



SAFETY DATA SHEET

EC Regulation No. 1907/2006 (REACH) modified with 2015/830/UE

Doc. N° 271072 SSE rev.0

Date of Revision:

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1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product number:

271072

Product name:

Strep Grouping B Rapid Latex Test Kit

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

Identified uses

Latex slide agglutination test for identification Streptococci of Lancefield groups B grown in culture.

1.3 Details of the supplier of the safety data sheet

Company

Mascia Brunelli S.p.A.

Viale Monza 272, 20128 Milano, Italy.

Tel.: 0039 02 25209.1

Fax: 0039 02 2576428

E-mail: mktg@masciabrunelli.it

1.4 Emergency telephone number

Emergency Phone
Milano)

0039 02 66101029 (Centro Antiveleni Niguarda Ca' Granda –

2 – HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards – none

3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Latex, Positive Control and Diluent contains sodium azide in amounts of 0.099%. At this concentration mixtures are not classified and are not to be labelled. Positive control contain also >0.02% of Thiomersal. At this concentration, mixture is not classified and is not to be labelled.

4- FIRST AID MEASURES

4.1 Description of first aid measures

If swallowed

If chemicals has been swallowed, wash out mouth with water. Do not swallow mouthwash. Seek medical advice.

In case of eye contact

wash out with plenty of water.

In case of skin contact

wash skin immediately with soap and water.

4.2 Most important symptoms and effects, both acute and delayed

no data available

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5 - FIRE-FIGHTING MEASURES

5.1 Extinguishing media

use dry sand cement. DO NOT USE water.

5.2 Special hazards arising from the substance or mixture

no data available

5.3 Advice for firefighters

This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper

Mascia Brunelli S.p.A., Viale Monza 272, 20128 Milan, Italy. Tel. n° ++39 02 25209.1, Fax n° ++39 02 2576428

E-mail: mktg@masciabrunelli.it; Web Site: www.masciabrunelli.it



personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel.

6- ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment, lab coat and gloves

6.2 Environmental precautions

Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. In any case avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Absorb with dry earth, sand or other non combustible material. Properly disinfect any spills. Test specimens require decontamination with bleach solution or appropriate germicide prior to pick up.

6.4 Reference to other sections

For disposal see section 13.

7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

For in vitro diagnostic use. Read the instructions for Use. Always follow Good Laboratory Practice when using this product. Avoid contact with eyes, skin and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2°C / 8°C. Keep all containers tightly closed until ready to use. Under these conditions reagents will retain the activity until the expiry date shown on the label on outer carton.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8- EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 Control parameters

Any specific protection and prevention measures should not be taken during use of the product.

Components with workplace control parameters

No information available

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use safety glasses.

Skin protection

Handle with gloves. Use with a lab coat.

Body Protection

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required.

9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form:	Latex Milky white aqueous suspension	Positive Control Clear/off white suspension	Enzyme Lyo white
b) Odour	no data available		
c) Odour Threshold	no data available		
d) pH	no data available		
e) Melting point/freezing point	no data available		
f) Initial boiling point and boiling range	no data available		
g) Flash point	no data available		
h) Evaporation rate	no data available		
i) Vapour pressure	no data available		
j) Vapour density	no data available		
k) Relative density	no data available		
l) Water solubility	no data available		
m) Viscosity	no data available		
n) Explosive properties	no data available		
o) Oxidizing properties	no data available		



9.2 Other safety information no data available

10 – STABILITY AND REACTIVITY

10.1 Reactivity	No known hazardous reactivity
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	no data available
10.4 Conditions to avoid	avoid contact with lead or copper plumbing.
10.5 Incompatible materials	no data available.
10.6 Hazardous decomposition products	no known hazardous decomposition products

11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information
Skin corrosion/irritation	Possibility of allergic sensitization should be considered.
Serious eye damage/irritation	No data available.
Respiratory or skin sensitisation	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
Summary of evaluation of the CMR properties	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available

12 – ECOLOGICAL INFORMATION

12.1 Toxicity	no data available
12.2 Persistence and degradability	no data available
12.3 Bio accumulative potential	no data available
12.4 Mobility in soil	no data available
12.5 Results of PBT and vPvB assessment	no data available
12.6 Other adverse effects	no data available

13 – DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
Contaminated packaging	Do not remove labels from containers for disposal or recycling. Observe all the attention and precautions listed for the product.

14 – TRANSPORT INFORMATION

The product is considered non dangerous for transportation

14.1 UN number	ADR/RID: - IMDG: - IATA: -
14.2 UN proper shipping name	ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods
14.3 Transport hazard class(es)	ADR/RID: - IMDG: - IATA: -
14.4 Packaging group	ADR/RID: - IMDG: - IATA: -
14.5 Environmental hazards	ADR/RID: no IMDG Marine pollutant: no IATA: no
14.6 Special precautions for user	no data available

15 – REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE
15.2 Chemical Safety Assessment	no data available



16 – OTHER INFORMATION

The information in this MSDS was obtained from current and reliable sources. Anyone using this information is solely responsible for the accuracy and applicability of this information to a particular use or situation.

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