

# Mascia Brunelli S.p.A.

VQ81602  
GONORREA Ag CARD

## Scheda di Dati di Sicurezza / Safety Data Sheet

Conforme all'Allegato II del REACH - Regolamento (UE) 2020/878  
According to Annex II to REACH - Regulation 2020/878

<b>Codice / Code:</b>	<b>VQ81602</b>
<b>Nome prodotto / Product name:</b>	<b>GONORREA Ag CARD</b>
<b>Descrizione d'uso / Intended use:</b>	<b>Test immunocromatografico rapido su card per la determinazione della <i>Neisseria gonorrhoeae</i> in campioni urogenitali, comprensivo di controllo positivo e negativo / Immunochromatographic rapid test for the detection of <i>Neisseria gonorrhoeae</i> in urogenital specimen, including positive and negative control</b>
<b>Fornitore / Supplier:</b>	<b>Mascia Brunelli S.p.A.</b> Viale Monza 272, 20128 Milano, Italia. Tel.: 0039 02 252091 E-mail: <a href="mailto:mktg@masciabrunelli.it">mktg@masciabrunelli.it</a>
<b>Componenti del kit / Kit components:</b>	<ol style="list-style-type: none"><li><b>Liquido Estrazione A / Extraction Solution A</b></li><li><b>Liquido Estrazione B / Extraction Solution B</b></li><li><b>Gonorrhea Test Device</b></li></ol>



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# SAFETY DATA SHEET

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

### 1.1 Product identifiers

Code: **VQ81602**  
Product name: **GONORREA Ag CARD\_Extraction solution A**

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

Identified use: **Extraction solution for sample treatment, to use for Gonorrea kit**

### 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\*\*](mailto: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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

### 2.2 Label elements

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

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

### 2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

No information on other hazards.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Irrilevant



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**3.2 Mixtures**

Extraction solution A contains: 50 mM HCl

The components are not hazardous or are below required disclosure limits.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

If signs of infection occur, seek medical attention.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Inhalation: Supply fresh air; seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Direct skin contact: In case of contact, immediately flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Direct eye contact: Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Ingestion: In case of ingestion, contact a poison control center or physician for instructions if feel uncomfortable.

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

Information not available

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

Information not available

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None known.

**5.2. Special hazards arising from the substance or mixture**

Due to the low content of chemical substances in the Extraction Reagent A and the small volume of the Extraction Reagent A, it will not cause harm.

**5.3. Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

**6.2. Environmental precautions**

Do not allow to enter sewers/surface or ground water. Keep contaminated washing water and dispose of appropriately.

**6.3. Methods and material for containment and cleaning up**

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.



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**6.4. Reference to other sections**

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

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Minimize contact and contamination of personal clothing and skin.  
Wash hands thoroughly after handling.  
See also section 8 below.

**7.2. Conditions for safe storage, including any incompatibilities**

Store in the original container at 4 to 30°C.

**7.3. Specific end use(s)**

Professional uses:  
Use as per instructions for use.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

No data available.

**8.2. Exposure controls**

Suitable engineering controls:  
Professional uses:  
No specific controls provided

Personal protective measures:

**HAND PROTECTION**  
Disposable gloves, nitrile rubber.

**SKIN PROTECTION**  
Wear normal work clothing.

**EYE PROTECTION**  
None required for normal use.

**RESPIRATORY PROTECTION**  
None required for normal use.

**THERMAL HAZARDS**  
No Hazard to report

**ENVIRONMENTAL EXPOSURE CONTROLS**  
Use according to good working practices, avoiding spillage into the environment.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	Liquid	
Colour	Colourless, clear	
Odour	Not available	
Melting point / freezing point	Not available	

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Initial boiling point	Not available
Flammability	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
pH	1 ± 0,2
Kinematic viscosity	Not available
Solubility	Soluble in water
Partition coefficient: n-octanol/water	Not available
Vapour pressure	Not available
Density and/or relative density	Not available
Relative vapour density	Not available
Particle characteristics	Not available

**9.2. Other information**

## 9.2.1. Information with regard to physical hazard classes

Information not available

## 9.2.2. Other safety characteristics

Information not available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No reactivity hazards.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

No data available.

**10.5. Incompatible materials**

None in particular.

**10.6. Hazardous decomposition products**

Does not decompose when used for its intended uses.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on available data, the classification criteria are not met

(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met



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- (c) severe ocular damage/eye irritation: based on available data the classification criteria are not met
- (d) respiratory or skin sensitization: based on available data the classification criteria are not met
- (e) germ cell mutagenicity: based on available data the classification criteria are not met
- (f) carcinogenicity: based on available data the classification criteria are not met
- (g) reproductive toxicity: based on available data the classification criteria are not met
- (h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
- (i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
- (j) aspiration hazard: based on available data, the classification criteria are not met.

**11.2. Information on other hazards**

**11.2.1. Endocrine disrupting properties**

Based on available data, there are no substances with endocrine-disrupting properties.

**11.2.2. Other information**

No information on other hazards.

