

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING


- 1.1 Product identifier:** PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate w/ 25 mM Hepes
- Other means of identification:**
Not relevant
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Used in biotechnology
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
MSE SAS FRANCE
15 Rue du Mans
49300 Cholet - France
Phone: +33 02 41 64 73 41
biosera@mse-sas.fr
www.biosera.com
- 1.4 Emergency telephone number:** ORFILA: 01 45 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Hazard statements:
Not relevant
Precautionary statements:
Not relevant
Supplementary information:
EUH210: Safety data sheet available on request.
- 2.3 Other hazards:**
Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Mixture composed of inorganic substances
Components:
In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 10035-04-8 EC: Non-applicable Index: Non-applicable REACH: 01-2119494219-28-XXXX	Calcium chloride · 2H₂O⁽¹⁾ Regulation 1272/2008 Eye Irrit. 2: H319 - Warning	Self-classified  1 - <2,5 %

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

- CONTINUED ON NEXT PAGE -

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

- CONTINUED ON NEXT PAGE -

biosera PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate w/ 25 mM Hepes

SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Calcium chloride · 2H ₂ O CAS: 10035-04-8 EC: Non-applicable	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	10 mg/m ³	Not relevant	5 mg/m ³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Calcium chloride · 2H ₂ O CAS: 10035-04-8 EC: Non-applicable	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	5 mg/m ³	Not relevant	2,5 mg/m ³

PNEC:

Not relevant

8.2 Exposure controls:

- CONTINUED ON NEXT PAGE -



biosera PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate w/ 25 mM Hepes

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)



A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Compulsory use of face mask	Filter mask for particles		EN 149:2001+A1:2009	Replace when an increase in resistance to breathing is observed.

C.- Specific protection for the hands



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN ISO 21420:2020 and EN ISO 374-1:2016+A1:2018

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.



D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Not relevant
Average molecular weight:	Not relevant

- CONTINUED ON NEXT PAGE -

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Solid
Appearance:	Powdery
Colour:	<input type="checkbox"/> Cream
Odour:	Not available
Odour threshold:	Not relevant *

Volatility:

Boiling point at atmospheric pressure:	Not relevant *
Vapour pressure at 20 °C:	Not relevant *
Vapour pressure at 50 °C:	Not relevant *
Evaporation rate at 20 °C:	Not relevant *

Product description:

Density at 20 °C:	1698,1 kg/m ³
Relative density at 20 °C:	1,698
Dynamic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 40 °C:	Not relevant *
Concentration:	Not relevant *
pH:	4,4 - 5
Vapour density at 20 °C:	Not relevant *
Partition coefficient n-octanol/water 20 °C:	Not relevant *
Solubility in water at 20 °C:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *
Melting point/freezing point:	Not relevant *

Flammability:

Flash Point:	Non-applicable
Flammability (solid, gas):	Not relevant *
Autoignition temperature:	480 °C
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *

Explosive (Solid):

Lower explosive limit:	Not relevant *
Upper explosive limit:	Not relevant *

Particle characteristics:

Median equivalent diameter:	Not relevant *
-----------------------------	----------------

9.2 Other information:
Information with regard to physical hazard classes:

Explosive properties:	Not relevant *
Oxidising properties:	Not relevant *
Corrosive to metals:	Not relevant *
Heat of combustion:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

biosera PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate w/ 25 mM Hepes

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Aerosols-total percentage (by mass) of flammable components: Not relevant *

Other safety characteristics:

Surface tension at 20 °C: Not relevant *

Refraction index: Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: Mixture based on inorganic substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- CONTINUED ON NEXT PAGE -

biosera PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate w/ 25 mM Hepes
SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: 4-aminobenzoic acid (3); Cholesterol (3)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Not relevant

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	LD50 oral	2031 mg/kg	
Calcium chloride · 2H2O	LD50 dermal		Rat
CAS: 10035-04-8	LC50 inhalation		
EC: Non-applicable			

11.2 Information on other hazards:
Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:
Acute toxicity:

Identification	Concentration		Species	Genus
	LC50	4630 mg/L (96 h)		
Calcium chloride · 2H2O	EC50	2400 mg/L (48 h)	Pimephales promelas	Fish
CAS: 10035-04-8	EC50	Not relevant	Daphnia magna	Crustacean
EC: Non-applicable				

Chronic toxicity:

Identification	Concentration		Species	Genus
	NOEC	230 mg/L		
Calcium chloride · 2H2O	NOEC <td>481 mg/L</td> <td>Oncorhynchus mykiss</td> <td>Fish</td>	481 mg/L	Oncorhynchus mykiss	Fish
CAS: 10035-04-8 EC: Non-applicable			Daphnia magna	Crustacean

12.2 Persistence and degradability:

- CONTINUED ON NEXT PAGE -

SECTION 12: ECOLOGICAL INFORMATION (continued)

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 04	inorganic wastes other than those mentioned in 16 03 03	Non-hazardous

Type of waste (Regulation (EU) No 1357/2014):

Not relevant

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Not relevant

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

- CONTINUED ON NEXT PAGE -

biosera PM-M1908 _ Medium 199 w/ Earle's Salts w/ L-Glutamine w/o Sodium Bicarbonate
w/ 25 mM Hepes

SECTION 15: REGULATORY INFORMATION (continued)

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

COMMISSION REGULATION (EU) 2020/878

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Classification procedure:

Not relevant

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -