



Mascia Brunelli S.p.A.

Revision nr. 4

Dated 16/10/2023

Printed on 16/10/2023

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Replaced revision: 3 (Printed on: 30/11/2017)

VQ81310 – STREP B CARD

SAFETY DATA SHEET

According to Annex II to REACH – Regulation 2020/878 and to Annex II to UK REACH

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

1.1 Product identifiers

Code: **VQ81310**
Product name: **STREP B CARD**

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

Identified use: Rapid test card for the detection of Group B Streptococcus from urogenital specimens. .
Professional use only.

Uses advised against: None identified. However, please use the product in accordance with the indications reported on the label and on the technical data sheet

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

Extraction reagent 1

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 toxicity, category 4

H302

Harmful if swallowed.

2.2 Label elements

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

Hazard pictograms:



Signal words: Warning

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P270 Do not eat, drink or smoke when using this product.



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P264 Wash thoroughly with plenty of water and soap after use.
P301+P312 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P330 Rinse mouth.
P391 Collect spillage.

Contains: SODIUM NITRITE

2.3 Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The STREP B CARD product is made up of three different components:

- 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)

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.

This SDS refers only to Extraction Reagent 1, aqueous solution (2M) of sodium nitrite. The only classified component of this kit.

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
SODIUM NITRITE		
CAS 7632-00-0 EC 231-555-9	< 14	Ox. Sol. 3 H272 ; Acute Tox. 3 H301, Eye Irrit 2 H319; Aquatic Acute 1 H400
INDEX 007-010-00-4		
REACH NUMBER 01-2119471836-27-xxxx		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4: First aid measures

4.1. Description of first aid measures

4.1.1. Routes of exposure:

If in eyes: Rinse cautiously with plenty of water for at least 15 minutes with the eyelid held wide open. Remove contact lenses, if present and easy to do. Continue rinsing. Do not rub eyes: mechanical action may cause corneal damage. Immediately call an Ophthalmologist.

If on skin (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with soap and plenty of water. Wash contaminated clothing before reuse. If skin looks altered or a large amount of product has been released, seek for immediate medical attention.

If swallowed: Rinse mouth. Do NOT induce vomiting. Call a doctor / physician in case of complications.

If inhaled: Move victim to fresh air and keep at rest in a position comfortable for breathing. If difficulties occur, consult a physician.

4.1.2. Personal protective equipment for first aid responders:

Wear protective gloves and clothes. If large release occurs also wear eye and face protection. (Refer to section 8 for personal protection).



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

Danger of pulmonary edema. Symptoms may appear later. Danger of meta-hemoglobin formation after ingestion.

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

As this mixture is not classified, it does not present particular dangers, in case, however, of discomfort following accidental ingestion, or in case of eye contact with irritation symptoms, contact a doctor.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

ABC powder.

5.2. Special hazards arising from the substance or mixture

Nitrogen oxides (NOx)

Indication: The substances mentioned can be released in the vicinity of a fire

5.3. Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

Areas surrounding a fire should be kept cool by jets of water to prevent the spread of fire. It is suggested, if possible, to remove the combustible material from the affected area. Stay upwind and avoid low areas. Wear full face mask and self-contained breathing apparatus as well as full protective fire-fighting clothing. Collect contaminated extinguishing water separately. Do not discharge into sewers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

In case of accidental release do not walk on the contaminated area and avoid any contact and further spread of the mixture. Remove any open flames present.

6.1.2. For emergency responders

Keep non trained personnel away from the area where the accidental release took place. Remove any flame and ignition source. Wear adequate clothing to proceed to cleaning up. Refer to section 8 for personal protection.

6.2. Environmental precautions

Avoid dispersion of the mixtures into drains, surface and ground water.

6.3. Methods and material for containment and cleaning up

6.3.1. Adequate containment techniques

Clean the contaminated area with a non-combustible absorbent cloth. Collect spilled product with non-combustible absorbent material.

6.3.2. Adequate recovery procedures

Absorb with an absorbent material (e.g. sand, diatomaceous earth, absorbent agents acidic or universal). Then proceed with the collection with suitable tools such as shovels and shovels. Place collected material in drums or other appropriate containers for disposal. Finish cleaning the contaminated surface by vacuuming and/or with water.

The mixture is miscible with water: if a large quantity of substance is accidentally released into water inform authorities.

6.4. Reference to other sections

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



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SECTION 7: Handling and storage

7.1. Precautions for safe handling

7.1.1. Recommendations on handling

Avoid contact with skin, eyes and clothing. Use only in a well-ventilated place. Process the product if possible in closed systems. If the unpackaged product is used, good vapor extraction is necessary. Do not mix with flammable substances. The usual precautionary measures for handling chemicals must be observed.

Fire and explosion protection: The substance/product is not combustible. The product is neither oxidizing, self-igniting nor explosive. The dried product, however, is oxidizing.

