matachana

SAFETY DATA SHEET
MATACHANA Sterilizing Solution

according to (REACH) Regulation (EC) No. 1907/2006
and to (CLP) Regulation (EC) No. 1272/2008,
in conjunction with Directives 91/155/EEC and 2001/58/EC

1. Identification of the mixture and of the company

1.1 Product identifier

MATACHANA LTSF-Sterilising solution
Formaldehyde content: 2%

1.2 Relevant identified uses of the substance or mixture and uses advised against

Sterilization solution to be used as sterilizing agent in sterilizers Matachana 130 LF (LTSF) according to European Standard EN 14180.

1.3 Details of the supplier of the safety data sheet

ANTONIO MATACHANA, S.A.
C/ Almogàvers, 174
E-08018 Barcelona
España

1.4 Emergency telephone number

Tel. +34 93 300 80 12 (Office hours)
e-mail: info@matachana.com

2. Hazards identification

2.1 Classification of the mixture acc. Regulation (EC) No. 1272/2008

Skin Sens. 1: H317
Carc. 1B: H350
Muta. 2: H341

Danger

2.2 Label elements acc. Regulation (EC) No. 1272/2008

Contents: Formaldehyde 2% (CAS No.: 50-00-0)

Hazard pictograms and signal word:

Hazard statements:	H317	May cause an allergic skin reaction.
	H350	May cause cancer.
	H341	Suspected of causing genetic defects.
Precautionary statements:	P202	Do not handle until all safety precautions have been read and understood.
	P261	Avoid breathing vapours.
	P280	Wear protective gloves.
	P302+P352	IF ON SKIN: Wash with plenty of soap and water.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P405	Store locked up.
Supplemental hazard statements:		
	EUH208	Contains formaldehyde. May produce an allergic reaction.

2.3 Other hazards

None.
According to Annex XIII of Regulation (EC) Nº 1907/2006 (REACH), formaldehyde is not classified as PBT nor mPmB.

3. Composition/information on ingredients

3.2 Mixtures

2% aqueous solution of formaldehyde (EC No. 200-001-08).

Substances that contribute to the hazards of the mixture:

Ingredients	CAS No.	Classification Directive 67/548/EC		Classification Regulation 1272/2008/EC		%
Formaldehyde	50-00-0	Car. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25 C; R34 R43		Carc. 1B; H350 Muta. 2 ; H341 Acute Tox. 3; H331 Acute Tox. 3; H311 Acute Tox. 3; H301 Skin Corr. 1B; H314 Skin Sens. 1; H317		1,8 - 2,2
		Specific concentration limits		Specific concentration limits		
		C ≥25 % 5 % ≤ C < 25 % C ≥25 % 5 % ≤ C < 25 % C ≥ 0,2 %	T; R23/24/25 Xn; R20/21/22 C; R34 Xi; R36/37/38 R43	C ≥25 % 5 % ≤ C < 25 % 5 % ≤ C < 25 % C ≥ 5 % C ≥ 0,2 %	Skin Corr. 1B; H314 Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 Skin Sens. 1; H317	

4. First aid measures

4.1 Description of first aid measures

Immediately remove any clothing that has been in contact with the product. Use plenty of water to rinse skin that has been in contact with the product.

4.2 Most important symptoms and effects, both acute and delayed

It is not considered to present a significant risk to human health under conditions of intended use. For further information see Section 2, on mixture hazards, and Section 11, on toxicological effects.

4.3 Indication of any immediate medical attention and special treatment needed

In case of insufficient ventilation place the affected person to fresh air.
In case of persistent discomfort seek medical attention.

5. Firefighting measures

5.1 Extinguishing media

In case of fire, the presence of the solution does not limit the use of extinction media resistant to alcohol generally available on the market.

5.2 Special hazards arising from the substance or mixture

The LTSF-Sterilizing Solution contains more than 95% water and is not flammable.

5.3 Advice for firefighters

In case of fire, the presence of the solution does not pose additional requirements for the fire fighting protective equipment.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not inhale the vapours. Ventilate the premises thoroughly.
Avoid all skin contact.

