

**Safety Data Sheet/Material Safety Data Sheet
ELISA Kits**

**(Complies with the requirements of regulation (EC) no.
1907/2006 (REACH), annex II)**

Version No. 1

**1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY/
UNDERTAKING**

1.1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

PRODUCT NAME: ELISA Kits

COMPONENTS
Microtiter strips
Calibrators/Standards/Controls
Enzyme conjugate
Washing buffer Concentrate
Sample diluent
Substrate
Stop solution

1.2. USE OF THE SUBSTANCE/PREPARATION

Enzyme immunoassay based on microtiter plate for the detection and quantitative determination of human antibodies against infectious agents in serum or plasma; in-vitro diagnostic

1.3. COMPANY / UNDERTAKING IDENTIFICATION

Details of the supplier of the safety data sheet

| | |
|---------------|---|
| Name | Alpha Diagnostic Intl Inc. |
| Address | 6203 Woodlake Ctr. San Antonio, TX 78244 |
| Telephone | 210-561-9515 (Monday to Friday, 9AM to 5PM EST) |
| Fax | 210-561-9544 |
| Contact email | service@4adi.com |

1.4. EMERGENCY TELEPHONE

In the event of a medical emergency, please dial 911.

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2. HAZARDS IDENTIFICATION

The components of the preparation are classified according to directive 1999/45/EC as follows:

| | | |
|------------------------|----------------------------|-------------------|
| CLASSIFICATION: | Microtiter strips | Not classified |
| | Calibrators | Not classified |
| | Enzyme conjugate | Not classified |
| | Washing buffer Concentrate | Not classified |
| | Sample diluent | Not classified |
| | Substrate | Not classified |
| | Stop solution | Corrosive, C, R34 |
| HEALTH HAZARDS: | Microtiter strips | Not applicable |
| | Calibrators | Not applicable |
| | Enzyme conjugate | Not applicable |
| | Washing buffer Concentrate | Not applicable |
| | Sample diluent | Not applicable |
| | Substrate | Not applicable |
| | Stop solution | Causes burns |

For detailed information to health effects and symptoms see section 11.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | |
|-------------------------------|----------------------------|--|
| SUBSTANCE / COMPONENT: | Microtiter strips | Commodity |
| | Calibrators | Preparation |
| | Enzyme conjugate | Preparation |
| | Washing buffer Concentrate | Preparation |
| | Sample diluent | Preparation |
| | Substrate | Preparation |
| | Stop solution | Sulfuric acid (H ₂ SO ₄), 0.5 M |

| Hazardous substance | Concentration | CAS No. | EC No. | Classification |
|---------------------|---------------|-----------|-----------|----------------|
| Sulfuric acid | 1-5% | 7664-93-9 | 231-639-5 | C, R35 |

See section 16 for the detailed text of the above stated r-phrases.

There are no ingredients contained in the preparation which are classified as harmful or polluting in the contained concentrations according to the actual state of knowledge of the manufacturer. The product is not hazardous in the sense of the directive 67/548/EC.

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4. FIRST AID MEASURES

| | | |
|-----------------------------------|--|--|
| INHALATION: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | Move person into fresh air. If not breathing give artificial respiration. In case of severe disturbance consult a physician. |
| INGESTION: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | |
| SKIN CONTACT: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | |
| EYE CONTACT: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | |
| PROTECTION OF FIRST AIDER: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Do not take any actions which are connected to any personal risk or which were not adequately trained. If vapors are suspected, wear appropriate air-purifying respirator. For first-aid providing persons there exists a possible risk due to mouth-to-mouth resuscitation. Remove contaminated clothing. Wear protective gloves. |
| ADVICE FOR PHYSICIANS: | No special treatment. Treat symptomatically. In the case of ingestion or inhalation of larger amounts consult toxicologist. | |
| SPECIAL TREATMENT: | No data available. | |

For detailed information to health impacts and symptoms see section 11.

