

KIT**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**

Product Name: FSH ELISA

Catalog #: KAPD1288

Kit Components: Microtiterwells
Calibrators
Enzyme conjugate
Substrate Solution
Stop Solution**1.2 Intended Use**

For In Vitro Diagnostic Use. See product literature for details.

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 OTHER INFORMATION**2.1 Single components with dangerous ingredients:**

According to Regulation (EC) No 1907/2006 (REACH) in combination with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) the products in the following table do not have to be classified as hazardous.

According to Article 31 of Regulation (EC) No 1907/2006 a safety data sheet has to be provided upon request where a mixture does not meet the criteria for classification as hazardous but contains a substance in a concentration of ≥ 1 % posing human health hazards. Therefore the safety data sheet for the single kit component Stop Solution is attached.

The other single components in these products neither contain a substance in a concentration of ≥ 1 % posing human health or environmental hazards; nor a substance in a concentration ≥ 0.1 % that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitizer category 1, respiratory sensitizer category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)

Therefore a safety data sheet for the other single components in the kit is not required for these products.

2.2 General Precautions:

- The products are for professional laboratory use only.
- Users should have a thorough understanding of the Instructions for Use prior to their use of this kit.
- Good Laboratory Practices (GLP) should be followed to ensure the safe use and disposal of the reagents.
- Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling reagents

2.3 Other information

Microplate : Each well can only be used once



STOP SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Stop Solution

Catalog #: Component of KAPD1288

1.2 Intended Use

Reagent for in vitro laboratory use. For professional use only.

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
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2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. However a safety data sheet is being supplied for it upon request as the component contain a substance which presents a health hazard within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements

No labelling required.

Hazard pictogram(s): None

Signal word(s): None

Hazard statement(s): None

Precautionary statement(s): None

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No. (EC No.) [Index No.]	Concentration in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)	
			Hazard class/ Hazard categories	Hazard statement
Kit component: <i>Stop Solution</i>				
sulphuric acid ... %	7664-93-9 (231-639-5) [016-020-00-8]	< 5.0 %	Skin Corr. 1A	H314

Full text of H-phrases: see section 16

4 FIRST AID MEASURES

4.1 Description of first aid measures

General information

If symptoms persist or in case of doubt, seek medical advice.

Inhalation

Supply fresh air; consult doctor in case of complaints.

Skin Contact

Remove contaminated clothes and shoes.

Clean with water and soap. If possible, also wash with polyethylene glycol 400.

Cover wound with a sterile dressing.

If skin irritation continues, consult a doctor.

Eye Contact

Protect unharmed eye.

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

Ingestion

Rinse mouth with water.

Spit liquid out again.

Drink lots of water and provide fresh air. Call a doctor immediately.

Never give anything by mouth to an unconscious person

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

The product is not combustible and does not support any combustion.

Use fire fighting measures suiting the environment.

For safety reasons unsuitable extinguishing agents:

No data available

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Sulphur oxides (SO_x)

Poisonous gases/vapours

5.3 Additional information

Protective equipment: Wear self-contained respiratory protective device.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Wear protective clothing.

Avoid any product contact.

6.2 Environmental Precautions

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

6.3 Methods and material for containment and cleaning-up

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

Rinse residues with water.

Make sure to recycle or dispose of in suitable receptacles.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with eyes and skin.

Keep the working area dry and clean.

Information about protection against explosions and fires: Observe the general rules of industrial fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

Store container tightly sealed at a cool and dry place with sufficient ventilation.

Information about storage in one common storage facility:

Store away from foodstuffs.

Refer to national regulations for storing hazardous chemicals.

Further information about storage conditions:

Store as directed in the relevant instruction for use.

7.3 Specific Use(s)

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Following information is available for the substance listed in section 3.2

Substance : Sulphuric acid					
CAS N°: 7664-93-9					
	Limit value – Eight hours		Limit value – Short term		
Country	ppm	mg/m³	ppm	mg/m³	Legal basis
European Union		0.05 Thoracic fraction			Directive 2009/161/EU
Germany (AGS)		0.1 Inhalable aerosol		0.1 Inhalable aerosol (1)	TRGS 900
Germany (DFG)		0.1		0.1 Inhalable aerosol (1) (2)	
Italy		0.05			
Spain		1		3	
USA - NIOSH		1			
USA - OSHA		1			

Remarks:

Germany (AGS): (1) 15 minutes average value

Germany (DFG): (1) 15 minutes average value (2) a momentary value of 0.2 mg/m³ should not be exceeded

Source: Based on GESTIS International Limit values Database, 2016-12

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures should be adhered to when handling chemicals.

