SECTION 1. Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product Identifier

Trade Name (As Labeled): Human Pepsinogen II ELISA

Catalog Number: KAPEPKT811

Kit Components:
Streptavidin Coated Microplate
Detecting Antibody
Capture Antibody
Dilution Buffer
Washing Buffer
TMB Substrate Solution
Stop Solution
Calibrators 0-5
Controls 1-2

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use Information: This ELISA (enzyme-linked immunosorbent assay) kit is intended for the quantitative determination of human Pepsinogen II levels in serum. Determination of human serum Pepsinogen II level would be a useful tool in the aid of diagnosing the functional states of acid-secreting gastric mucosa. This kit is for in vitro diagnostic use only.

Product Description: This ELISA is designed, developed and produced for the quantitative measurement of human pepsinogen I level in serum sample. The assay utilizes the two-site "sandwich" technique with two selected monoclonal antibodies that bind to different epitopes of human pepsinogen I without any cross-reaction to human pepsinogen II.

Uses Advised Against No information available.

1.3. Details of the Supplier of the Safety Data Sheet

Manufacturer's Name: DIAsource ImmunoAssays S.A.

Address: Rue du Bosquet,2
B-1348 Louvain-la-Nauve
Belgium

Telephone: + 32 (0) 10/84.99.11

E-mail address: products.support@diasource.be

1.4. Emergency Telephone Number

DIAsource (only office hours): + 32 (0) 10.84.99.11
Centre Anti-Poisons (BE): 070 245 245
Local Anti-Poison Center: Please refer to your local Anti-Poison Center!

SECTION 2. Hazards Identification

2.1. Classification of the Substance or Mixture

Stop Solution
Met. Corr. H290
Detecting Antibody
Skin Sense. (Category 1A), H317
Dilution Buffer
Skin Sense. (Category 1A), H317
Washing Buffer
Skin Sense. (Category 1A), H317
Calibrators and Controls
Skin Sense. (Category 1A), H317

2.2. Label Elements

Emergency Overview:
This Human Pepsinogen II ELISA Kit contains components making up this ELISA kit. This kit contains a Streptavidin Coated Microplate, Detecting Antibody, Capture Antibody, Dilution Buffer, Washing Buffer, TMB Substrate Solution, Stop Solution, Calibrators, and Controls.

Health Hazards:	Possible skin and eye irritant.
Flammability Hazards:	Non-Flammable solution.
Reactivity Hazards:	None Known.
Environmental Hazards:	Not expected to have significant environmental effects.
Emergency Considerations:	Emergency responders must wear the proper personal protective equipments (and have appropriate fire-suppression equipment) suitable for the situation to which they are responding.

Hazard Communication

Hazard Determining Components of Labeling: **Stop Solution (Sulfuric Acid)**
GHS Pictogram:

Signal Words:	Warning
Hazard Statement(s):	**H290:** May be corrosive to metals.
Precautionary Statement Prevention:	**P234:** Keep only in original container.
Precautionary Statement Response:	**P390:** Absorb spillage to prevent material damage.
Precautionary Statement	**P406:** Store in corrosive resistant container with resistant inner liner.

Storage:

Precautionary Statement Disposal Not Applicable.

Hazard Determining Components of Labeling: **Detecting Antibody, Dilution Buffer, Washing Buffer (ProClin™), and Calibrators and Controls**

GHS Pictogram:

Signal Words: Warning

Hazard Statement(s): **H317:** May cause an allergic skin reaction.

Precautionary Statement Prevention:
P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statement Response:
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P321: Specific treatment (See label).
P362+P364: Take off contaminated clothing and wash it before reuse.

Precautionary Statement Storage: N/A.

Precautionary Statement Disposal **P501:** Dispose of contents/container.

Health Hazards or Risk from Exposure:

Prolonged contact with the components in this kit may irritate the skin. Contact with eyes may cause irritation or redness. This product is designed to be used in a laboratory environment.

Acute: Individuals using this product should be wearing the proper personal protective equipment to prevent skin and eye contact.

Chronic: None known.

2.3. Other Hazards – None

SECTION 3. Composition/Information on Ingredients

3.1. Substances

This substance is a mixture.

