SAFETY DATA SHEET

According to Annex II to REACH - Regulation 2020/878/EU

Doc. N° VQ81406P SSE rev.5
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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 **Immunochromatographic 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 0039 02 66101029 (Centro Antiveleni 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 due to its pH 13-14. 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

GHS07

Signal word (CLP) Warning

Hazardous Ingredients Sodium hydroxide

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 IF IN EYES: 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

Results of PBT and vPvB assessment: PBT: not applicable
vPvB: not applicable

Endocrine disrupting properties: not applicable

No specific hazards for human and environment (also in case of abuse). But this product may contain material of animal origin (e.g. monoclonal antibodies) and should be handled as a potential carrier. Please notice the instructions for safe handling in section 4 and safe disposal of used device and specimen in section 13.

3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Individually sealed pouch: Each test strip is made up of the nitrocellulose membrane which is pre-coated with anti-genus specific lipopolysaccharide monoclonal antibody, on the test band region and goat anti-mouse IgG antibody on the control band region; the glass-fiber paper which is pre-coated with monoclonal anti-chlamydia antibody-colloidal gold conjugate, and is placed in a plastic device and stored in a sealed foil pouch containing dessicant.

Extraction solution A: solution with Sodium Hydroxide 0.2 M

Extraction solution B: Solution with Hydrochloric Acid 0.2 M

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 0.05% as preservative

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 (0,2 M)			
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 (0,2 M)			
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 Not a significant route of exposure. In case of unconsciousness, move exposed individual into fresh air. Seek medical attention if breathing is difficult or symptoms persist. If not breathing, give artificial respiration.

If swallowed Rinse mouth, give plenty of water to dilute the substance. Immediate medical attention is required.

In case of eye contact Extraction solution A, B or other components may cause slightly irritation upon contact, no adverse effects during normal usage. In case of eye contact, immediately wash eyes under running water for

at least 15 minutes, making sure that the eyelids are held open and immediately seek medical advice.

In case of skin contact Extraction solution A, B or other components may cause slightly irritation upon contact, no adverse effects during normal usage. In case of skin contact, remove any contaminated clothing and wash affected area immediately thoroughly with soap and water. Immediately seek medical advice if it causes itchiness and inflammation etc..

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

Treat affected person according to symptoms developing

5 - FIRE-FIGHTING MEASURES

5.1 Extinguishing media Suitable extinguishing media: dry chemical, carbon dioxide, alcohol-resistant foam or water spray. Use extinguishing measures appropriate to the source of the fire.
Unsuitable extinguishing media: no further relevant information available.

5.2 Special hazards arising from the substance or mixture

In the event of a fire, irritating fumes and toxic fumes may be formed (e.g. carbon monoxide, carbon dioxide).

5.3 Advice for firefighters Use extinguishing measures appropriate to the source of the fire. Wear self-contained breathing apparatus (SBCA) and full protective equipment.

6- ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.1.1 For non-emergency personnel Protective equipment-use safety goggles, nitrile gloves and lab coat. Emergency procedures-evacuate unnecessary personnel.

6.1.2 For emergency responders Protective equipment-equip clean up team with proper protection Emergency procedures-ventilate area.

6.2 Environmental precautions Avoid release to the environment. The used testing materials should be discarded in accordance with local, state and/or federal regulations as specimen might be infectious. Do not allow liquids to enter sink, drains, sewers.

6.3 Methods and material for containment and cleaning up

Soak up spills with inert solid as soon as possible. Collect spillage. Store away from other materials. Collect all waste in suitable and labeled containers and dispose of according to local legislation.

6.4 Reference to other sections Please refer to section 7 for information on safe handling.
Please refer to section 8 for information on personal protection equipment.
Please refer to section 13 for disposal information.

7 – HANDLING AND STORAGE

7.1 Precautions for safe handling The test is intended for professional use only. Use good laboratory practices, Avoid contact with eye and skin, do not ingest or inhale. Do not eat, drink or smoke while using this kit. Open pouch carefully and use test afterwards. Keep out of reach of children. Handle all specimens as if they contain infectious agents; Refer to EU directive 2000/54EC. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Wash hands and other

exposed areas before breaks and after work with mild soap and water. Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities

Keep product according to the package insert instructions, at 4-30°C in a dry and cool place. Keep away from heat sources.
Incompatibilities: strong bases, strong acids, sources of ignition, direct sunlight.