Provide eye bath and emergency shower.

Respiratory Protection:

Not required under normal use.

Hand Protection:

Protective gloves complying with EN 374 (nitrile rubber, Latex gloves).

The glove material has to be impermeable and resistant to the product/substance/preparation.

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.

Eye Protection:

Safety glasses

Skin Protection:

Protective work clothing, lab coat

9 PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties

(Appearance: Form Colour)	liquid colourless
Odour	odourless
Odour threshold	Not determined
pH	1.0
Melting point/freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not determined
Flammability (solid, gas)	Not applicable
Ignition temperature: Decomposition temperature:	Not determined
Self ignition temperature:	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits: Lower: Upper:	Not applicable Not applicable
Oxidizing properties:	No data available
Vapour pressure:	Not determined
Density:	Not determined
Relative density:	Not determined
Vapour density:	Not determined
Evaporation rate:	Not determined
Solubility in / Miscibility with Water:	Fully miscible
Partition coefficient (n-octanol/water):	Not determined
Viscosity:	Not determined

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

Thermal decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions

Corrosive effect on metals.

10.4 Conditions to Avoid

Heat.

10.5 Incompatible materials

Metals.

10.6 Hazardous Decomposition Products

No hazardous decomposition products if instructions for storage and handling are followed.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

LD/LC 50 values that are relevant for classification:

7664-93-9 sulphuric acid

Oral LD50 2140 mg/kg (rat)

Inhalative LC50/4 h 0.375 mg/L (rat)

(aerosol)

Although the LC50 values from the inhalation toxicity study theoretically trigger Classification with 'Toxic by inhalation', classification is not proposed. The effects of sulphuric acid following inhalation are entirely due to local irritation of the respiratory tract: there is no evidence for the systemic toxicity of sulphuric acid in any study as effects are limited to the site of contact. Classification for acute inhalation toxicity is not considered to be appropriate.

Skin corrosion/irritation

May cause irritation to the skin.

Serious eye damage/irritation

May cause irritation to the eyes.

Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

Additional toxicological information:

After swallowing: irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

No data available

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

7664-93-9 sulphuric acid

EC50/48h (static) > 100 mg/l (Daphnia magna) (OECD Guideline 202)

LC50/72h (static) > 100 mg/l (Desmodemus subspicatus) (OECD Guideline 201)

LC50/96h (static) > 16 < 28 mg/l (Lepomis macrochirus)

12.2 Persistence and degradability

No further relevant information available

12.3 Bioaccumulation

No further relevant information available

12.4 Mobility in soil

No further relevant information available

12.5 Results of PBT and vPvB assessment

Not applicable

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation:

Must be recycled or disposed of according to the regulations. Waste has to be classified according to the European Waste

Catalogue based on the identification of the waste generating source.

Smaller quantities can be disposed of with household waste.

European waste catalogue :

16 00 00 WASTES NOT OTHERWISE SPECIFIED IN THE LIST

16 05 00 gases in pressure containers and discarded chemicals

16 05 06* laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals

15 00 00 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED

15 01 00 packaging (including separately collected municipal packaging waste)

15 01 02 plastic packaging

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations.

Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

Recommended cleansing agent: Water; if necessary, with cleansing agents

14 TRANSPORT INFORMATION

UN No.	ADR, ADN, IMDG, IATA	Void
UN Proper shipping name	ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	ADR, ADN, IMDG, IATA	Void
Packing group	ADR, IMDG, IATA	Void
Environmental hazards	Not applicable	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.	

15 REGULATORY INFORMATION

This Safety Data Sheet is according to Commission Regulation (EU) 2015/830 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.1 Safety, health and environmental regulation/legislation specific for the substance or mixtureDirective 2012/18/EU

Named dangerous substances - ANNEX I Not listed.

National regulations

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water

Further information: None of the ingredients is listed.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

16 OTHER INFORMATION**"H code" used in this safety data sheet**

As mentioned in section 3 of the safety data sheet (not relevant for labelling of the product)

H314 : Causes severe skin burns and eye damage.

Abbreviations

AGS Ausschuss für Gefahrstoffe

DFG Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission)

LC50 Lethal concentration, 50 percent

LD50 Lethal dose, 50 percent

NIOSH National Institute for Occupational Safety and Health of USA

OSHA Occupational Safety and Health Administration of USA

TRGS Technische Regeln für Gefahrstoffe

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association



MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product Name: FSH ELISA

Catalog #: KAPD1288

Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2020-01-14

Revision number : 2