

The kit **Enzy-Well Helicobacter pylori IgA (REF 91062)** is an immunoenzymatic method for the qualitative determination of IgA-class antibodies to Helicobacter pylori in human serum.

Each kit is composed of:

MT PLATE

MICROPLATE 12 x 8 wells coated with Helicobacter pylori

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

CONTROL +

POSITIVE CONTROL 1 x 1.6 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: diluted human serum, containing anti-Helicobacter pylori IgA antibodies, in phosphate buffer 0.01 mol/L with BSA 1% and sodium azide 0.09%.

CONTROL CUT-OFF

CONTROL CUT-OFF 1 x 2 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: diluted human serum, at known concentration of anti-Helicobacter pylori IgA antibodies, in Phosphate buffer 0.01 mol/L with BSA 1% and sodium azide 0.09%.

CONJ

CONJUGATE 1 x 16 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: anti-human IgA monoclonal antibodies labelled with peroxidase, in phosphate buffer solution containing phenol 0.05% and Bronidox 0.02%.

IgA CONTROL -

IgA NEGATIVE CONTROL 1 x 1.6 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and / or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: human serum diluted in phosphate buffer 0.01 mol/L, with BSA 1% and sodium azide 0.09%.

WASH BUF 10x

WASHING BUFFER 10X 1 x 100 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: phosphate buffered saline (PBS), concentrated 10 times; contains Brij 0.5%

IgA SAMP DIL 50x

IgA DILUENT 50X 1 x 4.5 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: proteic solution concentrated 50 times, with monoclonal antibodies anti-human IgG, phenol 0.05% and Bronidox 0.02%.

SUBS TMB

SUBSTRATE 1 x 12 mL

The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: Tetramethylbenzidine 0.26 mg/mL and hydrogen peroxide 0.01% stabilized in citrate buffer 0.05 mol/L (pH 3.8).

H₂SO₄ 0.3 M

STOP SOLUTION 1 x 16 mL

The substance is classified as **dangerous** according to Regulation 1272/2008 and European Directive 1999/45/CE.

The material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.

Contents: solution of sulphuric acid, 0.3 mol/L.



MATERIAL SAFETY DATASHEET
ENZY-WELL STOP SOLUTION
(According to Regulation (EC) No. 1907/2006 e 453/2010)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 IDENTIFICATION OF THE PRODUCT

Product name: ENZY-WELL STOP SOLUTION
Product number: PF 93602
Brand: DIESE

1.2 IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Identified use: Professional use as laboratory reagent.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESE Diagnostica Senese SpA

Registered office:
Via A. Solari 19
20144 Milan, Italy
Tel: +39 02 4859121
Fax: +39 02 48008530

Production plant:
Via delle Rose, 10 – Loc. Tognazza
53035 Monteriggioni (SI), Italy
Tel: +39 0577 587111
Fax: +39 0577 318690

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: Centro Antiveleni, Ospedale Niguarda Ca' Granda - Milano
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera "S.G.Battista" – Molinette di Torino - Torino
Tel: +39 011 6637637

Centro Antiveleni – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Firenze
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Napoli
Tel: +39 081 7472870

web: http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:

Skin Corrosion – Category 1A

Dangerous components:

H314 - Causes severe skin burns and eye damage

Classificazione ai sensi delle Direttive 67/548/CEE e 1999/45/CE:

C - Corrosive

R-phrases:

R35 - Causes severe skin burns

2.2 LABEL ELEMENTS**Pictograms:** GHS05**Signal word:** Danger**Hazard statement:**

H314 - Causes severe skin burns and eye damage

Precautionary statement:*Prevention*

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P264 - Wash ... thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

Reaction

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P363 - Wash contaminated clothing before reuse

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310 - Immediately call a POISON CENTER or doctor/physician

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Storage

P405 - Store locked up.

Contains:

Sulphuric Acid

INDEX: 016-020-00-8

2.3 OTHER HAZARDS

None

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1 SUBSTANCE** Non applicable**3.2 MIXTURE**

Substance name	Conc.	Classification	
		Directive 67/548/CEE	EC Regulation 1272/2008
Sulphuric Acid			
Cas No 7664-93-9	<3%	C	R35 Skin Corr. 1A H314
EC No 231-639-5			
Index No 016-020-00-8			

4. FIRST AID MEASURES**4.1 DESCRIPTION OF FIRST AID MEASURES****General advice:**

Move the person from the exposure to open air. In case of severe condition consult a physician immediately and present this safety data sheet. Eyewash and shower for the treatment of emergency have to be present in the workplace.

Skin contact:

Take off the contaminated clothes and wash with copious amounts of water. If irritation persist consult a physician.

Eye contact:

Take off lenses (if present). Flush eyes with plenty of water for at least 15 minutes keeping eyelids opened. Consult immediately a physician.

Inhalation:

In case of severe condition consult a physician.

Ingestion:

Clean mouth with water and drink afterwards plenty of water. Do not induce vomiting. Do not administer any medicine if the person is unconscious. Consult immediately a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available



5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The mixture is not inflammable. However, in case of fire, irritating and/or toxic fumes can be released.