3.2. Mixtures

Hazard Classification: Stop Solution	CAS #	EINECS #	Amount	EC 1272/2008 Annex VI, Part 3 Classification
Sulfuric Acid	7664-93-9	231-639-5	< 5%	Met. Corr. H290

Hazard Classification: Detecting Antibody	**CAS #**	**EINECS #**	**Amount**	**EC 1272/2008 Annex VI, Part 3 Classification**
ProClin™ 300*	-	-	< 0.3%	
Mixture of 5-Chloro-2-Methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	55965-84-9	613-167-00-5	< 0.06%	Skin Sense. 1A, H317
Hazard Classification: Dilution Buffer	**CAS #**	**EINECS #**	**Amount**	**EC 1272/2008 Annex VI, Part 3 Classification**
ProClin™ 300*	-	-	< 0.3%	
Mixture of 5-Chloro-2-Methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	55965-84-9	613-167-00-5	< 0.06%	Skin Sense. 1A, H317
Hazard Classification: Washing Buffer	**CAS #**	**EINECS #**	**Amount**	**EC 1272/2008 Annex VI, Part 3 Classification**
ProClin™ 300*	-	-	< 0.06%	
Mixture of 5-Chloro-2-Methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	55965-84-9	613-167-005	< 0.06%	Skin Sen. 1A, H317
Hazard Classification: Calibrators and Controls	**CAS #**	**EINECS #**	**Amount**	**EC 1272/2008 Annex VI, Part 3 Classification**
ProClin™ 300*	-	-	< 0.06%	
Mixture of 5-Chloro-2-Methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	55965-84-9	613-167-005	< 0.06%	Skin Sen. 1A, H317
Hazard Classification: Capture Antibody	**CAS #**	**EINECS #**	**Amount**	**EC 1272/2008 Annex VI, Part 3 Classification**
Thimerosal	54-64-8	200-210-4	< 0.006 %	Not hazardous at this concentration.

* ProClin™ 300 is used as a preservative in the listed reagents. The hazardous ingredient in ProClin™ 300 is the reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [ECno. 220-239-6] (3:1).

SECTION 4. First-Aid Measures

4.1. Description of First Aid Measures

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and SDS to a health professional with the contaminated individual.

Eye Contact: If chemical contacts the eye, open victim's eyes while under gentle running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15

minutes. Remove contact lenses, if worn. Seek medical attention is irritation persists.

Skin Contact: Wash contacted area with soap and water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if irritation develops or persists.

Inhalation: Not a normal route of entry; however, if chemical is inhaled, or breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

Ingestion: If chemical is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and SDS with the victim to the health professional.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

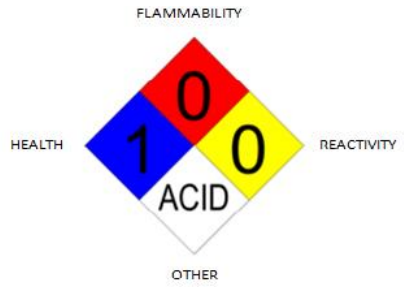
The most important symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

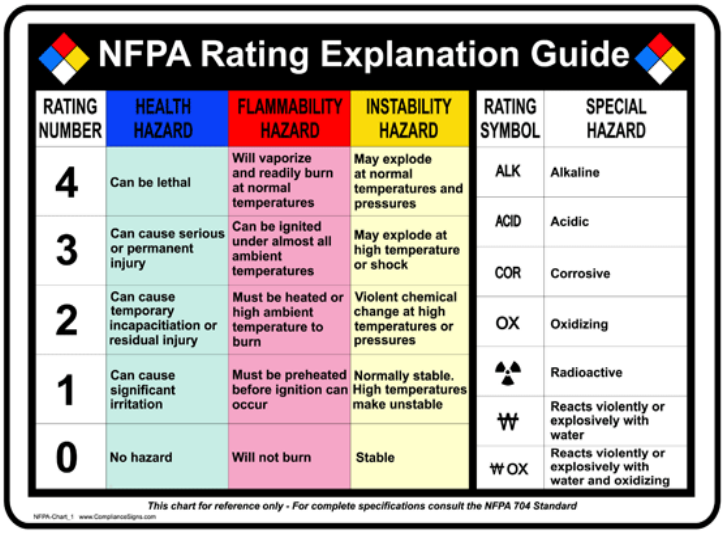
4.3. Indication of any Immediate Medical Attention and Special Treatment Needed

Medical Conditions Aggravated by Exposure: None known.

Recommendations to Physicals: Treat symptoms and eliminate overexposure.

SECTION 5. Firefighting Measures





5.1. Extinguishing Media

Fire Extinguishing Materials: Use extinguishing materials appropriate for surrounding fire.