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

Substance Name	CAS No.	OSHA (TWA)	ACGIH (TWA)
Sodium hydroxide	1310-73-2	2 mg/m3	2 mg/m^3 (Ceiling)
Hydrochloric Acid	7647-01-1	5 ppm, 7.5 mg/m^3 (Ceiling)	5 ppm, 7.5 mg/m^3 (Ceiling)

8.2 Exposure controls

8.2.1 Appropriate engineering controls Not relevant for this material. No special exposure controls applicable but see personal protection. General protection and hygienic measures: Handle samples as potentially infectious material.

8.2.2 Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses or face shield recommended.
Skin protection Lab coat.
Hand protection Disposable gloves (EN374). Latex/natural rubber, Nitrile rubber. Penetration time of glove material is not critical when the product is handled according to the instructions for use.
Respiratory protection Not normally required.
Thermal hazards No further relevant information available.
Other information do not eat, drink or smoke during use.
8.2.3 Environmental exposure controls No special measures are required.

9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Physical state: the strip is housed in plastic casing and placed in a foil pouch containing desiccant.
Extraction solution A containing 0.2M sodium hydroxide is liquid.
Extraction solution B containing hydrochloric acid is liquid.
Negative control is liquid.
Positive control is liquid.

b) Colour: Extraction solution A colorless and transparent.
Extraction solution B faintly yellow and transparent.
Negative control is transparent, colorless.
Positive control is transparent, colorless.

c) Odour: Odourless

d) Melting point/freezing point: not applicable for device
for Extraction solution A and B app. 0°C.
for negative and positive control app. 0°C.

e) Boiling point or initial boiling point and boiling range:
Not applicable for device
For Extraction solution A and B app 100°C
For negative and positive control app. 100°C

f) Flammability: The test kit, and Extraction Tubes: flammable under direct flame.

g) Lower and upper explosion limit: Not applicable

h) Flash point:	Not applicable
i) Auto-ignition temperature:	Not applicable
j) Decomposition temperature:	No data applicable
k) pH:	Not applicable for device 13-14 for Extraction solution A 6 for Extraction solution B 6,95 For negative control 6,95 For positive control
l) Kinematic viscosity:	Not applicable
m) Solubility:	Not applicable
n) Partition coefficient n-octanol/water (log value) :	Not applicable
o) Vapour pressure :	Not applicable
p) Density and/or relative density:	Not applicable
q) Relative vapour density:	Not applicable
r) Particle characteristics:	Not applicable
9.2 Other safety information	no additional physical and chemical parameters available

10 – STABILITY AND REACTIVITY

10.1 Reactivity	Under requested storage conditions: no special hazard known.
10.2 Chemical stability	Stable under requested storage conditions until the expiration date. Use immediately after opening the pouch.
10.3 Possibility of hazardous reactions	No hazardous reactions known.
10.4 Conditions to avoid	Freezing, direct sunlight, humidity and heat.
10.5 Incompatible materials	No special hazards known, but contact with strong acids, strong bases, strong oxidizing agents and strong reducing agent should be avoided.
10.6 Hazardous decomposition products	Plastic components: hazardous decomposition products during burning possible.

11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
11.1.1 Substances	Not applicable.
11.1.2 Mixtures	All concentration below declaration limit-No need to expect harm at the given concentrations.
a) Acute toxicity	Sodium hydroxide: No data available Hydrochloric acid: LD_{50} rabbit, oral 900 mg/kg LC_{50} rat, inhalation 3124 ppm/1H
b) Skin corrosion/irritation	Sodium hydroxide: rabbit, 50 mg/24H: severe irritation effects Hydrochloric acid: no data available. Extraction solution A and B may cause slightly skin irritation upon contact. But no irritation to skin during normal usage.
c) Serious eye damage/irritation	Sodium hydroxide: rabbit, 1%: severe irritation effects Hydrochloric acid: no data available. Extraction solution A and B may cause slightly eye irritation upon contact. But no irritation to eye during normal usage.
d) Respiratory or skin sensitisation	No data available.
e) Germ cell mutagenicity	No data available.
f) Carcinogenicity	No data available.
g) Reproductive toxicity	No data available.
h) STOT-single exposure	No data available.
i) STOT-repeated exposure	No data available.
j) Aspiration hazard	No data available.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties No data available.