6.2 Environmental precautions

Dilute with plenty of water.

6.3 Methods and material for containment and cleaning up

6.3.1 Accidental spills or leakages

Provide sufficient ventilation.
Dilute with plenty of water.
Wear protective gloves.
Collect any spilled solution with a cloth or paper towel or with hydrophilic material.
Dispose it by the sewer system or together with household rubbish.

6.3.2 Vapour/gas leaks from the sterilizer

Switch the sterilizer off by means of the main switch.
Ventilate the area.
Notify the Technical Service.

6.4 Reference to other sections

For conditions concerning the elimination, see Section 13.

7. Handling and storage

7.1 Precautions for safe handling

The product must be handled and used with care and in strict accordance with the instructions provided by the manufacturer.
Ensure good ventilation and wear protective gloves.

7.2 Conditions for safe storage, including any incompatibilities

Store the sterilizing solution only in its original container.
Storage temperature: +5 ºC to +40 ºC.
Store in a well-ventilated area, away from direct sunlight.
Protect against all unauthorised access.
Do not use after the expiry date shown on the container label or outer packaging.

7.3 Specific end uses

The Matachana LTSF Sterilizing Solution may only be used in Matachana LTSF sterilizers (formaldehyde based). These equipments operate completely automatically, as specified in European Standard EN 14180.

8. Exposure controls/personal protection

8.1. Control parameters

a) Exposure Limit Values:

EC No.	CAS No.	Name of the substance	Limit Value (TLV)	Limit Value (MAK)
200-001-8	50-00-0	Formaldehyde	0,37 mg/m^3 (0,3 ppm)	0,37 mg/m^3 (0,3 ppm)

b) Biological Limit Values:

Formaldehyde has no Biological Limit Value.

8. (Continues)

8.2 Exposure controls

8.2.1 Appropriate engineering controls

When the Matachana sterilizing solution used as intended in CE market Matachana LTSF sterilizers applying the specific criteria method according to the German Technical Regulation TRGS 513, Annex 5, the formaldehyde exposure permanently secure, held at the lowest level, is ensured. Accordingly, the TRGS 513 requirement for permanent air monitoring of the work area and other measures can be omitted.

Measurements made in accordance with German Technical Regulation TRGS 402 under these conditions proves that, if the sterilizers are properly used in accordance with the user instructions, the MAK value of 0,37 mg/m3 (0,3 ppm) set forth in TRGS 900 for formaldehyde is not reached with a wide safety margin, so it confirms that it is not necessary a continuous monitoring of the work space air.

8.2.2 Individual protection measures

a) Eye/face protection

No special measures required.

b) Skin protection

i) Hand protection

Wear waterproof protective gloves.

ii) Other

No special measures required.

c) Respiratory protection

When the Matachana sterilizing solution used as intended with the required fresh air supply of at least 100 m³/h respiratory protection is not required for compliance.
In case of leak and while the change of the bag is being made suitable respiratory protection must be used.

d) Thermal hazards

No special measures required.

8.2.3 Environmental exposure controls

No special measures required.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Aspect:	colourless, clear liquid
Physical state:	liquid
Colour:	colourless, clear
Odour:	Slightly penetrating
pH:	5-7 at 20 ºC
Boiling range:	78-100 ºC
Flash point:	> 68 ºC
Ignition temperature	> 300 ºC
Explosion hazard:	none
Vapour pressure:	approx. 50 hPa at 20 ºC
Density:	approx. 1 g/cm^3 at 20 ºC
Solubility in water:	unlimited
Viscosity (dynamic):	approx. 2 mPa at 20 ºC

9.2 Other information

No available data.

10. Stability and reactivity

10.1 Reactivity

Formaldehyde reacts with strong oxidising agents, strong bases, acids, nitrogen oxides and alkaline metals, among others.

10.2 Chemical stability

This product, in compliance with the indicated concentrations and storage conditions (see section 7.2) is a stable mixture. It is suitably stabilized by a low ethanol content.

