. biological exudates), acts with a wide range of action towards pathogenic microorganisms such as bacteria, fungi, mycobacteria, viruses and spores.

INSTRUCTIONS FOR USE

Preparation of the solution:

- **prepare the quantity of warm water required in the special tank, checking that the temperature is around 35 ° C: warm water helps dissolve the powder.**
- **pour the necessary dose per liter of water according to the wanted activity.**
- **mix the solution until a clear blue colored solution is obtained.**
- **wait 15 minutes before using the solution.**

Decontamination / Disinfection:

- **use 8 g per liter of water, immerse the instruments in the solution for 10 minutes.**
- **in case of persistence of organic residue, proceed washing the instruments using an appropriate detergent.**
- **for the activity described, the solution remains active for a maximum time of 7 days from the preparation (depending on the quantity of instruments treated).**

Sporicidal activity:

- **use 8 g per liter of water, immerse the instruments in the solution for 10 minutes**
- **for the activity described, the solution remains active for a maximum time of 24 hours from preparation.**

High-level disinfection / cold sterilization:

- **use 16 g per liter of water, immerse the instruments in the solution for 10 minutes.**
- **after the contact time, remove the instruments and rinse with sterile water.**
- **dry and store aseptically**
- **for the activity described, the solution remains active for a maximum time of 24 hours from preparation.**

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PACKAGING

Internal Code:	Primary packaging:	Secondary packaging:
B750	Jar of 500 g	Box containing 2 jars
B500	Sachets of 16 g	Box containing 50 sachets

Barcode	ITF	Box size (mm)	Pallet composition
8009110030046	08009110030046	168 w x 128 d x 156 h	180 ctn (6 floors x 30)
-		223 w x 113 d x 154 h	-

All primary packaging is according to the specifications provided by the Pharmacopoeia. The materials do not contain latex and are perfectly compatible with all components of the formulation.

COMPOSITION

100,0 g of product contain:
Tetracethylethylenediamine 25,0 g; Sodium percarbonate 42,0 g; coformulants q.s. to 100,0 g.

PRODUCT FORM

Granular powder. White color turning to blue.

ACTIVITY

Antimicrobial efficacy tests have been performed according to the following standards:

Norm	Activity	Active concentration	Contact Time
EN13727; EN14561	Bactericidal	0,4%	10 minutes
EN13624; EN14562	Lieviticita (C. Albicans)	0,4%	10 minutes
EN14563	Micobactericidal/Tubercolicidal	0,4%	10 minutes
EN13704	Sporicidal	0,8%	10 minutes
EN13624; EN14562	Fungicidal (A. Brasiliensis)	1,6%	10 minutes
EN14476	Virucidal	1,6%	10 minutes
EN14937	Cold sterilizer	1,6%	10 minutes

WARNINGS

Do not use on Aluminium and Nickel instruments.

VALIDITY

The product is valid for 2 years from the production date, it must be kept in its original packaging. The product fears moisture.

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GERMOCID POLVERE

HOW TO STORAGE

Store in a cool, dry place, away from heat sources.

QUALITY CONTROL

The components (raw materials, containers, labels, etc.) and the processing steps of each lot are regularly and carefully checked internally following the procedures of the Organization Quality Management System certified UNI EN ISO 9001 and UNI EN ISO 13485.

AUTHORIZATIONS

Medical Device CE 0546 class IIb in a compliance with Directive 93/42/EEC as amended by Directive 2007/47/EEC.

CONFIDENTIAL INFORMATION FOR PROFESSIONAL USERS