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5. FIRE-FIGHTING MEASURES

NOT SUITABLE EXTINGUISHING

| | | |
|---------------|----------------------------|-----------------------|
| MEDIA: | Microtiter strips | Not applicable |
| | Calibrators | Not applicable |
| | Enzyme conjugate | Not applicable |
| | Washing buffer Concentrate | Not applicable |
| | Sample diluent | Not applicable |
| | Substrate | Not applicable |
| | Stop solution | Do not use water jet. |

SUITABLE EXTINGUISHING MEDIA: Consider adjacent fires when choosing the extinguishing medium.

DANGEROUS COMBUSTION

PRODUCTS: No data available.

SPECIAL PROTECTIVE

EQUIPMENT FOR FIRE-FIGHTERS: Wear appropriate personal protective equipment. Wear pressure operated full-face respirator.

6. ACCIDENTAL RELEASE MEASURES

| | | |
|-----------------------------------|--|---|
| PERSONAL PRECAUTIONS: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } Do not take any actions which are connected to any personal risk or which were not adequately trained. Evacuate surrounding. Prohibit access for not protected persons. Do not touch or tread spilled substance. Avoid inhalation of vapors or mist. Care for sufficient ventilation. If ventilation is insufficient, wear respirator. Wear adequate personal protective equipment (see section 8). |
| ENVIRONMENTAL PRECAUTIONS: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | |
| METHODS FOR CLEANING: | Microtiter strips | } Sweep material and dispose in an appropriate labeled container. Dispose via an approved waste disposal company. |
| | Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } Eliminate leakage. Remove container from contaminated area. Swab with a cloth or adsorb with an inert dry material and dispose in an appropriate labeled container. Dispose via an approved waste disposal company. |

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7. HANDLING AND STORAGE

| | | | |
|----------------------|---|---|--|
| HANDLING: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } | After handling wash hands thoroughly. Do not ingest. Avoid contact with eyes, skin or clothes. Use only with sufficient ventilation. Do not inhale vapor or mist. After handling wash hands thoroughly. |
| STORAGE: | Store at 2-8°C. Protect from direct sun light. Store only in original containers. Do not store together with food. Keep containers closed until usage. After usage close opened containers again tightly. Do not store in unlabeled containers. Consider local regulations. | | |
| SPECIFIC USE: | According to the intended use of the instruction manual for the determination of antibodies against infectious agents. Do not use reagents for other purposes. | | |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. EXPOSURE LIMIT VALUES

| | |
|----------------------------|----------------|
| Microtiter strips | Not applicable |
| Calibrators | Not applicable |
| Enzyme conjugate | Not applicable |
| Washing buffer Concentrate | Not applicable |
| Sample diluent | Not applicable |
| Substrate | Not applicable |
| Stop solution | See table |

| | |
|-------------------------------|---|
| Substance | Sulfuric acid |
| Type of exposure limit | Threshold limit value (Germany 2009) |
| Exposure limit | 0.1 mg/m ³ determined as respirable aerosol fraction |
| Momentary value | 0.2 mg/m ³ determined as respirable aerosol fraction |
| Maximum exposure limit | exceeding factor 1, 15 min (mean), 4x/shift, 1 hour interval |

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8.2. EXPOSURE CONTROLS

**LIMITATION OF EXPOSURE IN
THE WORKING ENVIRONMENT:**

No special ventilation procedures. Common ventilation should be sufficient to limit exposure of the employees towards air pollutants. Optionally use process chambers, local exhaust fans or other technical equipment to keep exposition under recommended or mandatory limits.

HYGIENIC MEASURES:

After handling of chemical products as well as before eating, smoking or visit of a lavatory wash hands, forearms and optionally face thoroughly. Wash contaminated clothes before re-use. Ensure that close to the work environment eye wash stations and safety showers are available.

RESPIRATORY PROTECTION:

While handling according to the intended use no respiratory protection is necessary.