**SECTION 12: Ecological information**

**12.1. Toxicity**

Use according to good working practices, avoiding dispersing the product into the environment.

**12.2. Persistence and degradability**

Information not available.

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

Information not available.

**12.5. Results of PBT and vPvB assessment**

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

**12.6. Endocrine disrupting properties**

Based on available data, there are no substances with endocrine-disrupting properties.

**12.7. Other adverse effects**

Not applicable

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

**SECTION 14: Transport information**

**14.1. UN number or ID number**



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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.

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

No data available

**14.7. Maritime transport in bulk according to IMO instruments**

There is no provision for bulk transport

**SECTION 15: Regulatory information**

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

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878. Substances on Candidate List (art.59 REACH).

Based on available data, there are no SVHC substances present.

**15.2. Chemical safety assessment**

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

**SECTION 16: Other information**

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

No hazard to report. Classification procedure: Calculation method.

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates



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15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates

- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.



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# SAFETY DATA SHEET

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

### 1.1 Product identifiers

Code: **VQ81602**  
Product name: **GONORREA Ag CARD\_Extraction solution B**

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

Identified use: **Extraction solution for sample treatment, to use for Gonorrea kit**

### 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](mailto: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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

### 2.2 Label elements

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

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

### 2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

No information on other hazards.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Irrilevant



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### 3.2 Mixtures

Extraction solution B contains: 30 mM NaOH

The components are not hazardous or are below required disclosure limits.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

If signs of infection occur, seek medical attention.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Inhalation: Supply fresh air; seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Direct skin contact: In case of contact, immediately flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Direct eye contact: Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Ingestion: In case of ingestion, contact a poison control center or physician for instructions if feel uncomfortable.

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

Information not available

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

Information not available

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None known.

### 5.2. Special hazards arising from the substance or mixture

Due to the low content of chemical substances in the Extraction Reagent B and the small volume of the Extraction Reagent B, it will not cause harm.

### 5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

### 6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water. Keep contaminated washing water and dispose of appropriately.

### 6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.



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**6.4. Reference to other sections**

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

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Minimize contact and contamination of personal clothing and skin.  
Wash hands thoroughly after handling.  
See also section 8 below.

**7.2. Conditions for safe storage, including any incompatibilities**

Store in the original container at 4 to 30°C.

**7.3. Specific end use(s)**

Professional uses:  
Use as per instructions for use.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

No data available.

**8.2. Exposure controls**

Suitable engineering controls:  
Professional uses:  
No specific controls provided

Personal protective measures:

**HAND PROTECTION**  
Disposable gloves, nitrile rubber.

**SKIN PROTECTION**  
Wear normal work clothing.

**EYE PROTECTION**  
None required for normal use.

**RESPIRATORY PROTECTION**  
None required for normal use.

**THERMAL HAZARDS**  
No Hazard to report

**ENVIRONMENTAL EXPOSURE CONTROLS**  
Use according to good working practices, avoiding spillage into the environment.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	Liquid	
Colour	Colourless, clear	
Odour	Not available	
Melting point / freezing point	Not available	

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Initial boiling point	Not available
Flammability	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
pH	11 - 12
Kinematic viscosity	Not available
Solubility	Soluble in water
Partition coefficient: n-octanol/water	Not available
Vapour pressure	Not available
Density and/or relative density	Not available
Relative vapour density	Not available
Particle characteristics	Not available

**9.2. Other information**

## 9.2.1. Information with regard to physical hazard classes

Information not available

## 9.2.2. Other safety characteristics

Information not available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No reactivity hazards.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

No data available.

**10.5. Incompatible materials**

None in particular.

**10.6. Hazardous decomposition products**

Does not decompose when used for its intended uses.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on available data, the classification criteria are not met

(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met



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- (c) severe ocular damage/eye irritation: based on available data the classification criteria are not met
- (d) respiratory or skin sensitization: based on available data the classification criteria are not met
- (e) germ cell mutagenicity: based on available data the classification criteria are not met
- (f) carcinogenicity: based on available data the classification criteria are not met
- (g) reproductive toxicity: based on available data the classification criteria are not met
- (h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
- (i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
- (j) aspiration hazard: based on available data, the classification criteria are not met.

**11.2. Information on other hazards**

**11.2.1. Endocrine disrupting properties**

Based on available data, there are no substances with endocrine-disrupting properties.

**11.2.2. Other information**

No information on other hazards.

**SECTION 12: Ecological information**

**12.1. Toxicity**

Use according to good working practices, avoiding dispersing the product into the environment.

**12.2. Persistence and degradability**

Information not available.

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

Information not available.

**12.5. Results of PBT and vPvB assessment**

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

**12.6. Endocrine disrupting properties**

Based on available data, there are no substances with endocrine-disrupting properties.

**12.7. Other adverse effects**

Not applicable

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

**SECTION 14: Transport information**

**14.1. UN number or ID number**



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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.

