Scheda Informativa
Information Sheet

Codice / Code:	**UB80710-UB80720**
Nome prodotto / Product name:	**MONONUCLEOSI LATEX**
Descrizione d'uso / Intended use:	**Test di agglutinazione al lattice/Latex test agglutination**
Fornitore / Supplier:	**Mascia Brunelli S.p.A.** Viale Monza 272, 20128 Milano, Italia. Tel.: 0039 02 252091 E-mail: mktg@masciabrunelli.it

Componenti del kit / Kit components:

1. **MONONUCLEOSI LATEX**
2. **MONONUCLEOSI CONTROL +**
3. **MONONUCLEOSI CONTROL -**

INFORMATION SHEET

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

1.1 Product identifiers

Code: **UB80710-UB80720**
Product name: **MONONUCLEOSI LATEX - (component latex reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: Latex test agglutination

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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Hazard classification and indication:

2.2 Label elements
Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3 Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration >= 0.1%.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

SECTION 4: First aid measures

4.1. Description of first aid measures

GENERAL: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
EYES: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
SKIN: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
INGESTION: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.
INHALATION: Allow affected person to breathe fresh air. Allow the victim to rest.

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

Symptoms/effects: No expected to present a significant hazard under anticipated conditions of normal use.

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

Information not available

SECTION 5: Fire fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
Foam. Dry powder. Carbon dioxide. Water spray. Sand.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available.

5.3. Advice for firefighters

FIREFIGHTING INSTRUCTIONS
Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
PROTECTION DURING FIREFIGHTING
Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

FOR NON-EMERGENCY PERSONNEL
Emergency procedures: evacuate unnecessary personnel.
FOR EMERGENCY PERSONNEL
Protective equipment: equip cleanup crew with proper protection.
Emergency procedures: ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

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

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store only in the original container, in a cool, well ventilated place, away from heat sources. Keep containers closed when not in use.
Incompatible products: Strong bases, strong acids.
Incompatible materials: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

SODIUM AZIDE (26628-22-8)		
VLA-ED (OEL TWA) (1)	0,1	mg/m³ Dermal, VLI
VLA-EC (OEL STEL)	0,3	mg/m³ Dermal, VLI

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment: Avoid all unnecessary exposure.

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection
Eye protection: chemical goggles or safety glasses.

8.2.2.2. Skin protection
Hand protection: wear protective gloves.

8.2.2.3. Respiratory protection
Wear appropriate mask.

8.2.2.4. Thermal hazards
No additional information available

8.2.3. Environmental exposure controls

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	white	
Odour	odourless	
Melting point / freezing point	Not available	
Initial boiling point	Not available	
Flammability	Non flammable	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Not available	
Auto-ignition temperature	Not available	
Decomposition 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 applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Not known when used appropriately.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity (oral):	not classified
Acute toxicity (dermal):	not classified
Acute toxicity (inhalation):	not classified
Skin corrosion/irritation:	not classified
Additional information:	based on available data, the classification criteria are not met
Serious eye damage/irritation:	not classified
Additional information:	based on available data, the classification criteria are not met
Respiratory or skin sensitization:	not classified
Additional information:	based on available data, the classification criteria are not met
Germ cell mutagenicity:	not classified
Additional information:	based on available data, the classification criteria are not met
Carcinogenicity:	not classified
Additional information:	based on available data, the classification criteria are not met
Reproductive toxicity:	not classified
Additional information:	based on available data, the classification criteria are not met
STOT-single exposure:	not classified
Additional information:	based on available data, the classification criteria are not met
STOT-repeated exposure:	not classified
Additional information:	based on available data, the classification criteria are not met
Aspiration hazard:	not classified
Additional information:	based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties
No additional information available.

11.2.2. Other information
Potential adverse human health effects and symptoms: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity
Hazardous to the aquatic environment, short-term (acute): not classified
Hazardous to the aquatic environment, long-term (chronic): not classified

12.2. Persistence and degradability

Mononucleosi LATEX	
Persistence and degradability	Nor established

12.3. Bioaccumulative potential

Mononucleosi LATEX	
Bioaccumulative potential	Nor established

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available.

12.7. Other adverse effects

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations: dispose in a safe manner in accordance with local/national regulations.
Ecology – waste materials: avoid release to the environment.

SECTION 14: Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number
Not applicable

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Maritime transport in bulk according to IMO instruments
Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations
Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic

pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.2. Chemical safety assessment

No additional information available.

SECTION 16: Other information

Data sources: 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.

The classification complies with: ATP 12

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)
- 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.
Provide appointed staff with adequate training on how to use chemical products.
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.

INFORMATION SHEET

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

1.1 Product identifiers

Code: **UB80710-UB80720**
Product name: **POSITIVE CONTROL (reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: Positive control for latex test agglutination

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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Hazard classification and indication:

2.2 Label elements
Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3 Other hazards

Other hazards which do not result in classification: contains material from animal origin. No known test method can guarantee that products derived from human or animal sources will not transmit infectious agents. It is recommended that this product and assay material be handled as potential biohazard.

