



Safety Data Sheet
Indicatore per QUICK-STERIL

Safety Data Sheet dated 07/12/2007, version 0

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

Trade name: Indicatore per QUICK-STERIL
Trade code: 050201 (Cattani Code 060930)
Product type and use: Sterilization efficacy indicator

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

No specific hazards are encountered under normal product use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

5% - 7% phosphoric acid
N.67/548/CEE: 015-011-00-6 CAS: 7664-38-2 EC: 231-633-2
C; R34

4. FIRST AID MEASURES

Contact with skin:

Wash with plenty of water and soap.

Contact with eyes:

Wash immediately with water for at least 10 minutes.

Swallowing:

Induce vomiting. SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety-data sheet.

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 and made to rest in a well ventilated area. Should the patient feel unwell, 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 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:

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:

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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:
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:
Not needed for normal use.
Protection for hands:
Not needed for normal use.
Eye protection:
Not needed for normal use.
Protection for skin:
No special precaution must be adopted for normal use.
Exposure limit(s) (ACGIH):
phosphoric acid
VLE 8h: 1 mg/m³ VLE short: 2 mg/m³ TLV TWA: 0,25 ppm - 1 mg/m³ TLV STEL: 0,75 ppm - 3 mg/m³

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and colour:	Transparent liquid with indigo reflections
Odour:	Light sulphurous smell
pH:	about 2
Boiling point:	about 100 °C
Flash point:	non flammable
Relative density:	about 1

10. STABILITY AND REACTIVITY

Conditions to avoid:
Stable under normal conditions.
Substances to avoid:
None in particular.
Hazardous decomposition products:
None.

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.
phosphoric acid
LD50 (RABBIT) SKIN: 2740 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. In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION

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).

Special Provisions:
Safety data sheet available for professional user on request.

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:
R34 Causes burns.

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 Indicator (IIB class)		
INTENDED USE	CHROMATIC SEMI-QUANTITATIVE INDICATOR TO TEST THE MINIMUM EFFECTIVE CONCENTRATION OF QUICK-STERIL STERILIZER FOR SURGICAL INSTRUMENTS	
STANDARDS AND REGULATIONS APPLICABLE TO THE PRODUCT	GOV.DEC. 65 14/03/2003 DANGEROUS PRODUCT LABEL SMI	
	REG. 93/42 MEDICAL DEVICE SMI	
	UNI CEI EN ISO 14971:2009 RISKS MANAGEMENT	
	ITALIAN LAW 690 25/10/78 PREPACKED PRODUCTS SMI	
OFFICIAL CE EFFECTIVENESS TESTS	NOT REQUESTED	
CHEMICAL COMPOSITION	BASIC FUCSINE	0,09%
	SODIUM SULPHITE	0,3%
	WATER	q.s. 100
CHEMICAL-PHYSICAL CHARACTERISTICS	PH (as it is)	2,3
	DENSITY AT 20 °C (g/cm ³)	1,0 ± 0.005
	ASPECT AND COLOUR	TRASPARENT LIQUID
	ODOUR	LIGHT SULPHUROUS SMELL
	REFRACTION INDEX (R.I.)	1,375 ± 0.005
	SOLUBILITY IN WATER	Complete
PERFORMANCES	PASS = 0,3% OPA / FAIL = 0,1% OPA	
INSTRUCTION FOR USE	MIXED WITH 1:1 RATIO IN THE SOLUTION OF QUICK-STERIL AFTER 2 MINUTES, IT SHOWS A PURPLE COLOUR (TO BE COMPARED WITH THE COLOUR SHOWN ON THE LABEL).	
SHELF LIFE	1 YEAR FROM PREPARATION (IN ORIGINAL CONTAINER)	
STORAGE CONDITIONS	AWAY FROM DIRECT SUNLIGHT; KEEP AT TEMPERATURE 0÷ 40 °C	
FLAMMABILITY	NON FLAMMABLE	

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DANGER WARNING	//	
DANGER LABELLING	//	
UNIT CONTAINER	Components	100 ML YELLOW GLASS BOTTLE WITH RUBBER CAP (BAGNI VETRERIE) (OUR CODE 201080) + 5 ML GRADUATED SYRINGE (OUR CODE 203010) + ADAPTER (OUR CODE 206001)
	Bottle dimensions (mm)	Ø 50 X 100 H
	Weight (empty bottle) (g)	95 ± 5
	Weight (content) (g)	100 ± 1
	Pack characteristics	WHITE CARTON - PANTONE COLOUR - mm 100 x 70 x 133 H WEIGHT = g 50 ± 1
	Packing weight (g)	245 ± 5

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ATTACHEMENT A

Label for 100 ml bottle QUICK STERIL Indicator



QUICK STERIL INDICATORE

CATTANI GROUP

CE 0434



INDICATORE PER QUICK-STERIL è stato formulato unicamente per testare il contenuto in orto-Ftalaldeide (OPA) della soluzione sterilizzante di QUICK-STERIL alla concentrazione minima del 1,5%. Si deve usare prima dei trattamenti di sterilizzazione con soluzioni fresche o riusate per accertarsi della presenza del Principio Attivo in quantità efficace (MEC).

INFORMAZIONI D'USO:


1. Applicare l'adattatore al flacone facendo il tappo in gomma con l'ago di plastica nell'interio dell'adattatore stesso. L'adattatore non deve più essere rimosso dal flacone.
2. Avvitare la siringa graduata sul filetto dell'adattatore e, dopo aver capovolta il flacone, aspirare 1 cm³ di indicatore.
3. Svitare la siringa graduata ed aspirare un ulteriore cm³ della soluzione da testare.
4. Capovolgere alcune volte la siringa per favorire la miscelazione ed attendere esattamente 2 minuti prima di confrontare il colore che si sviluppa nella siringa con quello riportato sotto.
5. Svuotare la siringa nel lavello ed aspirare alcune volte un po' di acqua per la pulizia. Riporre il flacone, con l'adattatore inserito, e la siringa pulita ed asciutta nell'astuccio pronti per essere usati ancora.

ATTENZIONE: Valutare il colore esattamente dopo 2 minuti dalla miscelazione. Non usare il prodotto dopo la data di scadenza o se il suo colore fosse viola intenso. Proteggersi le mani con guanti monouso.

OK passa il test	NON passa il test
PASS	FAIL

Σ
100

Contiene < 0,1% Fucsina Basica
Contenuto: 100 cm³ (sufficiente per 100 prove)
It contains < 0,1% Basic Fuchsin
Content: 100 cm³ (enough for 100 tests).



...max.
40°C

...min.
0°C

Prodotto da/Manufactured by: **Magnolia s.r.l.**
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LOT Lotto n°
 Lot no.

Usare entro:
Use within:

Rev. 0 - 01/2008