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

No data available

**14.7. Maritime transport in bulk according to IMO instruments**

There is no provision for bulk transport

**SECTION 15: Regulatory information**

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

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878. Substances on Candidate List (art.59 REACH).

Based on available data, there are no SVHC substances present.

**15.2. Chemical safety assessment**

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

**SECTION 16: Other information**

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

No hazard to report. Classification procedure: Calculation method.

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates



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15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates

- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.



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# SAFETY DATA SHEET

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

### 1.1 Product identifiers

Code: VQ81602  
Product name: GONORREA Ag CARD\_Device

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

Identified use: Immunochromatographic rapid test for the detection of *Neisseria gonorrhoeae* in urogenital samples

### 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](mailto: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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

### 2.2 Label elements

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

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

### 2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

No information on other hazards.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Irrilevant



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### 3.2 Mixtures

Individually sealed pouch: One strip packed in a plastic cassette; 0,5 g silica gel dessicant

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

The components are not hazardous or are below required disclosure limits.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Inhalation: unlikely. Supply fresh air; consult doctor in case of complaint.

Direct skin contact: wash thoroughly with soap and water.

Direct eye contact: The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. Rinse cautiously with water for several minutes.

Ingestion: unlikely. If this happens, rinse the mouth with water. Seek medical attention in case of complaint.

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

Slightly irritant to skin.

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

Information not available

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.

### 5.2. Special hazards arising from the substance or mixture

Information not available

### 5.3. Advice for firefighters

Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

### 6.2. Environmental precautions

Do not allow the product to enter sewers/surface or ground water.

### 6.3. Methods and material for containment and cleaning up

Dispose of contaminated material as waste according to Section 13. Rinse off area with water.



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#### 6.4. Reference to other sections

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

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes. Keep out of reach of children.  
Do not eat or drink while working.  
See also section 8 below.

#### 7.2. Conditions for safe storage, including any incompatibilities

Store in the original container at 4 to 30°C.

#### 7.3. Specific end use(s)

Professional uses:  
Use as per instructions for use.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No data available.

#### 8.2. Exposure controls

Suitable engineering controls:  
Professional uses:  
No specific controls provided

Personal protective measures:

##### HAND PROTECTION

Disposable gloves, latex/natural rubber/nitrile rubber.

##### SKIN PROTECTION

Wear normal work clothing.

##### EYE PROTECTION

None required for normal use.

##### RESPIRATORY PROTECTION

None required for normal use.

##### THERMAL HAZARDS

No Hazard to report

##### ENVIRONMENTAL EXPOSURE CONTROLS

Use according to good working practices, avoiding spillage into the environment.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Solid	
Colour	White	
Odour	No odour	
Melting point / freezing point	Not applicable	

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Initial boiling point	Not applicable
Flammability	Not applicable
Lower explosive limit	Not explosive
Upper explosive limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Insoluble
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

**9.2. Other information**

## 9.2.1. Information with regard to physical hazard classes

Information not available

## 9.2.2. Other safety characteristics

Information not available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No reactivity hazards.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

Direct contact with a flame. Temperatures outside the range of 4-30° C. Avoid storing in places with high humidity.

**10.5. Incompatible materials**

None in particular.

**10.6. Hazardous decomposition products**

Does not decompose when used for its intended uses.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on available data, the classification criteria are not met

(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met



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- (c) severe ocular damage/eye irritation: based on available data the classification criteria are not met
- (d) respiratory or skin sensitization: based on available data the classification criteria are not met
- (e) germ cell mutagenicity: based on available data the classification criteria are not met
- (f) carcinogenicity: based on available data the classification criteria are not met
- (g) reproductive toxicity: based on available data the classification criteria are not met
- (h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
- (i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
- (j) aspiration hazard: based on available data, the classification criteria are not met.

**11.2. Information on other hazards**

**11.2.1. Endocrine disrupting properties**

Based on available data, there are no substances with endocrine-disrupting properties.

**11.2.2. Other information**

No information on other hazards.

**SECTION 12: Ecological information**

**12.1. Toxicity**

Use according to good working practices, avoiding dispersing the product into the environment. The product does not contain significant quantities of ingredients that are environmentally toxic.

**12.2. Persistence and degradability**

The product is non-biodegradable.

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

The product is predicted to have immobility in soil.

**12.5. Results of PBT and vPvB assessment**

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

**12.6. Endocrine disrupting properties**

Information not available

**12.7. Other adverse effects**

No adverse effects observed

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

**SECTION 14: Transport information**

**14.1. UN number or ID number**



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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.

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

No data available

**14.7. Maritime transport in bulk according to IMO instruments**

There is no provision for bulk transport

**SECTION 15: Regulatory information**

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

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878. Substances on Candidate List (art.59 REACH).

Based on available data, there are no SVHC substances present.

**15.2. Chemical safety assessment**

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

**SECTION 16: Other information**

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

No hazard to report. Classification procedure: Calculation method.

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament



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- 13. Regulation (EU) No. 1297/2014 of the Commission
- 14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
- 15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

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