Unsuitable Extinguishing Media: For this substance/mixture, no limitations of extinguishing agents are given.

5.2. Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosive Hazards:	The product is a water based mixture with no known fire or explosion hazards.
Explosion Sensitivity to Mechanical Impact:	Not sensitive.
Explosion Sensitivity to Static Discharge:	Not sensitive.
Flash Point:	Non-flammable.
Auto-ignition Temperature:	Not applicable.
Flammable Limits (%):	Lower and Upper: Not Applicable.

5.3. Advice for Firefighters

Special Fire-Fighting Procedures:	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or environmentally sensitive areas.

SECTION 6. Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Spill and Leak Response:	Proper protective equipment should be used. Personnel should be trained for spill response operations.
Spills:	Trained personnel following pre-planned procedures should handle non-incidental releases. Absorb spilled materials using polypads or other suitable absorbent material. Place all spill residue in an appropriate container and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, State, and local procedures.

6.2 Environmental Precautions

Prevent further spillage if safe. Clean spillage area thoroughly and dispose of as described in section 6.1.

6.3 Methods and Material for Containment and Cleaning up

Absorb spilled materials using polypads or other suitable absorbent material. Place all spill residue in an appropriate container and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, State, and local procedures.

6.4 Reference to Other Sections

For further information, see section(s) 2,8, 13.

SECTION 7. Handling and Storage

7.1. Precautions for Safe Handling

Work and Hygiene Practices: As with all chemicals, avoid getting this product on you or in you. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing mists or sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

7.2. Conditions for Safe Storage, Including any Incompatibilities

Storage and Handling Practices: Store product in properly labeled, closed containers at temperatures between 2-8°C. Protect from physical damage. Keep containers closed when not in use.

7.3. Specific End Use(s)

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8. Exposure Controls/Personal Protection

8.1. Control Parameters

Ventilation and Engineering Controls: Use with adequate ventilation to ensure exposure levels are maintained below the established limits. Currently, International exposure limits are not established for all components of this product.

Please check with competent authority in each country for the most recent limits in place.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable standards for relevant details.

8.2. Exposure Controls

Respiratory Protection: If exposure limits are exceeded, use only respiratory protection authorized in the US Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent US State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

Eye Protection: Splash goggles or safety glasses with side shields recommended. If necessary, refer to US OSHA29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Hand Protection: Compatible protective gloves recommended. Wash hands after removing gloves. If necessary refer to US OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Body Protection: Use body protection appropriate for task. Coveralls, rubber aprons, or chemical protective clothing made from natural rubber are generally acceptable, depending upon the task. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in US OSHA 29 CFR 1910.139.

SECTION 9. Physical and Chemical Properties

9.1. Information on Basic Physical and Chemical Properties

Vapor Density:	Not Applicable
Specific Gravity @ 20°C:	No data, (water = 1).
Vapor Pressure:	No data @ 20°C.
Physical State:	Liquid.
Density and/or Relative Density:	No data available.
Color:	Clear to yellowish
Odor:	Odorless
Odor Threshold:	Not Applicable
Evaporation Rate (n –BaAC =1):	Not Applicable
Melting Point/Freezing Point:	Not established.
Boiling Point or Initial Boiling Point and Boiling Range:	Not established
Flammability:	Not Flammable
Lower and Upper Explosion Limit:	Not Applicable
Flash Point:	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Kinematic Viscosity:	No data available.
Solubility in Water:	Soluble.
pH:	Not established.
Partition Coefficient n-octanol/water (log value):	Not Applicable.
Particle Characteristics	Not Applicable.

9.2. Other Information – None.

SECTION 10. Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical Stability

Stable under ordinary conditions of use and storage.

10.3. Possibility of Hazardous Reactions

Hazardous depolymerization will not occur.

10.4. Conditions to Avoid

Temperatures above or below the recommended storage range.

10.5. Incompatible Materials

No information available.

10.6. Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

SECTION 11. Toxicology Information

11.1. Information on Hazard Classes as Defined in Regulation (EC) No 1272/2008

Acute Toxicity:	Oral: No data available. Inhalation: No data available. Dermal: No data available.	
Skin Corrosion/Irritation:	No data available. Irritancy of product not known.	
Serious Eye Damage/Irritation:	No data available.	
Respiratory or Skin Sensitization:	No data available. This product is not known to cause human or respiratory sensitization.	
Germ Cell Mutagenicity:	No data available.	
Carcinogenicity:	Suspected Cancer Agent:	The components of this product are not listed by agencies tracking the carcinogenic potential of chemical compounds as follows: NTP Regulated: No IARC Regulated: No OSHA Regulated: No
Reproductive Toxicity:	Listed below is information concerning the effects of this product and its components on the human reproductive system. Mutagenicity: Embryotoxicity:	 The components of this product are not reported to produce mutagenic effects in humans. The components of this product are not reported to produce embryotoxic effects in humans.

