

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Trade name: Quick-Steril
Trade code: 050110 (Code Cattani 060920)
Product type and use: Concentrate for chemical sterilizer

Company:

Magnolia srl - via Natta 6/A - 43122 Parma – Italy
Tel. +39 (0)521 607604 – Fax +39 (0)521 399967
e-mail: info.magnolia@cattani.it

Emergency telephone number of the company and/or of an authorised advisory centre:
BIRMINGHAM HOSPITALS POISONS UNIT - +44 8706006266

Person in charge of the safety data sheet:

Dr. E. Marcolini – Tel. +39 (0)521 538804 / e-mail: magnoliasrl@virgilio.it

2. HAZARDS IDENTIFICATION

The product is harmful following acute exposure to it and poses a serious health threat if ingested.
If inhaled, the product causes irritation in the airways. and if brought into contact with the skin, it causes appreciable inflammation, with erythema, scabs, and oedema.
If brought into contact with the eyes, the product causes serious eye injury, such as opacity of the cornea or lesions to the iris.
If brought into contact with the skin, the product may cause sensitisation of the skin.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components within the meaning of EEC directive 67/548 and corresponding classification:

20% - 25% ortho-phthal-aldehyde
T,Xi; R25-37/38-43-41

12.5% - 15% alkyl polyglycosides
Xi; R41

12.5% - 15% ethanol
N.67/548/CEE: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6
F; R11; substance with a Community workplace exposure limit

5% - 7% propan-2-ol
N.67/548/CEE: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7
F,Xi; R11-36-67

4. FIRST AID MEASURES

Contact with skin:

Immediately take off all contaminated clothing.

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.

Contact with eyes:

Wash immediately and thoroughly with running water, keeping eyelids raised, for at least 10 minutes. Following this, protect the eyes with sterile gauze or a clean, dry, handkerchief. OBTAIN A MEDICAL EXAMINATION.

Do not use eyewash or ointment of any kind (before obtaining an examination or advice from an eye specialist).

Swallowing:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

A suspension of activated charcoal in water, or liquid paraffin may be administered.

Inhalation:

Ventilate the premises. The patient is to be removed immediately from the contaminated premises to rest in a well ventilated area. OBTAIN MEDICAL ATTENTION.

5. FIRE-FIGHTING MEASURES

Recommended extinguishers:

Water, CO2, Foam, Chemical powders, according to the materials involved in the fire.

Extinguishers not to be used:

None in particular.

Risks arising from combustion:

Avoid inhaling the fumes.

Protective equipment:

Use protection for the respiratory tract.

6. ACCIDENTAL RELEASE MEASURES

Measures for personal safety:

Use a mask, gloves and protective clothing.

Environmental measures:

Limit leakages with earth or sand.

If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

Cleaning methods:

Rapidly recover the product. To do so, wear a mask and protective clothing.

If the product is in a liquid form, stop it from entering the drainage system.

Recover the product for re-use if possible, or for elimination. The product might, where appropriate, be absorbed by inert material.

After the product has been recovered, rinse the area and materials involved with water.

7. HANDLING AND STORAGE

Handling precautions:

Avoid contact and inhalation of the vapours. See, too, paragraph 8 below.

Do not eat or drink while working.

Incompatible materials:

None in particular.

Storage conditions:

Always keep the containers tightly closed.

Instructions as regards storage premises:

Adequately ventilated premises.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged, e.g. CEN/FFP-2(S) or CEN/FFP-3(S).

Protection for hands:

Use protective gloves that provides comprehensive protection, e.g. P.V.C., neoprene or rubber.

Eye protection:

Use close fitting safety goggles and/or visor conforming to BS 2092 GRADE 1).

Protection for skin:

Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or viton.

