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*Laboquick Helicobacter pylori Ag - LHAG.01*

## 1 Identification of the Substance/Preparation and the Company/Undertaking

### **Product details**

**Trade Name:** Laboquick Helicobacter pylori Ag Rapid Test

**Article Number:** LHAG.01

**REF Number:** LHAG.01

**Application of the Substance/Preparation:** For in vitro Diagnostic Use

### **Manufacturer/Supplier:**

Koroglu Medical Devices Ltd  
1776/23 Sok. No:4/A Mevlana Mah.  
Bornova - Izmir - Turkey  
Phone: +90 232 388 73 74

### **Information Supplied by:**

Minias Globe Diagnostics Srl Technical Direction  
E-mail: info@mgdsrl.it  
Phone. +39 019 824844;  
9:00 - 17:30 Monday - Thursday, 9:00 - 16:00 Friday

### **Information in case of Emergency:**

Centro Antiveleni (CAV) Ospedale Niguarda Ca' Granda  
Phone. +39 02 66101029; 24h/7d

## 2 Hazards Identifications

**Hazards Designation:** Void

### **Information concerning particular hazards for human and environment:**

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

## 3 Composition/information on ingredients

### **Chemical characterization**

#### **Description:**

Nitro Cellulose Membrane Coated Antibody  
Antigen Compound  
Polyethylene Pippette for Sample  
No Hazardous Material is included.

## 4 First aid measures

### **General information:**

No special measures required

#### **After inhalation:**

No special measures required

#### **After skin contact:**

No special measures required

#### **After eye contact:**

No special measures required

#### **After swallowing:**

Do not induce vomiting without medical advice. If symptoms persist call a physician.

### 5 Fire-fighting measures

**Suitable extinguishing agents:**

*CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.*

**Unusual hazards:**

*None known.*

**Special protective equipment for firefighters:**

*No special measures required.*

### 6 Accidental release measures

**Personal precautions:**

*In case of release, consult sections 7 and 8.*

**Environmental precautions:**

*Do not flush into surface water or sanitary sewer system. Do not let product enter drains.*

**Cleaning/collecting measures:**

*Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).*

### 7 Handling and storage

**Handling:**

**Information for safe handling:**

*No special precaution is necessary if used correctly.*

**Storage:**

*Refer to the package insert or product label for additional information on storage conditions*

### 8 Exposure controls/Personal protection

**Ingredients with limit values that require monitoring at the workplace:**

*Not required.*

**Personal protective equipment:**

**General protective and hygienic measures:**

*Follow good laboratory practice (GLP).*

*The usual precautionary measures must be adopted when handling chemicals.*

**Protection of hands:**

*Disposable gloves will be needed when working with infectious diseases samples.*

**Material of gloves:**

*Lattice or natural rubber.*

**Penetration time of glove material:**

*The exact break through time has to be pointed out by the manufacturer of the protective gloves and has to be observed.*

**Eye protection:**

*Safety glasses are recommended during refilling.*

**Body protection:**

*Lab coat.*

## 9 Physical and chemical properties

### General Information

<b>Form</b>	Liquid
<b>Color</b>	Colourless
<b>Odour</b>	Odourless

### Change in physical state

<b>Melting point/Melting range:</b>	Not applicable
<b>Boiling point/Boiling range:</b>	Not applicable

<b>Fash point:</b>	Not applicable
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<b>Autoignition:</b>	Not selfigniting
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<b>Danger of explosion:</b>	Not explosive
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<b>Vapour pressure at 20 °C:</b>	Not applicable
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<b>Density at 20 °C</b>	Not applicable
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<b>Solubility in / Miscibility with water:</b>	Not applicable
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<b>pH-value at 20 °C</b>	Not applicable
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## 10 Stability and reactivity

*This product is stable until the expiration date indicated on the label under the specified storage conditions. There are no known reactivities with these components. Refer to the kit insert for further information.*

## 11 Toxicological information

None available.

## 12 Ecological information

None available.

## 13 Disposal consideration

*Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.*

## 14 Transport information

**Land transport ADR/RID (cross-border): -**

**ADR/RID-GGVs/E Class: -**

**Maritime transport IMDG: -**

**IMDG Class: -**

**Marine pollutant: No**

**Air transport ICAO-TI e IATA-DGR: -**

**ICAO/IATA Class: -**

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### **15 Regulatory information**

**Labeling according to EU guidelines:**

*The product is not subject to identification regulations under EC Directives.*

### **16 Other information**

*The data and recommendations contained herein are based upon information believed by Minias Globe Diagnostics after reasonable investigation and research, to be accurate; however, Minias Globe Diagnostics does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Minias Globe Diagnostics In no case shall be liable for incidental or consequential damages, including lost profit.*

**Reason for revision:** *Update based 1907/2006/EC, Article 31 regulation*

**Training hints:** *Only for professional user working with IVD tests.*

**Prepared by:** *Koroglu Medical Devices Ltd Technical Direction*

**\*Data compared to the previous version altered.**