

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE Human Anti-Gliadin IgG ELISA kit
	Catalogue#	KAPEPKT831
	Kit components	Gliadin Coated Microplate Detecting Antibody Dilution Buffer Washing Buffer TMB Substrate Solution Stop Solution Calibrators 0-4 Controls 1-2 Specimen Diluent
1.2	Intended Use	In vitro diagnostic use
1.3	Company	DIAsource ImmunoAssays S.A. Rue de l'Industrie, 8 B-1400 Nivelles Belgium
1.4	In emergencies	Call your local emergency centre

2. HAZARDS IDENTIFICATION**Detecting Antibody, Specimen Diluent, Calibrators 0 to 4, Controls 1 and 2**

Animal material is potentially infectious.

3. COMPONENTS AND HAZARDOUS INGREDIENTS

	<u>EINECS nr.</u>	<u>CAS nr.</u>
Detecting Antibody, Specimen Diluent, Calibrators 0 to 4, Controls 1 and 2 Contains material from bovine origin.		
Washing Buffer <i>Proclin 300</i> <0,0015% of the mixture 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one	T,N;R23/24/25-34-43-50/53	55965-84-9
Stop Solution Contains 4,8% sulphuric acid	C; R35	231-639-5 7664-93-9

4. FIRST AID MEASURES**All components**

- After ingestion:*
- Wash out mouth with water provided person is conscious
 - Call a physician immediately
- After inhalation:*
- Do not induce vomiting
 - If inhaled, remove to fresh air.
 - If not breathing, give artificial respiration.
 - If breathing is difficult, give oxygen
- After skin contact:*
- Wash immediately with plenty of water for at least 15 minutes
 - Remove contaminated clothing and shoes
 - Call a physician
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes.
 - Assure adequate flushing by separating the eyelids with fingers.
 - Call a physician

5. FIRE FIGHTING MEASURES**All Kit Components**

- Suitable extinguishing media:*
- Water spray
 - Alcohol-resistant foam
 - Dry chemical powder
 - Carbon dioxide
- Unsuitable extinguishing media:*
- No data available
- Special exposure hazards:*
- No generation of hazardous or toxic gases in dangerous quantities
- Instructions:*
- Prevent contact with skin and eyes
- Special protective equipment for firefighters:*
- In event of fire, wear self-contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES**All Kit Components**

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. HANDLING AND STORAGE**All Kit Components***Handling:*

- Avoid contact with skin and eyes
- Avoid formation of aerosol

Storage:

- Keep container tightly closed in a well ventilated place
- Meet the legal requirements
- Containers which are opened must be carefully resealed and kept in an upright position to prevent leakage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Exposure limits***Sulfuric acid:*

		mg/m ³
Poland	NDS	1
	NDSCh	3
	NDSP	-
Denmark	OEL-TWA	1
Germany	TRGS - OEL	1
Norway	OEL	0.2
Sweden	LLV	1
Switzerland	OEL	1
United Kingdom	OEL	1

8.2 Control of Exposure**8.2.1 Exposure to persons***All Kit Components*

- Respiratory Protection:* - Use respirators
Eye protection: - Chemical Safety goggles
Hand protection: - Protective Gloves
Skin protection: - Protective clothing

8.2.2 Exposure to environment*Active ingredient of ProClin 300*

- Aquatic Classification: Very toxic to aquatic organisms
May cause long-term adverse effects in the aquatic environment
- Ozone Classification: No data available

Sulfuric acid

Aquatic Classification: Not classified

Ozone Classification: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Gliadin Coated Microtiterplate: microtiterplate
Detecting Antibody, Dilution Buffer, Washing Buffer, TMB Substrate Solution, Stop Solution, Calibrators 0-4, Controls 1-2, Specimen Diluent: Liquid

10. STABILITY AND REACTIVITY**Washing Buffer***Storage stability:* stable under recommended storage conditions*Materials to avoid:* strong oxidizing agents, reducing agents, amines, mercaptans*Hazardous decomposition products:* carbon oxides, nitrogen oxides (NO_x), sulphur oxides, hydrogen chloride gas**Stop Solution***Stability:* Stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* Sulfur oxides*Conditions/Materials to avoid:* Protect from moisture and strong oxidizing agents, do not allow water to enter the container and avoid contact with water**Other Kit Components***Stability:* All components are stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities*Conditions/Materials to avoid:* None known**11. TOXICOLOGICAL INFORMATION****Wash Concentrate****Active ingredient of Proclin 300**

Acute toxicity: LD50 Oral – rat – male : 3.600 mg/kg
LD50 Dermal – rabbit – male : > 3.500 mg/kg

Irritation and Corrosion: Skin – rabbit – severe skin irritation
Eyes – rabbit – severe eye irritation

Sensitization: Remarks: causes sensitization

Chronic exposure: Carcinogenicity: no data available

Signs and symptoms of exposure:

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes and skin, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi,

pneumonitis, pulmonary edema, burning sensation, cough, wheezing, laryngitis, shortness of breath, headache, nausea, vomiting, dermatitis. To the best of our knowledge the chemical, physical and toxicological properties have not been thoroughly investigated

Stop solution**Sulphuric acid**

Acute toxicity	LD50 Oral Rat	: 2140 mg/kg
	LC50 Inhalation Rat	:510 mg/ M3/2H

Signs and symptoms of exposure

- Causes burns.
- May be harmful if absorbed through the skin.
- Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
- Toxic if inhaled.
- May be harmful if swallowed.
- Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes and skin.
- Inhalation may result in spasm, inflammation and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.
- Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting.

12. ECOLOGICAL INFORMATION**12.1 Ecotoxicity****Active ingredient in Proclin 300**

Aquatic Classification:	Very toxic to aquatic organisms May cause long-term adverse effects in the aquatic environment
Ozone Classification:	No data available

12.2 Mobility

No information available

12.3 Persistence and degradability

No information available

12.4 Bioaccumulation

Sulfuric acid: The substance is considered as not bioaccumulative: Log Pow = NA
BCF = NA

13. WASTE DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC)

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- Calibrators 0 to 5 and Controls 1 and 2 are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.

14. TRANSPORT INFORMATION

Land transport	ADR/RID regulation
Sea transport	IMDG regulation
Air transport	IATA regulation

15. REGULATORY INFORMATION

Classification according to directives 67/548/EEC, 1999/45/EC.
Not applicable.

16. OTHER INFORMATION

This product is designed for use by professionals.

Risk phrases referred to in paragraph 2&3:

R23/24/25	: Toxic by inhalation, in contact with skin and if swallowed
R34	: Causes burns
R35	: Causes severe burns.
R43	: May cause sensitization by skin contact.
R50/53	: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where DIA has not been reported.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore,



MATERIAL SAFETY DATA SHEET

(According to 91/155/EEC et seq.)

Product Name: DIASOURCE Human Anti-Gliadin IgG ELISA kit

Catalog #: KAPEPKT831

handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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