HAND PROTECTION:

Wear chemical resistant impenetrable gloves according to the specifications of directive 89/686/EC and the resulting standard EN 374. Time of penetration of the glove material: permeation level ≥ 6 .

EYE PROTECTION:

To avoid exposition against liquid spills, mist, gases or dust wear safety goggles with side protection according to the specifications of directive 89/686/EC and the resulting standard EN166.

BODY PROTECTION:

Wear closed lab coat.

**MONITORING OF EXPOSURE IN
THE WORKING ENVIRONMENT:**

For methods of monitoring the respiratory exposition against chemical substances see the European standard EN 689.

**LIMITATION AND MONITORING OF
ENVIRONMENTAL EXPOSURE:**

Monitor the emission of ventilation and process equipment for ensuring the compliance with the requirements of environment protection laws. In case of exceeding threshold values install exhaust air washers, filters or other appropriate technical equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. GENERAL INFORMATION

| | | |
|----------------------------|----------------------------|-------------------|
| PHYSICAL STATE: | Microtiter strips | plastic plate |
| | Calibrators | liquid |
| | Enzyme conjugate | liquid |
| | Washing buffer Concentrate | liquid |
| | Sample diluent | liquid |
| | Substrate | liquid |
| | Stop solution | liquid |
| | COLOR: | Microtiter strips |
| Calibrators | | blue |
| Enzyme conjugate | | red |
| Washing buffer Concentrate | | clear |
| Sample diluent | | blue |
| Substrate | | clear |

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9.2. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

| | | |
|---------------------------|---|---|
| PH: | Microtiter strips | Not applicable |
| | Calibrators | 6-8 |
| | Enzyme conjugate | 6-8 |
| | Washing buffer Concentrate | 6-8 |
| | Sample diluent | 6-8 |
| | Substrate | 3-4 |
| | Stop solution | <1 |
| BOILING POINT: | Microtiter strips | Not applicable |
| | Calibrators | } Lowest known value (water): 100°C/212°F |
| | Enzyme conjugate | |
| | Washing buffer Concentrate | |
| | Sample diluent | |
| | Substrate | |
| | Stop solution | |
| MELTING POINT: | Microtiter strips | Not applicable |
| | Calibrators | } May melt at 0°C/32°F This specification is based on the ingredient water. |
| | Enzyme conjugate | |
| | Washing buffer Concentrate | |
| | Sample diluent | |
| | Substrate | |
| | Stop solution | |
| SOLUBILITY: | Microtiter strips | Not applicable |
| | Calibrators | } Complete solubility in cold and hot water. |
| | Enzyme conjugate | |
| | Washing buffer Concentrate | |
| | Sample diluent | |
| | Substrate | |
| | Stop solution | |
| VAPOR PRESSURE: | Microtiter strips | Not applicable |
| | Calibrators | } 23.4 mbar at 20°C/68°F This specification is based on the ingredient water. |
| | Enzyme conjugate | |
| | Washing buffer Concentrate | |
| | Sample diluent | |
| | Substrate | |
| | Stop solution | |
| NO AVAILABLE DATA: | To flash point, explosion limits, ignition temperatures, viscosity, oxidizing properties, density, partition coefficient (octanol/water). | |

10. STABILITY AND REACTIVITY

10.1. CONDITIONS TO AVOID

Microtiter strips
Calibrators
Enzyme conjugate
Washing buffer Concentrate
Sample diluent
Substrate
Stop solution

Components of the product are stable.
Under the specified storage conditions
no degradation or polymerization will
occur.

Thermal stress.

10.2. MATERIALS TO AVOID

Microtiter strips
Calibrators
Enzyme conjugate
Washing buffer Concentrate
Sample diluent
Substrate
Stop solution

When handled according to the intended
use no hazardous reactions are to be
expected.

Strong bases.

10.3. DANGEROUS DECOMPOSITION PRODUCTS

Under the specified storage and handling conditions no dangerous decomposition products are formed. In the case of fire, dangerous decomposition products (carbon oxides, nitric oxides, sulfuric oxides) may occur.