Exposure limit(s) (ACGIH):

ethanol

TLV TWA: 1000 ppm, A4 - 1884,25 mg/m³, A4 TLV STEL: A4

propan-2-ol

TLV TWA: 200 ppm, A4 - 491,53 mg/m³, A4 TLV STEL: 400 ppm, A4 - 983,07 mg/m³, A4

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and colour: Light blue liquid

Odour: aldehydic

pH: 5 - 8

Flash point: 38 °C

Relative density: 1,048 g/cm³

Solubility in water: total

10. STABILITY AND REACTIVITY

Conditions to avoid:

Stable under normal conditions.

Substances to avoid:

None in particular.

Hazardous decomposition products:

It may generate flammable gases on contact with dithiocarbamates, elementary metals (alkalis, alkaline earth), and nitrides.

It may generate toxic gases on contact with dithiocarbamates.

It may catch fire on contact with oxidising mineral acids, elementary metals (alkalis and alkaline earth), nitrides, powerful oxidising agents, and powerful reducing agents.

11. TOXICOLOGICAL INFORMATION

The concentration of each substance should be borne in mind in assessing the toxicological effects deriving from the preparation.

Set out below is the toxicological information relating to the main substances in the preparation.

ethanol

LD50 (RABBIT) ORAL: 6300 MG/KG

LD50 (RAT) ORAL SINGLE DOSE: 7060 MG/KG

12. ECOLOGICAL INFORMATION

Adopt good working practices, so that the product is not released into the environment.

13. DISPOSAL CONSIDERATIONS

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION

ADR-UNO number:	1987
ADR-Class:	3
Code:	F1
Packing group:	III
Label:	3

15. REGULATORY INFORMATION

Council Directive 67/548/EEC (Classification, packaging and labelling of dangerous substances) and subsequent amendments. Commission Directive 1999/45/EC (Classification, packaging and labelling of dangerous preparation) and subsequent amendments. Commission Directive 98/24/EC (Protection of the health and safety of workers from the risk related to chemical agent). Commission Directive 2000/39/EC (Occupational exposure limit values). Regulation (EC) No 1907/2006 (REACH).

Symbols:

Xn Harmful

R Phrases:

R22 Harmful if swallowed.

R37/38 Irritating to respiratory system and skin.

R41 Risk of serious damage to eyes.

R43 May cause sensitization by skin contact.

S Phrases:

S24 Avoid contact with skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39 Wear suitable gloves and eye/face protection.

S7 Keep container tightly closed.

Contents:

ortho-phthal-aldehyde

Where applicable, refer to the following regulatory provisions :

Directive 2003/105/CE ('Activities linked to risks of serious accidents').

16. OTHER INFORMATION

Text of R phrases referred to under heading 3:

R11 Highly flammable.

R25 Toxic if swallowed.

R36 Irritating to eyes.

R37/38 Irritating to respiratory system and skin.

R41 Risk of serious damage to eyes.

R43 May cause sensitization by skin contact.

R67 Vapours may cause drowsiness and dizziness.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