7.1.1.2. Any incompatibilities

Provide for any precautionary measures against electrostatic charging - keep sources of ignition away - have fire extinguishers at hand.

7.1.1.3. Dangerous operations and conditions and related countermeasures

Avoid breathing fumes/gases/fog/vapors/aerosols.

7.1.1.4. Environmental release control

Avoid release into the environment. Store in a tightly closed container.

7.1.2. Recommendations on hygiene to be kept in workplaces

Do not eat, drink or smoke in areas where the material is stored, handled or processed. Personnel handling the product are advised to wash their hands thoroughly before eating, drinking and smoking.

7.2. Conditions for safe storage, including any incompatibilities

Separate from acids. Keep away from oxidizable substances. Keep away from ammonium salts. Store the product at 2-30°C in a dry place. Do not freeze or expose to temperatures above 30°C.

7.3. Specific end use(s)

None in particular (Professional use)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limits: None

8.1.1.1. National limits in accordance with directive 98/24 / EC: None

8.1.1.2. National limits in accordance with the directive 2004/37 / CE and with the adjects 2014/113 / EU of the commission: None

8.1.1.3. Other national limits: None

8.1.1.4. National biological limits in compliance with directive 98/24 / EC, and with the decision 2014/113 / EU of the commission: None

8.1.1.5. Other national biological limits: None.

8.1.2. Information on the procedures of recommended monitoring:

Refer to the UNI EN 689: 2018 standard (Atmosphere in the workplace - Measurement of exposure by inhalation to chemical agents - Strategy for checking compliance with occupational exposure limit values).

8.1.3. National biological limits and / or limits of possible contaminants formed during the use of the substance: Not applicable.

8.1.4. Values of DNEL and PNEC, if available:

CAS: 7632-00-0: Sodium Nitrite

DNEL Worker: Short term exposition – systemic effects, Inhalation: 2 mg/m3

CAS: 7632-00-0: Sodium Nitrite

PNEC

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Fresh water: 0,0054 mg/l
Marine water: 0,00616 mg/l
Intermittent releases: 0,0054 mg/l
Sediment (fresh water): 0,0195 mg/kg
Sediment (marine water): 0,0223 mg/kg
Soil: 0,000733 mg/kg
STP: 21 mg/l

8.1.5. Recommendations for management effective of the risk based on control bands (control banding):

Refer to section 8.2

8.2. Exposure controls

Good industrial hygiene should be adopted.

8.2.1. Appropriate engineering control:

Engineering controls: Provide general and/or local exhaust ventilation. Provide flowing water and eye washing equipment.

8.2.2. Individual protection measures, such as personal protective equipment:

Eye protection: Safety glasses according to EN166.

Skin protection: Wear suitable industrial clothing depending on the kind of processing in order to avoid skin contact.

Hand protection: Wear approved protection gloves, according to EN 374 and EN 388, depending on the kind of processing/manipulation.

Respiratory protection: If vapors are formed, use an approved filter respirator.

Thermal hazards: Wear heat resistant gloves in case of hot handling.

8.2.3. Environmental exposure control:

In case of leakage, suck off the substance as much as possible. Observe the exposure limits and eventually clean the exhaust air if they are exceeded. If reuse of the recovered product is not applicable, dispose in accordance with the local law. Inform the competent authority in case of leakage into the atmosphere or entry into waterways, soil or drains.

Other advices: Nothing to report.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	liquid	
Colour	Pink/red	
Odour	Characteristic	
Melting point / freezing point	Liquid at room temperature	
Initial boiling point	Not available	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	> 100 °C	
Auto-ignition temperature	Not available	
pH	About 9	
Kinematic viscosity	Not available	
Solubility	Fully miscible with water	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	



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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

Explosives:	Substance has no chemical groups associated with explosive properties. According to column 2 of Annex VII of Reg. 1907/2006 (REACH) the study does not need to be performed.
Flammable gases:	Not applicable.
Aerosols:	Not applicable.
Oxidizing gases:	Not applicable.
Gases under pressure:	Not applicable.
Flammable liquids:	Not applicable.
Flammable solids:	Not flammable.
Self-reactive substances and mixtures:	Not applicable.
Pyrophoric liquids:	Not applicable.
Pyrophoric solids:	Not applicable.
Self-heating substances and mixtures:	Not applicable.
Substances and mixtures, which emit flammable gases In contact with water:	Not applicable.
Oxidizing liquids:	This mixture is not oxidising, but contains oxidising substances (sodium nitrite).
Oxidizing solids:	Not applicable
Organic peroxides:	Not applicable.
Corrosive to metals:	Non tested.
Desensitized explosives:	Not applicable.

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 (see Section 7).

10.3. Possibility of hazardous reactions

Reducing substances, oxidizable substances, ammonium salts, amines, amine compounds, acids.

