

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Helicobacter Pylori

Catalog #: RAPU08V400

Kit Components: Test cassette
Sample Droppers
Buffer
Capillary Tubes

1.2 Intended Use

A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H.pylori) in whole blood, serum or plasma. For professional in vitro diagnostic use only.

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: tech.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

2.2.1 Labelling according to regulation (EC) No. 1272/2008

Hazard pictograms and Signal word: Not applicable

2.2.2 Hazardous components for labeling

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

Not applicable

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Component	Cas n°	EINECS n°	Class	Conc.
ProClin 300	613-167-00-5	-	C, Xn, Xi, N R34, R20/21/22, R43, R50/53 GHS05, GHS07, GHS09 H302, H314, H317,H410	0.02 %

For the wording of the listed phrases refer to section 16.

4 FIRST AID MEASURES

4.1 Description of first aid measures

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the strip.

After Inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Immediately rinse eye thoroughly with plenty of water. Remove contact lenses and continue rinsing for at least 15 minutes. Get immediate medical attention.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	No special fire-fighting procedure required.
Unsuitable extinguishing media	Use fire-extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for fire fighters

Dry-chemical fire extinguisher.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental Precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning-up

Clean up with broom.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must remove before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific Use(s)

The H. pylori Antibody Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment:

General protective and hygienic measures	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use.
Eye Protection	Safety glasses
Body protection	Lab coat

8.2.3 Enviromental exposure controls

There are no special precautions and measures. See section 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Solid
Appearance	White appearance and some content of the test strip is purple
Odour	Odourless
Odour threshold	not established
Flash point	not established
Self-igniting	Product is not known to be self-igniting
Danger of explosion	There is no substances in the kit could lead to the danger of explosion
Melting point	not established
Boiling point	not established
Vapour pressure	not established
Density (20°C)	not established
pH-value at 20°C	not established
Solubility in water	The product almost could not solute in the water.

9.2 Other safety information

Other physical-chemical data were not determined.

10 STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

10.2 Chemical Stability

All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions

Almost impossible.

10.4 Conditions to Avoid

High humidity and the temperature out of 2-30°C.

10.5 Incompatible materials

None known.

10.6 Hazardous Decomposition Products

None known.

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects**

The following toxicological information are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the strip.

Acute toxicity	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity	No data available/ not applicable.
Carcinogenicity	No data available/ not applicable.
Mutagenicity	No data available/ not applicable.
Toxicity for reproduction	No reproductive toxic effect known.

12 ECOLOGICAL INFORMATION**12.1 Toxicity**

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulation

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

No data available.

13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Product	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.
European waste catalogue	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
Packaging	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further informations.

14 TRANSPORT INFORMATION**14.1 UN-Number**

Not applicable

14.2 UN proper shipping name

ADR/RID: Not applicable

IMDG-Code / ICAO-TI / IATA-DGR: Not applicable

14.3 Transport hazard class

No hazardous good.

14.4 Packing group

Not applicable

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

14.6 Special precautions for user

See sections 6-8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging.

15 REGULATORY INFORMATION**15.1 Safety, health and environmental regulation/legislation specific for the substance or mixture**

EU regulations: Not applicable

Germany: Not applicable

15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment.

16 OTHER INFORMATION**General information**

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

Hazard statements:

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H410 Very toxic to aquatic life with long lasting effects.

Risk phrases:

R34 Causes burns.

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R43 May cause sensitisation by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Legend:

ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route.

RID: Règlement internationale concernant le transport des marchandises dangereuses par chemin de fer.

IMDG: International Maritime Code for Dangerous goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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