ACGIH - Threshold Limit Values - 2004 edition

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

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QUICK-STERIL CONCENTRATE FOR CHEMICAL STERILIZER	
INTENDED USE	CONCENTRATE FOR CHEMICAL STERILIZATION OF SURGICAL INSTRUMENTS
STANDARDS AND REGULATIONS APPLICABLE TO THE PRODUCT	GOV.DEC. 65 14/03/2003 DANG. PROD. LABELLING AND FURTHER MODIF. AND INTEGR.
	REG. 93/42 MED. DEV. AND FURTHER MODIF. AND INTEGR.
	UNI CEI EN ISO 14971:2009 RISKS MANAG.
	ITALIAN LAW 690 25/10/78 PREPACKED PRODUCTS AND FURTHER MODIF. AND INTEGR.
	UNI EN 980:2009 GRAPHICAL SYMBOLS
OFFICIAL CE EFFECTIVENESS TESTS	STANDARD UNI EN 13727:2004–14561:2006 - BACTERICIDAL EFFECTIVENESS STANDARD UNI EN 13624:2004–14562:2006 - FUNGICIDAL EFFECTIVENESS BIOLAB TEST REPORT AM 928 DTD 03/08/2004 BIOLAB TEST REPORT AM 1170 DTD 17/10/2005 STANDARD UNI EN 14476:2007 – VIRUCIDAL EFFECTIVENESS BIOLAB TEST REPORT AM 1170-3 DTD 17/10/2005 STANDARD UNI EN 14348:2005–prEN 14563:2002 TUBERCULICIDE EFFECTIVENESS BIOLAB TEST REPORT AM 928-1 DTD 18/01/2005 BIOLAB TEST REPORT AM 1359 DTD 31/05/2006 STANDARD AFNOR NF T 72-190 – SURFACE SPORICIDAL ACTIVITY BIOLAB TEST REPORT AM1170-5 DTD 14/02/2006 STANDARD UNI EN 13704:2005 – SUSPENSION SPORICIDAL ACTIVITY BIOLAB TEST REPORT AM 1170-4 DTD 28/09/2005
CHEMICAL COMPOSITION	19.9% ORTHO-PHTHALALDEHYDE 0.9% NON-IONIC TENSIDE 12.5% ETHANOL 7.5% ISOPROPANOL 12.5% ALKYL POLYGLYCOSIDE
CHEMICAL-PHYSICAL CHARACTERISTICS	PH (as it is) 5 - 8
	DENSITY AT 20°C (g/cm ³) 1.0425 ± 0.005
	ASPECT AND COLOUR LIGHT BLU LIQUID
	ODOUR TYPICAL phenolic
	REFRACTION INDEX (R.I.) 1.411 ± 0.005
	SOLUBILITY IN WATER Complete
PERFORMANCES	EFFECTIVE AGAINST : - BACTERIA (STAPHYLOCOCCUS AUREUS, PSEUDOMONAS AERUGINOSA, ENTEROCOCCUS HIRAE), AND - FUNGI (CANDIDA ALBICANS, ASPERGILLUS NIGER) - VIRUSES (POLIOVIRUS TYPE 1, ADENOVIRUS TYPE 5) - MYCOBACTERIA (MYCOBACTERIUM TERRAE) - BACTERIA SPORIGENIC (BACILLUS SUBTILIS, BACILLUS CEREUS, CLOSTRIDIUM SPOROGENES)
INSTRUCTION FOR USE	SOLUBILIZED AT 1.5% IN WATER IS READY FOR USE (IMMERSION OF THE CLEANED UP INSTRUMENTS TO BE STERILIZED)
SHELF LIFE	2 YEARS FROM PREPARATION (IN ORIGINAL CONTAINER)
STORAGE CONDITIONS	AVOID DIRECT SUNLIGHT; KEEP AT TEMPERATURE 0-40° C
FLAMMABILITY	38° C (FLAMMABLE ONLY FOR TRANSPORT)

