# KIT

## 1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

### 1.1 Product identifier

| | |
|---|---|
| Product Name: | FSH ELISA |
| Catalog #: | KAPD1288 |
| Kit Components: | Microtiterwells<br>Calibrators<br>Enzyme conjugate<br>Substrate Solution<br>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: products.support@diasource.be

### 1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11
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 31of 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
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: products.support@diasource.be

### 1.4 Emergency telephone

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Please refer to your local Anti-Poison Center!

## 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:** *Stop Solution* | | | | |
| 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 (SOx)
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<br>**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<br>Thoracic fraction | | | Directive 2009/161/EU |
| Germany (AGS) | | 0.1<br>Inhalable aerosol | | 0.1<br>Inhalable aerosol (1) | TRGS 900 |
| Germany (DFG) | | 0.1 | | 0.1<br>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<br>Colour | liquid<br>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:<br>Decomposition temperature: | <br>Not determined |
| Self ingnition temperature: | Product is not self-igniting. |
| Danger of explosion: | Product does not present an explosion hazard. |
| Explosion limits:<br>Lower:<br>Upper: | <br>Not applicable<br>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<br>Water: | <br>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 (aerosol) | LC50/4 h | 0.375 mg/L (rat) |

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 (Desmodesmus 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 ofMARPOL73/78 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 mixture

Directive 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

**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** : 2023-03-14
**Revision number** : 3