



SAFETY DATA SHEET

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

Doc. N° VQ81210P SSE rev.2
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1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product number:

VQ81210P

Product name:

STREP A CARD PLUS

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

Identified uses

Immuno-chromatographic rapid test for the detection of Group A Streptococcus from throat swabs, including controls

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

Classification according to Regulation (EC) No 1272/2008

Extraction solution 1

Acute toxicity, (Category 4), H302

Eyes irritation (Category 2), H319

Aquatic acute toxicity (Category 4), H413

2.2 Label elements

According to Regulation (EC) No 1272/2008

Extraction solution 1

Pictogram



Signal word

Attention

Hazard statement(s)

H302

harmful if swallowed

H319

causes serious eye irritation

H413

May cause long-lasting harmful effects to aquatic life

Precautionary statement(s)

P264

Wash hands thoroughly after use

P270

Do not eat, drink or smoke during use

P273

Avoid release to the environment

P280

Eye protection

P330

Rinse mouth

P301 + P312

If swallowed call a POISON CENTER or doctor

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

P337+P313

If eye irritation persists get medical advice

P501

Dispose of contents in accordance with local regulation

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Supplemental Hazard

Restricted to professional users

2.3 Other hazards

none

3 – COMPOSITION/INFORMATION ON INGREDIENTS**3.2 Mixtures**

- | | |
|------------------------------|--|
| 1) Individually sealed pouch | one strip packed in a plastic cassette; 0,5 g silica gel dessicant |
| 2) Extraction solution 1 | Aqueous solution (2M) containing color indicator and inorganic salt:
Water 84-88%; sodium nitrite <14% (w/w); phenol red <0.02% |
| 3) Extraction solution 2 | Aqueous, acidic solution (0.3M): Water 98-99%; Acetic acid <1% (w/w) |
| 4) Positive Control: | stabilized buffered solution containing non infectious components.
Solution contains 0.05% of sodium azide as preservative. |
| 5) Negative control: | saline solution with biological additives and bacteriostatics agents.
0.05% sodium azide as preservative |

Note: the strip is composed of nitrocellulose membrane, vinyl matte adhesive, fiber absorbent pad, fiber sample pad, fiber conjugate pad. The nitrocellulose membrane and the fiber conjugate pad contain dried biological substances preserved by sodium azide <0.1%. The identity of each biological substance is confidential. Preparation not dangerous. Extraction solution 2 is a not dangerous preparation; content Acetic acid with % that not require label in according to Regulation (CE) No 1272/2008.

Hazardous ingredients according to Regulation (EC) No 1272/2008 – Extraction solution 1

Component		Classification	Concentration
Sodium nitrite			
N° CAS	7632-00-0	Ox. Sol. 3; Acute Tox. 3; eye Irrit 2 ; aquatic acute 1 H272; H301; H319, H400	< 14%
N° CE	231-555-9		

For the full text of the H-Statements and P-Phrases mentioned in this Section, see Section 16

4- FIRST AID MEASURES**4.1 Description of first aid measures****If inhaled**

Inhalation of any component in this kit is unlikely. If a component is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

If swallowed

Ingestion of small amounts of the extraction solutions or of the controls should not be toxic, however, a physician should be immediately. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.

In case of eye contact

The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. In case of contact with the extraction solutions or with the controls, immediately flush eyes with plenty of water.

In case of skin contact

In case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be hazardous by skin contact, but clean the skin after use is advisable.

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**

For small fires, use water, chemical powder or CO₂.

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 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. Wash hands thoroughly after use

6.2 Environmental precautions

Avoid release to the environment

6.3 Methods and material for containment and cleaning up

Card: clean up affected area with absorbent cloth. Use a laboratory disinfectant.

Extraction solution 1: Wash hands thoroughly after handling. Clean up affected area, carefully soak up spilled liquid with a non-combustible sorbent.

Extraction solution 2: Wash hands thoroughly after handling. Clean up affected area, neutralize with soda ash or sodium bicarbonate. Absorb spill with non-combustible inert material/sorbent.

Controls: Use adsorbent paper towel or cloth to adsorb the spill solution and dispose or clean the contaminated surface in accordance with local procedures or appropriate standards.

6.4 Reference to other sections

For disposal see section 13.

7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

Don't eat, drink, smoke in laboratory area. Use the product according to the product insert.

7.2 Conditions for safe storage, including any incompatibilities

Keep product at 2-30°C in a dry place. Do not freeze or expose to temperature higher than 30°C. Keep away from children.

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

Components with workplace control parameters

It doesn't contain substances with occupational exposure limit value

8.2 Exposure controls

Appropriate engineering controls

Restricted to professional users. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

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

	Card	Extract sol 1	Extract sol 2	Negative control	Positive Control
a) Appearance Form:	white solid	pink liquid	liquid, transparent	transparent, liquid colorless	transparent, liquid clear yellowish
b) Odour	odorless	odorless	sour, pungent odor resembling vinegar	odorless	odorless
c) Odour Threshold	no data available	no data available	no data available	no data available	no data available
d) pH	no data available	about 9	about 2.6	no data available	no data available
e) Melting point/freezing point	no data available				
f) Initial boiling point	no data available				



and boiling range	
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 data available
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	no data available
10.4 Conditions to avoid	card: direct contact with a flame. Temperatures outside the range of 2-30° C. extraction solutions: only to be used for sample dilution. Controls: no data available
10.5 Incompatible materials	extraction solution 1: avoid amines, ammonium salts, cyanides and reducing agents. extraction solution 2: avoid strong oxidizing agents, most common metals (except aluminum), strong bases and amines
10.6 Hazardous decomposition products	card: nitrocellulose membrane can dissolve in amines esters, ketones and ether-alcohols and may react with strong acids or alkalis

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 Card: concentration of sodium azide is < 0.1% Extraction solution 1: harmful if swallowed. May cause severe eye irritation. May cause long-lasting harmful effects to aquatic life. Extraction solution 2: Acetic acid may be irritating to the eyes, skin and respiratory system. Prolonged or repeated skin contact may cause dermatitis. This preparation is <25% (w/w) acetic acid so it is not a toxic preparation. Controls: concentration of sodium azide is <0.1%

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

no data available

15.2 Chemical Safety Assessment

no data available

16 – OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H302 harmful if swallowed
H319 causes serious eye irritation
H413 May cause long-lasting harmful effects to aquatic life

Further information

Restrictions on use no data available

Advice no data available

Literary reference no data available

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