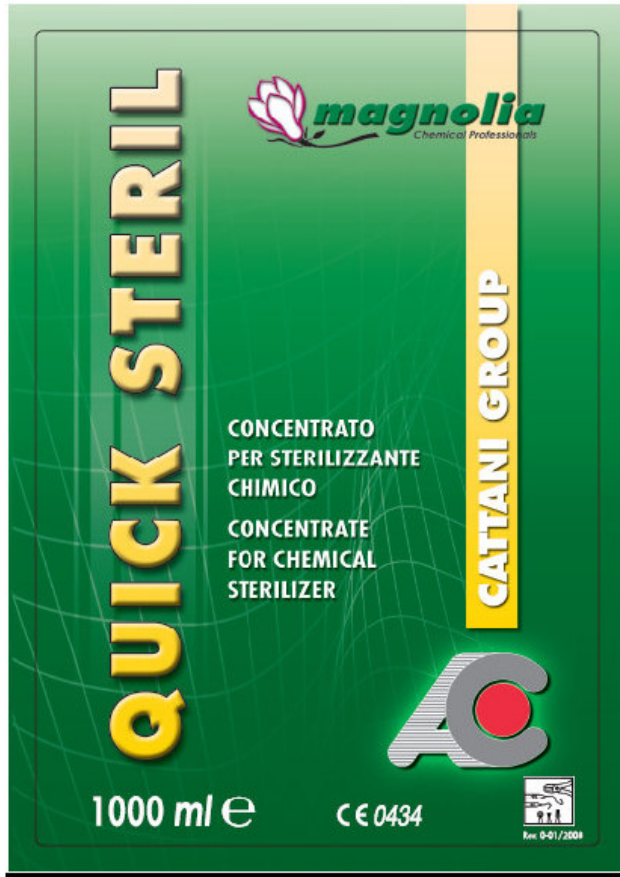
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DANGER WARNING	X _n	
DANGER LABELLING	R41 – R22 – R43 S24 – S26 – S37/39 – S7	
BIODEGRADABILITY OF COMPONENTS	ALL THE COMPONENTS ARE CLASSIFIED AS “EASILY DEGRADABLE” APART FROM: ORTHO-PHTHALALDEHYDE OF WHICH DATA ARE NOT AVAILABLE AT THE TIME BEING – (IT IS NOT CLASSIFIED AS DANGEROUS FOR THE ENVIRONMENT = R50/53).	
UNIT CONTAINER	Pack characteristics	PLASTIVALLE 1000 ML HDPE BOTTLE WITH GRADUATED DISPENSER AND TWO CAPS (RED AND BLUE) (OUR CODE 201070)
	Dimensions (mm)	67 X 135 X 257 H
	Weight (empty bottle+caps) (g)	87 ± 1
	Weight (content+bottle) (g)	1129 ± 10 (WITH CAPS)
	Label	PE, WORK-AND-TURN PRINTING (SEE ATTACHMENT A)
MULTI-UNIT CONTAINER	Pack characteristics	CORRUGATED QUADRICOLOUR PRINTED CARTON (OUR CODE 303090)
	Dimensions (carton) (mm)	255 x 140 x 270 H 165 g
	Content	NO.4 1000 ML BOTTLES
	Weight (kg)	4.690

PALLETIZZAZIONE LAYOUT

(for EUROPALLET : from _120_ **CARTONBOX** / no. _5_ **LAYERS** / **HEIGHT** 145 CM

1 l bottle Label
CONCENTRATE FOR CHEMICAL
STERILIZER



INDICAZIONI D'USO: Questo sterile, stabile e inodore il "Quick-Steril" è indicato per gli strumenti chirurgici da non essere assorbiti termicamente. Può essere utilizzato in vaschette di ABS, polietilene, polipropilene, acido base e vetro.

Preparazione: Diluire 15 ml di concentrato in ogni litro di acqua per preparare una soluzione sterilizzante in 8 ore. In un'ora 60 ml di prodotto per ogni litro di acqua. Il tempo di sterilizzazione si riduce a 4 ore (vedere la tabella sottostante). La soluzione si può usare a riscossa di strumenti più puliti ed essiccati. Concentrato apto, lo soluzione può essere utilizzata una sola volta, controllata l'efficacia con l'apposita "Indicatore per Quick-Steril" al fine di verificare la concentrazione minima efficace (MCE). È consigliabile verificare l'efficacia anche dalla soluzione appena preparata. Dopo il tempo di sterilizzazione è indispensabile risciacquare con acqua delimitata sterile.