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

GENERAL: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
EYES: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
SKIN: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
INGESTION: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.
INHALATION: Allow affected person to breathe fresh air. Allow the victim to rest.

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

Symptoms and effects: Not expected to present a significant hazard under anticipated conditions of normal use.

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

Information not available

SECTION 5: Fire fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture
Information not available.

5.3. Advice for firefighters

FIREFIGHTING INSTRUCTIONS
Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

FOR NON-EMERGENCY PERSONNEL
Emergency procedures: evacuate unnecessary personnel.
FOR EMERGENCY PERSONNEL
Protective equipment: equip cleanup crew with proper protection.
Emergency procedures: ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

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

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a cool, well ventilated place, away from heat sources. Keep containers away from any incompatible products: strong bases, strong acids. Keep containers away from any incompatible materials: sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Information not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

SODIUM AZIDE (26628-22-8)		
VLA-ED (OEL TWA) (1)	0,1	mg/m³ Dermal, VLI
VLA-EC (OEL STEL)	0,3	mg/m³ Dermal, VLI

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment: Avoid all unnecessary exposure.

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection
Eye protection: chemical goggles or safety glasses.

8.2.2.2. Skin protection
Hand protection: wear protective gloves.

8.2.2.3. Respiratory protection
Wear appropriate mask.

8.2.2.4. Thermal hazards
No additional information available

8.2.3. Environmental exposure controls

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	odorless	
Melting point / freezing point	Not available	
Initial boiling point	Not available	
Flammability	Non flammable	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Not available	
Auto-ignition temperature	Not available	
pH	8,2	
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 applicable	

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

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Not known when used appropriately.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity (oral):	not classified
Acute toxicity (dermal):	not classified
Acute toxicity (inhalation):	not classified
Skin corrosion/irritation:	not classified pH 8,2
Additional information:	based on available data, the classification criteria are not met
Serious eye damage/irritation:	not classified pH 8,2
Additional information:	based on available data, the classification criteria are not met
Respiratory or skin sensitization:	not classified
Additional information:	based on available data, the classification criteria are not met
Germ cell mutagenicity:	not classified
Additional information:	based on available data, the classification criteria are not met
Carcinogenicity:	not classified
Additional information:	based on available data, the classification criteria are not met
Reproductive toxicity:	not classified
Additional information:	based on available data, the classification criteria are not met
STOT-single exposure:	not classified
Additional information:	based on available data, the classification criteria are not met
STOT-repeated exposure:	not classified
Additional information:	based on available data, the classification criteria are not met
Aspiration hazard:	not classified
Additional information:	based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties
No additional information available.

11.2.2. Other information
Potential adverse human health effects and symptoms: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute): not classified
Hazardous to the aquatic environment, long-term (chronic): not classified

12.2. Persistence and degradability

Mononucleosi Positive Control	
Persistence and degradability	Nor established

12.3. Bioaccumulative potential

Mononucleosi Positive Control	
Bioaccumulative potential	Nor established

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

12.6. Endocrine disrupting properties
No additional information available

12.7. Other adverse effects
Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations: dispose in a safe manner in accordance with local/national regulations.
Ecology – waste materials: avoid release to the environment.

SECTION 14: Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number
Not applicable

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Maritime transport in bulk according to IMO instruments
Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations
Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Data sources: 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.

The classification copmplies with: ATP 12

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
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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.
Provide appointed staff with adequate training on how to use chemical products.
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.
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INFORMATION SHEET

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

1.1 Product identifiers

Code: **UB80710-UB80720**
Product name: **NEGATIVE CONTROL (reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: Negative control for latex test agglutination

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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Hazard classification and indication:

2.2 Label elements
Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3 Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration >= 0.1%.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

SECTION 4: First aid measures

4.1. Description of first aid measures

Not specifically necessary. Observance of good industrial hygiene is recommended.

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: Fire fighting measures

5.1. Extinguishing media

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

Use breathing equipment if fumes or powders are released into the air. 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

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. 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

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. 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

No additional information available.

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION
None required.

SKIN PROTECTION
None required.

EYE PROTECTION
None required.

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

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	liquid	

Colour	transparent
Odour	odorless
Melting point / freezing point	Not available
Initial boiling point	Not available
Flammability	Non flammable
Lower explosive limit	Not available
Upper explosive limit	Not available
Flash point	> 60°C
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 applicable

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

There are no particular risks of reaction with other substances in normal conditions of use..

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11: Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

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

Acute toxicity (oral): not classified
Acute toxicity (dermal): not classified
Acute toxicity (inhalation): not classified

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

SERIOUS EYE DAMAGE / IRRITATION
Does not meet the classification criteria for this hazard class

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

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

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

Information not available

12.2. Persistence and 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

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14: Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number
Not applicable

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Maritime transport in bulk according to IMO instruments
Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations
Seveso Category - Directive 2012/18/EU: None

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

None

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

Information not available

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

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)
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