10.3 Possibility of hazardous reactions

Formaldehyde with chlorhydric acid forms bis(chloromethyl) ether, an important carcinogenic agent. Formaldehyde can react violently with strong oxidising agents and alkaline materials. It reacts explosively with nitrous oxide (at 180°C), with performic acid, aniline, nitromethane, magnesium carbonate and hydrogen peroxide.

10.4 Conditions to avoid

Respect storage conditions (see section 7.2).

10.5 Incompatible materials

Strong oxidising agents, strong bases, acids, nitrogen oxides and alkaline metals.

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

11. Toxicological information

11.1 Information on toxicological effects

11.1.1 Toxicokinetics, metabolism and distribution

Formaldehyde is an intermediate part of the natural metabolism in humans (About 50 mg/day). Permanent share in the blood is about 3 mg/L. Content in cigarette smoke: about 1.5 mg.

Primary irritant effect: In the respiratory tract irritant
Slightly irritating to the skin
Irritating to the eye

May cause sensitization by skin contact.
May cause cancer and it is suspected of causing genetic defects.

11.1.2 Acute effects toxicity tests / assessments

Moderately toxic:

8 h inhalation in cats	820 mg/kg	[3]
LD_{50} in rats (oral)	800 mg/kg	
LD_{50} in rabbits (subcutaneous)	240 mg/kg	

11.1.3 Experiences made from practice

"At indoor air levels of or below 124 μg/m³ is virtually no carcinogenic effect to expect more" [1]

"The low odour threshold and inhalation irritation are early signals simultaneously from a critical formaldehyde exposure." [2]

[1] A.Hensel, Bundesinstitut für Risikobewertung (Berlin), in Mitteilung 14/2006 v. 29.05.2006.
[2] A.Kramer, F.-A. Pitten, K.J. Freundt, R. Andermatten: Nutzen-Risiko-Bewertung von Formaldehyd als Desinfektionswirkstoff und Antiseptikum. Hyg Med 21 (1996), 536–557.

12. Ecological information

12.1 Toxicity

All ingredients composing the Matachana Sterilizing Solution exist in nature as biological products of the metabolism. Moreover, at the concentrations used here, they decompose readily and naturally into carbon dioxide and water, due to the effects of light, heat and oxygen.

12.2 Persistence and degradability

According to the intended use, the product can be diluted in water at a ratio of <1:200. The substance can then be disposed of by the sewer piping without any problem, and readily decomposes into basic biological substances.

12.3 Bioaccumulative potential

No relevant.

12.4 Mobility in soil

The Matachana Sterilizing Solution acts as water in terms of mobility. Segregation of its constituents does not occur.

12.5 Results of PBT and vPvB assessment

Formaldehyde:
According to Annex XIII of Regulation (EC) Nº 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): It does not meet the criteria to be classified as PBT (persistent / bioaccumulative / toxic) nor as mPmB (very persistent / very bioaccumulative).

12.6 Other adverse effects

None.

13. Disposal considerations

13.1 Waste treatment methods

Residual amounts can be disposed via the waste water system. Rinse afterwards with clean water.

Follow all applicable local regulations.

Containers that are completely emptied and rinsed with water can be disposed via the domestic waste or returned to the manufacturer for disposal.

14. Transport information

The MATACHANA LTSF-Sterilising solution is not a hazardous product for the purposes of the different regulations relating to the transport by land (ADR, RID), sea and air (ICAO, IATA).

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation (EC) nº 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

- Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out for this mixture.

16. Other information

The MATACHANA Sterilizing Solution may only be used in strict compliance with the instructions for use or the operation manual of the Matachana 130 LF – LTSF (*) sterilizer by personnel with adequate training. Attention is drawn to German regulation TRGS 513 and the operating relevant process and substance specific criteria in Annex 5.

The information contained herein is based on our current knowledge. It does not represent any warranty concerning the properties of the equipment, nor does it constitute a contractual relationship.

(*) LTSF - Low Temperature Steam and Formaldehyde