Spettro / tempo d'azione:

Concentrazione d'uso	Attività Battericida UNI EN 13737:2004 UNI EN 14541:2004	Attività fungicida UNI EN 13424:2004 UNI EN 14542:2004	Attività Tuberculicida UNI EN 14344:2005 per EN 14543:2002	Attività Virucida UNI EN 14474:2007	Attività Sporicida (BIF - Sporicidante) UNI EN 13704:2005 AEMER NF T 72-190
1,5%	< 60 minuti	< 60 minuti	< 30 minuti	< 5 minuti	< 4 ore
0,5%	< 5 minuti	< 5 minuti	< 5 minuti	< 5 minuti	< 4 ore

Avvertenze:

- Utilizzare sempre guanti protettivi (si consiglia guanti in nitrile)
- Evitare il contatto con la pelle (il prodotto può essere irritante) e con gli occhi (il prodotto può essere irritante) e con le mucose (il prodotto può essere irritante) e con le mucose (il prodotto può essere irritante)
- Il prodotto è compatibile con tutti i metalli e plastici ma è bene tenerne una vecchia provetta.
- Non miscelare con altri prodotti.
- Non versare il liquido nella fognatura.

QUICK-STERIL - Concentrate for Chemical Sterilizer

DIRECTIONS FOR USE: Read according to the directions. "Quick-Steril" is a high-level disinfectant and a sterilizer for surgical instruments which cannot be sterilized thermally. It can be used in ABS, polyethylene, polypropylene, acid base and glass bottles.

Solution preparation: Dilute 15 ml of concentrate in 1 liter of water for a sterilizing solution which is proven to be effective in 8 hours. With 60 ml of product for 1 liter of water the sterilizing action is shortened to 4 hours (see table below). The solution is one ready for the treatment of the instruments which have been previously rinsed clean and dried. It kept in a covered bottle. The solution can be used again, provided that you check its efficacy by means of the special "Indicator for Quick-Steril" (Quick-Steril Indicator) which allows to verify the solution minimum effective concentration (MCE). We recommend to check also the efficacy of the new prepared solution. After sterilization the instruments must be rinsed with sterile distilled water. Activity spectrum/Time:

Disinfection concentration	Bactericidal action UNI EN 13737:2004 UNI EN 14541:2004	Fungicidal action UNI EN 13424:2004 UNI EN 14542:2004	Tuberculicidal action UNI EN 14344:2005 per EN 14543:2002	Virucidal action UNI EN 14474:2007	Sporicidal activity (Sporiciding effect) UNI EN 13704:2005 AEMER NF T 72-190
1,5% (15ml/l of water)	Within less than 60 min.	Within less than 60 min.	Within less than 30 min.	Within less than 5 min.	Within less than 4 hours
0,5% (50ml/l of water)	Within less than 5 min.	Within less than 5 min.	Within less than 5 min.	Within less than 5 min.	Within less than 4 hours

Warnings:

- Wear always protective gloves (nitrile gloves are recommended).
- Do keep in contact with the product for a long time, light exposure and sunny surfaces (plastic bottles) can get stained with black color; also in reaction of Quick-Steril with porous (stainless steel, lacquer, etc.) should not help to remove such stains.
- The product is compatible with all metals and plastics, but we recommend carrying out a preliminary test on rubber parts.
- Do not mix with other products.
- Do not release the empty bottles into the environment.

Caution:

- R01 Evitare il contatto con la pelle / Avoid skin contact.
- R22 Irritante per l'acqua / Irritant to water.
- R51 Pericoloso per l'ambiente acquatico / Very toxic to aquatic life.
- S26 In caso di contatto con gli occhi, lavare immediatamente e abbondantemente con acqua e sapone in modo continuo / In case of contact with eyes, rinse immediately with plenty of water and mild soap.
- S34 Evitare il contatto con la pelle / Avoid contact with skin.
- S37/39 Evitare il contatto con gli occhi / Evitare il contatto con le mucose / Evitare il contatto con la pelle / Avoid contact with eyes / Avoid contact with skin.
- SF Conteneri di rifiuti ben chiusi / Keep containers tightly closed.

Prodotto da - Manufactured by:
Magnolia s.r.l. - Via Natta, 4/c - 43100 Pienza (Italy)
Tel. +39 (0)521 687664 - Fax +39 (0)521 399967

Contiene anidride carbonica CO2
Contiene Olio-Piccolo-Volume 20%

1000 ml e CE 0434

Rec 0-01/2008