11.2.2 Other information No additional information available.

12 – ECOLOGICAL INFORMATION

The device contains one or more chemical substances supplied in small quantities. In the form supplied, they are not classified as dangerous within the meaning of the definitions of the Council of European Communities Regulation 1272/2008-EC (CLP). The test device should be discarded in accordance with local, state and/or federal regulations see point 13 of MSDS–No ecological risk.

12.1 Toxicity no results of ecotoxicity studies available.

12.2 Persistence and degradability the device contains plastic and other components that are not readily degradable: plastic components degrade very slowly.

12.3 Bio accumulative potential accumulation in organisms not anticipated.

12.4 Mobility in soil the test is predicted to have low mobility in soil. The Extraction solution A and B are predicted to have high mobility in soil.

12.5 Results of PBT and vPvB assessment not applicable. This product/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties no data applicable.

12.7 Other adverse effects no data available.

13 – DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste disposal company for information.
Extraction Solution A and B, controls: Chemical residues and remains should be routinely handled as special waste. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. This must be disposed of in compliance with the Directive on waste 2008/98/EC and other laws of the country concerned.
Used Tests, controls and plastic ware: Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.

European waste catalogue Extraction Solution A, B, controls and Tests: 18 01 07 (chemicals other than those mentioned in 18 01 06).
Used Tests and plastic ware: 18 01 03 (waste whose collection and disposal is subject to special requirements in order to prevent infection.)

Packaging Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as regulated for the contaminant (see individual European waste catalogue numbers). Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14 – TRANSPORT INFORMATION

The product is considered non dangerous for transportation

14.1 UN number not applicable

14.2 UN proper shipping name not applicable

14.3 Transport hazard class(es) not classified as dangerous for transport

14.4 Packaging 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

15 – REGULATORY INFORMATION

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

In Vitro diagnostics medical devices according directive 98/79/EC. Labeling according EU-guidelines EN ISO 15223-1: 2021.

The product is a mixture which is not subject to Regulation (EC) No 1005/2009, (EU) 2019/1021, (EC) No 649/2012 of the European Parliament and of the Council.

No restriction or prohibited within the meaning of the definitions of the following Council of European Communities Directives: Directive 2000/54/EC, REACH REGULATION (EC) No 2020/878+subsequent amendments and REGULATION (EC) No 1272/2008 (CLP)+subsequent amendments.

15.2 Chemical Safety Assessment not applicable

16 – OTHER INFORMATION

The information herein is based on our current knowledge, which subject to be correct but does not intend to be all-inclusive and shall only be used as a guide. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. The supplier Mascia Brunelli S.p.A. shall not be held liable for any damage resulting from handling or from contact with the above product. Final determination of suitability of any material is the sole responsibility of the user.

Legend to abbreviations and acronyms

LD50: Median lethal dose

LC50: Median lethal concentration

OSHA: U.S. Occupational Safety and Health Administration

ACGIH: American Conference of Governmental Industrial Hygienists.

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

IFU: Instruction for use

ATE:Acute toxicity estimate

Met. Corr. 1: Substance or mixture corrosive to metals, category 1

Skin Corr. 1A: Skin corrosion/irritation, category 1A

Skin Corr. 1B: Skin corrosion/irritation, category 1B

Skin Irrit. 2: Skin corrosion/irritation, category 2

Eye Irrit. 2: Serious eye damage/eye irritation, category 2

Eye Irrit.2A:Serious eye irritation,

STOT SE 3: Specific target organ toxicity-single exposure, Category 3

H290: May be corrosive to metals

H314: Causes severe skin burns and eye damage

H315: Causes skin irritation

H318: Causes serious eye damage

H319: Causes serious eye irritation

H335: May cause respiratory irritation