SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **311501BL**
Product name: **ADRENALINA 5 mM**

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

Identified use: **Laboratory chemical, platelet aggregation reagent**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Acute Tox. 2, Eye Dam. 1

H300 Fatal if swallowed.
H318 Causes serious eye damage.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:


GHS06 GHS05

Signal words: Danger

Hazard statements:

H300 Fatal if swallowed.
H318 Causes serious eye damage.
EUH031 Contact with acids liberates toxic gases.

Precautionary statements:

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P310	Immediately call a POISON CENTER/doctor/…..
P264	Wash ... thoroughly after handling.
P330	Rinse mouth.

Contains: Sodium Bisulphite
Epinephrine Bitartrate

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
EPINEPHRINE BITARTRATE		
CAS: 51-42-3	9 ≤ x < 10,5	Acute Tox. 2, H300
EC: 200-097-1		LD50 Orale: 4 mg/kg
REACH – No.: --		
INDEX – No.: --		
SODIUM BISULPHITE		
CAS: 7681-57-4	5 ≤ x < 6	Acute Tox. 4, H302
EC: 231-673-0		Eye Dam. 1, H318, EUH031
REACH – No.: --		LD50 Orale: 1540 mg/kg
INDEX – No.: 016-063-00-2		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

Direct skin contact: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

Direct contact with eyes: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

Ingestion: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.
Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ``σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία``»
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
	TLV-ACGIH	ACGIH 2022

SODIUM BISULPHITE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLA	ESP	5				
VLEP	FRA	5				
TLV	GRC	5				
GVI/KGVI	HRV	5				
TLV	NOR	5				
WEL	GBR	5				
TLV-ACGIH		5				

Predicted no-effect concentration - PNEC		
Normal value in fresh water	1	mg/l
Normal value in marine water	0,1	mg/l
Normal value of STP microorganisms	75,4	mg/l

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation								225 mg/m3

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

If the product may or must come into contact or react with acids, suitable technical and/or organisational measures should be taken to prevent the development of toxic and/or inflammable gases.

HAND PROTECTION
In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).
Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION
None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	White powder	
Colour	White	
Odour	Not available	
Melting point / freezing point	Not available	
Initial boiling point	Not applicable	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Not applicable	
Auto-ignition temperature	Not available	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	Not available	
Relative vapour density	Not available	
Particle characteristics	Not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10: Stability and reactivity

10.1. Reactivity

Information not available

10.2. Chemical stability

Information not available

10.3. Possibility of hazardous reactions

Contact with strong acids causes the development of toxic gases.

10.4. Conditions to avoid

Information not available

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11: Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information
Information not available

Information on likely routes of exposure
Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Information not available

Interactive effects
Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	38,04 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

SODIUM BISULPHITE

LD50 (Dermal):	> 2000 mg/kg Rat
LD50 (Oral):	1540 mg/kg Rat

EPINEPHRINE BITARTRATE

LD50 (Oral):	4 mg/kg MOUSE

SKIN CORROSION / IRRITATION
Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION
Causes serious eye damage

RESPIRATORY OR SKIN SENSITISATION
Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY
Does not meet the classification criteria for this hazard class

CARCINOGENICITY
Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY
Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE
Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE
Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD
Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

SODIUM BISULPHITE

LC50 - for Fish	215 mg/l/96h pesci
EC50 - for Crustacea	89 mg/l/48h dafnie
EC50 - for Algae / Aquatic Plants	48 mg/l/72h alghe

12.2. Persistence and degradability

SODIUM BISULPHITE

Solubility in water	> 10000 mg/l

Degradability: information not available

12.3. Bioaccumulative potential

Information not available.

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

Information not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
Waste transportation may be subject to ADR restrictions.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14: Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA: 2811

14.2. UN proper shipping name

ADR / RID: TOXIC SOLID, ORGANIC, N.O.S. (EPINEPHRINE BITARTRATE)
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (EPINEPHRINE BITARTRATE)
IATA: TOXIC SOLID, ORGANIC, N.O.S. (EPINEPHRINE BITARTRATE)

14.3. Transport hazard class(es)

ADR / RID:	Class: 6.1	Label: 6.1
IMDG:	Class: 6.1	Label: 6.1
IATA:	Class: 6.1	Label: 6.1

14.4. Packing group

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards

ADR / RID: NO
IMDG: NO
IATA: NO

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 60	Limited Quantities: 0,5 kg	Tunnel restriction code: (D/E)
	Special provision: -		
IMDG:	EMS: F-A, S-A	Limited Quantities: 0,5 kg	
IATA:	Cargo:	Maximum quantity: 100 Kg	Packaging instructions: 676
	Passengers:	Maximum quantity: 25 Kg	Packaging instructions: 669
	Special provision:	A3, A5	

14.7. Maritime transport in bulk according to IMO instruments
Information not relevant

SECTION 15: Regulatory information

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

Seveso category:
H2 – ACUTE TOXIC

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Contained substance

Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 2 and point 3

Acute Tox. 1 = Acute Toxicity, category 1

Acute Tox. 2 = Acute toxicity, category 2

Acute Tox. 4 = Acute Toxicity, category 4

Eye Dam. 1 = Serious eye damage, category 1

H300 = Fatal if swallowed.

H302 = Harmful if swallowed.

H318 = Causes serious eye damage.

EUH031 = Contact with acids liberates toxic gas.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)

- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

CALCULATION METHODS FOR CLASSIFICATION
Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.
Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

This SDS replaces and cancels all previous ones.