Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

biosera

PM-C1522_McCoy's 5A w/ L-Glutamine w/o Sodium Bicarbonate

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

1.1 Product identifier:

PM-C1522_McCoy's 5A w/ L-Glutamine w/o Sodium Bicarbonate

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:

None

2.3 Other hazards:

Product does not meet PBT/vPvB criteria Endocrine-disrupting properties: The product does not meet the criteria.

** Changes with regards to the previous version

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS **

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Mixture composed of inorganic substances

Components:

None of the substances contained in the mixture are above the limits specified in Annex II of Regulation (EC) No 1907/2006

** Changes with regards to the previous version

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Consult a doctor in case of discomfort showing the SDS for the product.

By inhalation:

In case of symptoms, move the person affected into fresh air.

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 with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

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SECTION 4: FIRST AID MEASURES (continued)

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

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

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:

Isolate leaks provided that there is no additional risk for the people performing this task.

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.

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

Reference to other sections:

See sections 8 and 13.

6.4

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

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SECTION 7: HANDLING AND STORAGE (continued)

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

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 not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

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):

Not relevant

DNEL (General population):

Not relevant

PNEC:

Not relevant

8.2 Exposure controls:

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	Filter mask for particles		EN 149:2001+A1:2009	Replace when an increase in resistence to breathing is observed.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory hand protection	Protective gloves against minor risks	CATI		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

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CTION 8: EXPOSURE	CONTROLS/PERSON/	AL PROTECT	ION (continued)		
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 t the manufacturer's instructions. Use if there is risk of splashing.	
E Body protection				1	
Pictogram	PPE Work clothing	Labelling CAT I	CEN Standard	Remarks 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 regulation in EN ISO 6529:2013, EN ISO 6530:2005, EN IS 13688:2013, EN 464:1994.	
	Anti-slip work shoes	CAT II	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 regulation in EN ISO 20345:2012 y EN 13832-1:2007	
F Additional emerge	ency measures			•	
It is not necessary	y to take additional emerged	gency measure	S.		
Environmental exp	osure controls:				
V.O.C. density at Average carbon n Average molecula	umber: Not re	m ³ (0 g/L) elevant elevant			
	AND CHEMICAL PROP				
	sic physical and chemi		5:		
	tion see the product data	isheet.			
Appearance: Physical state at 20 °	C.	Solid			
	С.	Powe			
Appearance: Colour:			available		
Odour:			Not available		
Odour threshold:			relevant *		
Volatility:					
Boiling point at atmos	spheric pressure:	Not	relevant *		
Vapour pressure at 2		Not	relevant *		
Vapour pressure at 5	0 °C:	Not	relevant *		
Evaporation rate at 2	0 °C:	Not	relevant *		
Product description	n:				
		1893	3,5 kg/m³		
Density at 20 °C:		2000			
Density at 20 °C: Relative density at 20) °C:	1,89	4		
•		1,89	4 relevant *		
Relative density at 20	20 ºC:	1,89 Not			

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SECT	ION 9: PHYSICAL AND CHEMICAL PROPERTIES	(continued)
	Kinematic viscosity at 40 °C:	Not relevant *
	Concentration:	Not relevant *
	pH:	4,2 - 4,8
	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 *
2	Other information:	
	Information with regard to physical hazard class	es:
	Explosive properties:	Not relevant *
	Oxidising properties:	Not relevant *
	Corrosive to metals:	Not relevant *
	Heat of combustion:	Not relevant *
	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 inform	mation 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:

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Safety data sheet This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation PM-C1522_McCoy's 5A w/ L-Glutamine w/o Sodium Bicarbonate SECTION 10: STABILITY AND REACTIVITY (continued) Acids Wate 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: LD50 oral > 2000 mg/kg (rat) **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 Corrosivity/Irritability: Based on available data, the classification criteria are not met B- Inhalation (acute effect): Acute toxicity : Based on available data, the classification criteria are not met Corrosivity/Irritability: Based on available data, the classification criteria are not met C- Contact with the skin and the eyes (acute effect): - Contact with the skin: Based on available data, the classification criteria are not met - Contact with the eyes: Based on available data, the classification criteria are not met D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction): - Carcinogenicity: Based on available data, the classification criteria are not met IARC: 4-aminobenzoic acid (3) Mutagenicity: Based on available data, the classification criteria are not met Reproductive toxicity: Based on available data, the classification criteria are not met E- Sensitizing effects: - Respiratory: Based on available data, the classification criteria are not met - Skin: Based on available data, the classification criteria are not met F- Specific target organ toxicity (STOT) - single exposure: Based on available data, the classification criteria are not met 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 Skin: Based on available data, the classification criteria are not met H- Aspiration hazard: Based on available data, the classification criteria are not met Other information: Not relevant

Specific toxicology information on the substances:

Not available

11.2 Information on other hazards:

Endocrine disrupting properties

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

Other information

Not relevant

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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 12.1 Toxicity: Not available 12.2 Persistence and degradability: Not available 12.3 Bioaccumulative potential: 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 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

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SECTION 15: REGULATORY INFORMATION (continued)

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.

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.:

COMPOSITION/INFORMATION ON INGREDIENTS (SECTION 3):

Removed substances

Calcium chloride · 2H2O (10035-04-8)

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16): • Supplementary information

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:

Not relevant

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 Dose 50 EC50: Effective 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.