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11. TOXICOLOGICAL INFORMATION

| | | |
|----------------------|--|---|
| INHALATION: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } No health effects known. } May cause irritation of the respiratory system. |
| INGESTION: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } No health effects known. } May cause irritations in mouth or throat. |
| SKIN CONTACT: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } No health effects known. } May cause irritation of the skin. |
| EYE CONTACT: | Microtiter strips Calibrators Enzyme conjugate Washing buffer Concentrate Sample diluent Substrate Stop solution | } No health effects known. } May cause irritation of the eyes. |

The following information is based on sulfuric acid as ingredient of the stop solution:

| | |
|----------------|-------------------------------|
| LD50: | 2140 mg/kg (rat) |
| Sensitization: | No sensitizing effects known. |

Further information of the components to chronic toxicity, carcinogenicity, mutagenicity, teratogenicity or reproductive toxicity is not available.

12. ECOLOGICAL INFORMATION

The following information is based on sulfuric acid as ingredient of the stop solution. For all other components no data are available.

AQUATIC TOXICITY: Harmful effects on water organisms due to pH shift. Quantitative data to the ecological effects of the product are not available.

WATER HAZARD CLASS: WGK 1 (according to annex 2 of the German administrative rule for substances harmful to water): weakly harmful to water.

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13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: Consider all national environmental protection requirements and waste disposal laws as well as local rules. Avoid spreading of spilled material through contact with soil, water courses, drains or canalization.

HAZARDOUS WASTE: According to our current knowledge no hazardous waste in the sense of the European directive 91/689/EC.

14. TRANSPORT INFORMATION

This product is not subject to the rules of the following traffic systems:

Street traffic: ADR (directive 94/55/EC)
 Rail traffic: RID (directive 96/49/EC)
 Sea traffic: IMDG
 Air traffic: ICAO/IATA

15. REGULATORY INFORMATION

**IDENTIFICATION ACCORDING TO
EUROPEAN DIRECTIVES:**

The classification and identification was performed according to the European directives 67/548/EC and 1999/45/EC (including amendments) and consider the intended use of the product. A Chemical Safety Assessment was not conducted for substances included in this preparation.

R-PHRASES:

| | | |
|----------------------------|------|--|
| Microtiter strips | } to | This product is not classified according to European laws. |
| Calibrators | | |
| Enzyme conjugate | | |
| Washing buffer Concentrate | | |
| Sample diluent | | |
| Substrate | | |
| Stop solution | | |
| | | R34: Causes burns. |

S-PHRASES:

| | | |
|----------------------------|-----|--|
| Microtiter strips | } S | 36: Wear suitable protective clothing. |
| Calibrators | | |
| Enzyme conjugate | | |
| Washing buffer Concentrate | | |
| Sample diluent | | |
| Substrate | | |
| Stop solution | | |
| | | S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible). |

EUROPEAN INVENTORY:

Sulfuric acid as ingredient of the stop solution not listed.

NATIONAL RULES:

German administrative rule for substances harmful to water (VwVwS):
 WGK 1 (according to annex 2): weakly harmful to water.
 German regulation for industrial safety (BetrSichV): no classification.

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16. OTHER INFORMATION

**COMPLETE TEXT OF THE
R-PHRASES ACCORDING TO
SECTION 2 AND 3:**

| | | |
|----------------------------|---|---------------------------|
| Microtiter strips | } | Not applicable. |
| Calibrators | | |
| Enzyme conjugate | | |
| Washing buffer Concentrate | | |
| Sample diluent | | |
| Substrate | | |
| Stop solution | | |
| | | R34: Causes burns. |
| | | R35: causes severe burns. |

DOCUMENT HISTORY:

Version 1: 2016-11-07 (creation and release)

HINT:

The information is based on our present knowledge, but is not a guaranty of special product properties and establishes no legal relationship.