	Teratogenicity:	The components of this product are not reported to produce teratogenic effects in humans.
	Reproductive Toxicity:	The components of this product are not reported to produce reproductive effects in humans.

STOT-Single Exposure: No data available.
STOT-Repeated Exposure: No data available.
Aspiration Hazard: No data available.

11.2. Information on Other Hazards

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12. Ecological Information

12.1. Toxicity

No data available.

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

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

12.6. Endocrine Disrupting Properties

No data available.

12.7. Other Adverse Effects

All work practices must be aimed at eliminating environmental contamination.

Environmental Fate: No data available.

SECTION 13. Disposal Considerations

13.1. Waste Treatment Methods

Preparing waste for disposal: Waste disposal must be in accordance with appropriate US Federal, State, and local regulations, those of Canada, Australia, EU Member States, and Japan.

SECTION 14. Transport Information

14.1. UN Number or ID Number

UN Number:	None. This product is not classified as dangerous goods
DOT Classification:	Non-regulated material. This product is not classified as dangerous goods
DOT Labeling Requirements:	None. This product is not classified as dangerous goods
IATA Labeling Requirements:	None. This product is not classified as dangerous goods

14.2. UN Proper Shipping Name

None. This product is not classified as dangerous goods.

14.3. Transport Hazard Class(es)

US Department of Transportation (DOT) Shipping Regulation:	This product is not classified as dangerous goods, per US DOT regulations, under 49 CFR 172.101.
Transport Canada, Transportation of Dangerous Goods Regulation:	This product is not classified as Dangerous Goods, per regulations of Transport Canada.
International Air Transport Association (IATA):	This product is not classified as Dangerous Goods, by rules of IATA.
International Maritime Organization (IMO) Designation:	This product is not classified as Dangerous Goods by the International Maritime Organization.
European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)	This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

14.4. Packing Group

This product is not classified as dangerous goods.

14.5. Environmental Hazards

This product is not classified as dangerous goods.

14.6. Special Precautions for User

This product is not classified as dangerous goods.

14.7. Marinetime Transport in Bulk According to IMO Instruments

This product is not classified as dangerous goods.

SECTION 15. Regulatory Information

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

United States Regulations:

Sara Reporting Requirements:	None.
Marine Pollutant:	This product contains no components listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.
TSCA:	All components in this product mixture are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals or are exempt from listing.
SARA 311/312:	None.
US CERCLA Reportable Quantity (RQ):	None.
US TSCA Inventory Status:	All of the components of this product are listed in the TSCA Inventory or exempt.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65):	This product does not contain any component above the 0.1% level which is listed as a California Proposition 65 chemical. *Note: the chemical identity of some or all components present is confidential business information (trade secret) and is being withheld as permitted by 29 CFR 1910.1200 (i).*

Canadian Regulations:

Canadian DSL/INDSL Inventory Status:	All of the components of this product are on the DSL Inventory or exempt.
Canadian Environmental Protection Act (CEPA) Priorities Substances Lists:	No component of this product is on the CEPA First Priorities Substance Lists.
Canadian Whims Classification and Symbols:	Not regulated.

15.2. Chemical Safety Assessment

Chemical safety assessment not available.

SECTION 16. Other Information

All chemicals may pose unknown hazards and should be used with cautions. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, DIAsource ImmunoAssays S.A. assumes no responsibility for the completeness or accuracy of the information contained herein. Users should consider this data as only a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials, as well as the safety and health of employees, customers, and protection of the environment.

Hazard Statements	Precautionary Statements
H290: May be corrosive to metals. **H317:** May cause an allergic skin reaction.	**P234:** Keep only in original container. **P390:** Absorb spillage to prevent material damage. **P406:** Store in corrosive resistant container with resistant

Refer to Section 2.2. for complete list of hazard statements.

inner liner.
P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P321: Specific treatment (See label).
P362+P364: Take off contaminated clothing and wash it before reuse.
P501: Dispose of contents/container.

Refer to section 2.2 for complete list of precautionary statements.

MSDS established : 2023-09-18
Revision number : 3