

CE SAFETY DATA SHEET

according to Directives 91/155/EEC and 2001/58/EC
about classification, packaging and labelling of dangerous substances

1. Identification of the preparation and of the company/undertaking

1.1 Trade name

MATACHANA LTSF-Sterilising solution
Formaldehyde content: 2%

1.2 Use of the substance / preparation

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

1.3 Company identification

ANTONIO MATACHANA, S.A.
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Tel.: +34 93 300 80 12
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1.4 Emergency telephone

ANTONIO MATACHANA, S.A. (SPAIN)
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2. Composition/information on ingredients

2.1 Chemical composition

2% aqueous solution of formaldehyde with a low content of ethanol (used as stabilizer)

CE number: Formaldehyde 200-001-8
 Ethanol 200-578-6

2.2 Classification under the Dangerous Substances Regulation

Danger symbol: Xn harmful

Risk phrases: R40 limited evidence of a carcinogenic effect
 R43 may cause sensitization by skin contact

3. Hazards identification

Irritating to eyes, respiratory system and skin

Possibility of harmful effects for health by inhalation, ingestion or skin contact.

Possible carcinogenic effects (classified as carcinogenic category 3 according to Annex I of Directive 67/548/EEC about dangerous substances). See section 11.

Possible risk of irreversible effects.

4. First aid measures

4.1 Inhalation

Move away the affected person from the exposure area, taking him/her to a place where fresh air is available. If the irritation persists, seek medical assistance.

4.2 Skin contact

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.

4.3 Eye contact

In case of eye contact, rinse with plenty of water. Use an eye bath if available. Visit an eye specialist.

4.4 Ingestion

Drink plenty of water and seek medical assistance.

5. Fire-fighting measures

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

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

6. Accidental release measures

6.1. Personal precautions

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

6.2. Environmental precautions

Dilute with plenty of water.

6.3. Methods for cleaning up

6.3.1. Accidental spills or leakages

Provide sufficient ventilation.
 Dilute with plenty of water.
 Wear protective gloves if necessary.
 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.
 Rinse with plenty of water.

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.

7. Handling and storage

7.1. Handling

The product must be handled and used in strict accordance with the instructions at all times. Keep the container tightly closed; open and handle with care. Ensure good ventilation.
 Keep away from food and drink.
 Transfer only to the manufacturer's original containers provided for this purpose. When transferring, avoid all contact with skin and eyes. Wear protective gloves.

7.2. Storage

Store the sterilizing solution only in its original container.
 Storage temperature: +5° C to +40° C
 Store away from food, drink and animal feed.
 Protect against all unauthorised access.
 Do not use after the expiry date shown on the container label or outer packaging.

8. Exposure controls/personal protection

8.1 Additional instructions for the design of technical facilities

The Matachana LTSF Sterilizing Solution may only be used in Matachana LTSF sterilizers (formaldehyde gas-based). This equipment operates completely automatically, as specified in European Standard EN 14180.
 A report issued by TÜV Nord (a technical inspection society) in accordance with German regulation TRGS 402 proves that, if these machines are properly used in accordance with the user instructions, the MAK value of 0,6 mg/m³ (0,5 ppm) set forth in TRGS 900 for formaldehyde is not reached with a wide safety margin, so it is not necessary a continuous monitoring of the work space air.

8.2 Exposure limit values

CE 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)	0,6 mg/m ³ (0,5 ppm)
200-578-6	64-17-5	Ethanol	1880 mg/m ³ (1000 ppm)	1900 mg/m ³ (1000 ppm)

8.3 Personal protection equipment

When transferring the substance to another container, and in case of spillage, wear water-tight gloves (rubber or silicone), and if it is necessary, safety glasses.

9. Physical and chemical properties

9.1 Appearance

State: Liquid
Colour: Clear, colourless
Odour: Slightly penetrating

9.2 Important safety data

Boiling range: 78-100° C
Flash point: > 68° C
Ignition temperature > 300 °C
Explosive properties: none
Vapour pressure: approx. 50 hPa at 20° C
Density: approx. 1 g/cm³ at 20° C
Solubility in water: unlimited
Viscosity (dynamic): approx. 2 mPa at 20°C
pH: 5-7 at 20°C

10. Stability and reactivity

Follow the storage conditions (see section 7.2).

This product reacts with strong oxidising agents, nitromethane and magnesium carbonate.

No hazardous decomposition products are known.

11. Toxicological information

11.1 Toxicity

LD₅₀ in rats (oral) > 800 mg/kg
LD₅₀ in rabbits (subcutaneous) > 240 mg/kg

11.2 Main irritating effects:

Irritating to the respiratory system.
Moderately irritating to the skin.
Irritating to the eyes.

11.3 Possible sensitization due to skin contact

11.4 According to Annex I of Directive 67/548/EEC regarding Dangerous Substances

Formaldehyde is classified into Category 3 carcinogenic substance, i.e., suspected of possible carcinogenic effects in humans, although sufficient information for definitive classification is not available. Based on tests performed with animals, there are some signs (although not sufficient) that the substance may warrant classification as a Category 2 substance (indications that the substance might cause cancer).

12. Ecological information

12.1 Ecotoxicity

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 Mobility

The Matachana Sterilizing Solution acts as water in terms of mobility. There is not separation of its constituents.

12.3 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.

12.4 Bioaccumulative potential

Not relevant.

12.5 Other adverse effects

None.

13. Disposal considerations

Waste amounts can be disposed of by the normal sewer system. Rinse afterwards with clean water.

Formaldehyde can be completely neutralised by using a sodium sulphite solution. Follow all applicable local regulations.

Once the containers have been completely emptied and rinsed with water, they may be disposed of with household rubbish or sent to the manufacturer.

14. Transport information

The Matachana sterilising solution is not a hazardous product for the purposes of the different regulations relating to land, sea and air transport.

15. Regulatory information

15.1 Symbols



Xn

Xn	Harmful Contains formaldehyde (2%)
Risk phrases:	R40 Limited evidence of a carcinogenic effect R43 May cause sensitization by skin contact
Safety phrases:	S23 Do not breathe gas / vapour S24/25 Avoid contact with skin and eyes

15.2 National regulations

National regulations which implement the following provisions must be followed:

- Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
- Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
- Directive 1999/45/EC of the European Parliament and of the council concerning the approximation of the laws, regulations and administrative provisions of the member states relating to the classification, packaging and labelling of dangerous preparations.

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 (*) (Low Temperature Steam with Formaldehyde) sterilizer by personnel with adequate training.

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