10.4. Conditions to avoid

See SDS Section 7 - Handling and Storage.

10.5. Incompatible materials

Strong acids, combustible materials.

10.6. Hazardous decomposition products

Nitrogen oxides in case of fire.

SECTION 11: Toxicological information

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

Acute toxicity

No experimental data are available on the mixture. According to the data available on the ingredients, this mixture is classified as harmful if swallowed. (Sodium nitrite: LD50 rat (oral): 180 mg/kg).



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Skin corrosion/irritation

No experimental data are available on the mixture. According to the data available on the ingredients, this mixture is not classified.

Serious eye damage/eye irritation

No experimental data are available on the mixture. According to the data available on the ingredients, this mixture is not classified.

Respiratory or skin sensitisation

No experimental data are available on the mixture. According to the data available on the ingredients, this mixture is not classified.

Germ cell mutagenicity

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Carcinogenicity

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Reproductive toxicity

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Specific target organ toxicity - single exposure

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Specific target organ toxicity - repeated exposure

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Aspiration hazard

No experimental data are available on the mixture. According to the acute toxicity data available on the ingredients, this mixture is not classified.

Information on likely routes of exposure:

Skin / eye contact with the product as it is are the most likely routes of exposure. Inhalation of mists / vapors is not expected to be a relevant route of exposure.

Symptoms related to the physical, chemical and toxicological characteristics:

In case of accidental contact with the mixture, a slight irritation of eyes and / or skin may occur in particularly sensitive people.

Delayed and immediate effects and chronic effects from short and long term exposure:

See Above

Interactive Effects:

Information not available

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties:

Data not available

SECTION 12: Ecological information

12.1. Toxicity

According to the information available on the ingredients, the product is not classified in accordance with the criteria established by EC Regulation 1272/2008 regarding the dangers to the aquatic environment. However, sodium nitrite is classified as Aquatic Acute 1 (LC50 (96 h) 0.54 - 26.3 mg/l, *Salmo gairdneri*).

12.2 Persistence and degradability

Mixture based on inorganic ingredients

12.3 Bioaccumulative potential

None, blend based on inorganic ingredients not bioaccumulant

12.4 Mobility in soil

Information not available

12.5 Results of PBT and vPvB assessment



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This mixture does not contain components considered to be persistent, bioaccumulative or toxic (PBT), or very persistent and very bioaccumulative (vPvB), Sodium nitrite is inorganic.

12.6. Endocrine disrupting properties:

Data not available.

12.7. Other adverse effects:

None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose residues and packaging in accordance with local and state laws. Dispose of hazardous products according to European Waste Catalogue (EWC).

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, no dangerous goods

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)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

Nothing to report

14.7. Transport in bulk according to annex II of MARPOL 73/78 and the IBC code

Not applicable

SECTION 15: Regulatory information

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

Reg. 1907/2006/EC (REACH)

Substances in candidate list: None.

Substances in REACH annex XVII: None.

Substances in REACH annex XIV: None.



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Reg. 1272/2008/EC (CLP) Mixture classified as Acute Tox 4 (oral).

Seveso (dir. 2012/18/UE): Not applicable

15.2. Chemical safety assessment

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

SECTION 16: Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox./ Acute Toxicity - **H301** Toxic if swallowed.

Eye Dam./Irrit.- Eye Damage/irritation - **H319** Causes serious eye irritation.

Aquatic Acute 1 - **H400** Very toxic to aquatic life.

Ox. Sol.- Oxidant solids - **H272** May intensify fire: OXIDISER.

This Safety Data Sheet is prepared in accordance with Annex II of Reg. (EC) No. 1907/2006 (REACH) as amended by Reg. (EC) No. 878/2020 and refers to the mixture as supplied.

If this mixture is used as a component of another mixture, this safety data sheet cannot be automatically considered valid.

LEGEND:

ADN = European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways;

ADR = Agreement concerning the International Carriage of Dangerous Goods by Road;

EC50 = Effective Concentration 50 (concentration that causes a certain effect in 50% of a population);

EINECS = European Inventory of Existing Commercial chemical Substances;

IATA DGR = International Air Transportation Association's Dangerous Goods Regulation;

INCI = International Nomenclature Cosmetic Ingredient;

IMDG = International Maritime Dangerous Goods;

LC50 = Lethal Concentration 50 (Lethal Concentration killing 50% of the tested individuals);

LD50 = Lethal Dose 50 (Lethal dose killing 50% of the tested individuals);

NOAEL = No Observed Adverse Effect Level;

REACH = Registration, Evaluation and Authorization of Chemicals;

RID = Regulation concerning the International Carriage of Dangerous Goods by Rail.

BIBLIOGRAPHY

Data are sourced from the REACH registration dossier, available on the ECHA dissemination tool web page and the SDS of the used raw materials.

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