5.3 ADVICE FOR FIREFIGHTERS

If necessary, wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Keep people not involved in the intervention operations away. Ensure an adequate ventilation of the affected area. Wash with plenty of water all the body parts entered in contact with the mixture immediately. Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water and soil.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Absorb on inert material (sand/earth). Collect the spilled material with mechanical means and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For more information on disposal see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well-ventilated area. Avoid the contact with eyes and skin and the inhalation of vapors.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store at 2-30°C, away from basic substances.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits

Description	Type	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
Sulphuric Acid	TLV-ACGIH 2008	0.2			

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals. Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift.

Appropriate engineering controls:

Ensure an adequate ventilation of the working area.

Personal Protective Equipment:

Suggestions on the use of specific PPE are indicated below. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections:

Chemical-resistant gloves, comply with EN 374.

Eye protections:

Safety goggles side shields

Body protections:

Work outfits for complete skin protection

Respiratory protection:

Not required under normal work activities

8.3 ENVIRONMENTAL EXPOSURE CONTROLS

Do not discard residuals in the environment. Discard the empty containers as hazardous waste.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Form	Liquid
Odour	No data available
Odour Threshold	No data available
pH	< 0.5
Freezing/Melting point	No data available
Initial boiling and melting point range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limit	Not applicable
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Water solubility	Soluble in water
Partition coefficient: n-octano/water	No data available
Autoignition temperature	Not applicable
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY E REACTIVITY

10.1 REACTIVITY

No data available

10.2 CHEMICAL STABILITY

Stable under the recommended transport, handling and storage conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

The mixture reacts with the basic and/or oxidizing substances with formation of heat.

10.4 CONDITIONS TO AVOID

Avoid contact with basic and/or oxidizing substances.

10.5 INCOMPATIBLE MATERIALS

Basic substances.



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10.6 HAZARDOUS DECOMPOSITION PRODUCTS

When heated or in case of fire, vapors that are potentially dangerous to health (SOx) may be produced.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

The mixture is corrosive for skin and eyes.

Acute toxicity:	No data available
Skin irritation:	Corrosive for skin and mucous membranes
Eye irritation:	Severe eye damages
Subcutaneous sensitization:	No data available
Germ cell mutagenesis:	No data available
Carcinogenicity:	No data available
Reproduction toxicity:	No data available
Organ specific toxicity (on single or repeated exposure):	No data available
Acute inhalation toxicity:	No data available
Other information	No data available

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

Use according to good working practices, avoiding release to the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

12.2 PERSISTENCE AND DEGRADABILITY

No data available

12.3 BIOACCUMULATIVE POTENTIAL

No data available

12.4 MOBILITY IN SOIL

No data available

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

No data available

12.6 OTHER ADVERSE EFFECTS

The disposal into drains or water bodies can result in a decreasing of the pH value. A low pH value harms aquatic organisms.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Serum samples and reagents used should be treated as infectious waste.
The product and its containers should be considered special waste.
Their transport and disposal should be performed by authorized specialized companies according to the law.



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14. TRANSPORT INFORMATION

Even if the mixture is classified as hazardous by the transport regulations (see table below), the exemptions to the classification of ADR Chapter 3.5 - *Dangerous goods packed in excepted quantities* – can be applied.

These goods must be transported by vehicles authorized to the transport of hazardous goods according to the requirements of the current edition of ADR and to the national regulations.

People, responsible for the loading and unloading of this dangerous good must be trained on all the risks deriving from the substance and on procedures to be taken in case of emergency.

ADR/RID:			
UN N°	2796	Class:	8
Classification:	C1	Packaging group:	II
Tunnel restriction code:	(E)		
If subject to the following characteristics is ADR exempt: Exemption for limited quantities: 1L Exemption for expected quantities: <ul style="list-style-type: none">Maximum quantity for the internal package: 30 mlMaximum quantity for the external package: 500 ml			
Sea transport (IMDG Code):			
UN N°	2796	Class:	8
Packaging group:	II	EmS:	F-A, S-B
Marine polluting agent	no		
Air transport (ICAO-IATA):			
Class:	8	Packaging group:	II
Name:	Sulphuric Acid (not containing more than 51% of acid)		
Label:	n.8		

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Classification and labeling is done in accordance with the directives 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:

The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk.

European Standards:1907/2006/EC:

Not applicable

Directive 96/82/EC (Seveso Directive):

Not applicable

15.2 CHEMICAL SAFETY ASSESSMENT

Not performed for the product.



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16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

Text of hazard statements set out in paragraph 3

H314 Causes severe skin burns and eye damage

Text of risk phrases set out in paragraph 3

R35 Causes severe burns.

REFERENCES:

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and technical adjustments
3. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
4. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
5. Commission Regulation (EU) 453/2010
6. ECHA European Chemicals Agency www.echa.europa.eu
7. The Merck Index.
8. Handling Chemical Safety
9. NIOSH - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique

DIESE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not been accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control, the users, under their own responsibility, must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes each previous edition.