



# SAFETY DATA SHEET

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

Doc. N° VQ81406 SSE rev.4

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

### 1.1 Product identifiers

Product number:

VQ81406

Product name:

CHLAMYDIA TRACHOMATIS

### 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*

### 1.3 Details of the supplier of the safety data sheet

Company

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Viale Monza 272, 20128 Milano, Italy.

Tel.: 0039 02 25209.1

Fax: 0039 02 2576428

E-mail: [mktg@masciabrunelli.it](mailto: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

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

### 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**

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 (%)
<b>Sodium hydroxide</b>			
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%
<b>Hydrochloric Acid</b>			
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 extraction solution 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 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 CO<sub>2</sub>.

**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 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

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

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

a) Appearance Form:	Card white solid	Extraction solution A: colourless, liquid, B: liquid, colourless
transparent		odorless
b) Odour	odorless	odorless
c) Odour Threshold	no data available	no data available
d) pH	no data available	A: 13-14; B: about 6
e) Melting point/freezing point	no data available	A and B: about 0°C
f) Initial boiling point and boiling range	no data available	A and B: about 100°C
g) Flash point	no data available	no data available
h) Evaporation rate	no data available	no data available
i) Vapour pressure	no data available	no data available
j) Vapour density	no data available	no data available
k) Relative density	no data available	no data available
l) Water solubility	no data available	easy soluble
m) Viscosity	no data available	no data available
n) Explosive properties	no data available	no data available



o) Oxidizing properties no data available no data available

**9.2 Other safety information** no data available

## 10 – STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No known hazardous reactivity
<b>10.2 Chemical stability</b>	Stable under recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	no data available
<b>10.4 Conditions to avoid</b>	Direct contact with a flame. Temperatures outside the range of 2-30 ° C. Avoid storing in places with high humidity.
<b>10.5 Incompatible materials</b>	no data available.
<b>10.6 Hazardous decomposition products</b>	no known hazardous decomposition products

## 11 – TOXICOLOGICAL INFORMATION

<b>11.1 Information on toxicological effects</b>	
<b>Acute toxicity</b>	Product does not present an acute toxicity hazard based on known or supplied information
<b>Skin corrosion/irritation</b>	Solution A and B could cause skin irritation after contact. No irritation if used in normal condition.
<b>Serious eye damage/irritation</b>	Solution A and B could cause serious eye irritation after contact. No irritation if used in normal condition.
<b>Respiratory or skin sensitisation</b>	No data available.
<b>Germ cell mutagenicity</b>	No data available.
<b>Carcinogenicity</b>	no ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex 1.
<b>Reproductive toxicity</b>	No data available.
<b>Summary of evaluation of the CMR properties</b>	No data available.
<b>STOT-single exposure</b>	No data available.
<b>STOT-repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available

## 12 – ECOLOGICAL INFORMATION

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

## 13 – DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	
<b>Product</b>	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
<b>Contaminated packaging</b>	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

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



## **15 – REGULATORY INFORMATION**

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### **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**

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