



SAFETY DATA SHEET

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

Doc. N° VQ81406P SSE rev.4
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1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product number: **VQ81406P**
Product name: **CHLAMYDIA TRACHOMATIS CARD PLUS**

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

Identified uses **Immuno-chromatographic rapid test for the qualitative detection of *Chlamydia trachomatis* including positive and negative control**

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 Antiveneni Niguarda Ca' Granda – Milano)

2 – HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Device: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008
Extraction solution A: solution with 0,2 M Sodium Hydroxide, hazardous for skin and eyes. H315, H319.
Extraction solution B: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008
Positive control: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008
Negative control: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

2.2 Label elements

According to Regulation (EC) No 1272/2008 [CLP] for Extraction Solution A



Pictograms

Avvertenza

Warning

Hazard statements (CLP)

H315: Causes skin irritation
H319: causes serious eye irritation

Precautionary Statements (CLP)

P264 Wash thoroughly after handling.
P280 Wear protective gloves, protective clothing, eye protection, face protection.
P305+P351+P338 IN CASO DI CONTATTO CON GLI OCCHI: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/ attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.
P501-Dispose of contents in an appropriate container observing applicable local regulations.

**2.3 Other hazards – none****3 – COMPOSITION/INFORMATION ON INGREDIENTS****3.2 Mixtures**

Negative control:	saline solution with biological additives and bacteriostatics agents. 0.05% sodium azide as preservative
Positive Control:	cell lisate in Chlamydia suspension. Inactivated solution. Containing sodium azide 0.1% as preservative
Individually sealed pouch:	One strip packed in a plastic cassette; 0,5 g silica gel dessicant
Extraction solution A:	solution with Sodium Hydroxide 0.2 M
Extraction solution B:	Solution with Hydrochloric Acid 0.2 M

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

Hazardous components according to Regulation (EC) No 1272/2008 included in Extraction solutions

Component	Classification raw material	Classification of the mixture – specific concentration limits	Concentration (%)
Sodium hydroxide			
CAS No.: 1310-73-2 EINECS No.: 215-185-5 EC index No.: 011-002-006 REACH Registration No.: 01-2119457892-27	Met. Corr. (1) H290; Skin Corr. (1A) H314	Skin Corr. 1A, H314: C ≥ 5 % Skin Corr. 1B, H314: 2 % ≤ C < 5 % Skin Irrit. 2, H315: 0.5 % ≤ C < 2 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 %	0,8%
Hydrochloric Acid			
CAS No.: 7647-01-1 EINECS No.: 231-595-7 EC index No.: 017-002-01-X REACH Registration No.: Not available	Skin Corr. (1B) H314; STOT SE (3) H335	Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315: 10 % ≤ C < 25 % Eye Irrit. 2, H319: 10 % ≤ C < 25 % STOT SE 3, H335: C ≥ 10 %	0,73%

For the full text of the H-Statements 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 Negative control or Positive control or of the extraction solutions 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 solution, immediately flush eyes with plenty of water. Seek medical attention if symptoms persist. The extraction solution A could cause irritation to contact. In case of contact with the negative control or Positive control, immediately flush eyes with plenty of water.

In case of skin contact

The extraction solutions could cause skin irritation to the contact, not effect if used normally. However in case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. 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 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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

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 4-30°C. Do not freeze. 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

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

The positive control and all the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

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 A	Extract sol B	Negative control	Positive Control
a) Appearance Form:	white solid	colourless liquid	liquid, faintly yellow	transparent, liquid colorless	transparent, liquid colorless
b) Odour	odorless				
c) Odour Threshold	no data available				
d) pH	no data available A: 13-14; B: about 6				
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	no data available.
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	Solution A and B could cause skin irritation after contact. No irritation if used in normal condition.
Serious eye damage/irritation	Solution A and B could cause serious eye irritation after contact. No irritation if used in normal condition.
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 safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE
no data available

15.2 Chemical Safety Assessment

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.

No one is relieved from liability for the use of the information contained in this safety data sheet.

Mascia Brunelli S.p.A. does not in any way warrant or imply the applicability, viability or use of this information to any person or for use in any situation.

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