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

1.1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

PRODUCT NAME: Enzyme immunoassays (various) for the determination of human antibodies against infectious agents

COMPONENTS: Microtiter strips
Calibrators
Enzyme conjugate
Washing buffer (10x 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

COMPANY: Immunolab GmbH
Otto-Hahn-Str. 16
34123 Kassel
Germany
Tel.: +561 4917420-0

EMAIL ADDRESS OF THE RELEVANT OFFICIAL ADVISORY BODY: DRS@immunolab.de

1.4. EMERGENCY TELEPHONE

For queries please contact telephone number +561 491742-0 (technical service, business hours 8 a.m. to 4:30 p.m.) or the emergency center for intoxication in Munich (Tel.: +89 19240) or any other adequate institution.

2. HAZARDS IDENTIFICATION

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

CLASSIFICATION:

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microtiter strips</td>
<td>Not classified</td>
</tr>
<tr>
<td>Calibrators</td>
<td>Not classified</td>
</tr>
<tr>
<td>Enzyme conjugate</td>
<td>Not classified</td>
</tr>
<tr>
<td>Washing buffer (10x concentrate)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sample diluent</td>
<td>Not classified</td>
</tr>
<tr>
<td>Substrate</td>
<td>Not classified</td>
</tr>
</tbody>
</table>
Material Safety Data Sheet

ELISA Kits – Infectious Diseases

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

Version No. 1

Date of creation/revision: 2009-12-23

MSDS IFS-01_en Seite 2/10

Stop solution Corrosive, C, R34

HEALTH HAZARDS:

Microtiter strips Not applicable
Calibrators Not applicable
Enzyme conjugate Not applicable
Washing buffer (10x 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

<table>
<thead>
<tr>
<th>SUBSTANCE / COMPONENT:</th>
<th>Microtiter strips</th>
<th>Commodity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrators</td>
<td>Preparation</td>
<td></td>
</tr>
<tr>
<td>Enzyme conjugate</td>
<td>Preparation</td>
<td></td>
</tr>
<tr>
<td>Washing buffer (10x concentrate)</td>
<td>Preparation</td>
<td></td>
</tr>
<tr>
<td>Sample diluent</td>
<td>Preparation</td>
<td></td>
</tr>
<tr>
<td>Substrate</td>
<td>Preparation</td>
<td></td>
</tr>
<tr>
<td>Stop solution</td>
<td>Sulfuric acid (H₂SO₄), 0.5 M</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous substance</th>
<th>Concentration</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>1-5%</td>
<td>7664-93-9</td>
<td>231-639-5</td>
<td>C, R35</td>
</tr>
</tbody>
</table>

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.

4. FIRST AID MEASURES

INHALATION:

Microtiter strips
Calibrators
Enzyme conjugate
Washing buffer (10x 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 (10x concentrate)
Sample diluent
Substrate
Stop solution

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. In case of severe disturbance consult a physician.
# Material Safety Data Sheet

**ELISA Kits – Infectious Diseases**

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

**Version No. 1**

## SKIN CONTACT:
- **Microtiter strips**
- **Calibrators**
- **Enzyme conjugate**
- **Washing buffer (10x concentrate)**
- **Sample diluent**
- **Substrate**
- **Stop solution**

Rinse skin with plenty of water. Remove contaminated clothes and protective gloves. Wash clothes thoroughly before reuse. Clean shoes. In case of severe disturbance consult a physician.

## EYE CONTACT:
- **Microtiter strips**
- **Calibrators**
- **Enzyme conjugate**
- **Washing buffer (10x concentrate)**
- **Sample diluent**
- **Substrate**
- **Stop solution**

Rinse thoroughly with plenty of water for at least 15 minutes. In case of severe disturbance consult a physician.

## PROTECTION OF FIRST AIDER:
- **Microtiter strips** Not applicable
- **Calibrators** Not applicable
- **Enzyme conjugate** Not applicable
- **Washing buffer (10x concentrate)** Not applicable
- **Sample diluent** Not applicable
- **Substrate** Not applicable
- **Stop solution** 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.

## 5. FIRE-FIGHTING MEASURES

### NOT SUITABLE EXTINGUISHING MEDIA:
- **Microtiter strips** Not applicable
- **Calibrators** Not applicable
- **Enzyme conjugate** Not applicable
- **Washing buffer (10x 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.
6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x 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 (10x concentrate)
- Sample diluent
- Substrate
- Stop solution

Avoid spreading and drain-off of spilled material as well as contact with soil, watercourses, drains or canalization. Contact responsible department, if environmental contaminations were caused (drains, watercourses, soil or air).

METHODS FOR CLEANING:

- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x concentrate)
- Sample diluent
- Substrate
- Stop solution

Sweep material and dispose in an appropriate labeled container. Dispose via an approved waste disposal company.

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.

7. HANDLING AND STORAGE

HANDLING:

- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x 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.
Material Safety Data Sheet
ELISA Kits – Infectious Diseases

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

Version No. 1

Date of creation/revision: 2009-12-23

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Type of exposure limit</th>
<th>Exposure limit</th>
<th>Momentary value</th>
<th>Maximum exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microtitre strips</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calibrators</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enzyme conjugate</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing buffer (10x concentrate)</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample diluent</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substrate</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop solution</td>
<td>See table</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>Threshold limit value (Germany 2009)</td>
<td>0.1 mg/m³ determined as respirable aerosol fraction</td>
<td>0.2 mg/m³ determined as respirable aerosol fraction</td>
<td>excessing factor 1, 15 min (mean), 4x/shift, 1 hour interval</td>
</tr>
</tbody>
</table>

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. GENERAL INFORMATION

PHYSICAL STATE:
- Microtiter strips: plastic plate
- Calibrators: liquid
- Enzyme conjugate: liquid
- Washing buffer (10x concentrate): liquid
- Sample diluent: liquid
- Substrate: liquid
- Stop solution: liquid

COLOR:
- Microtiter strips: white/clear
- Calibrators: blue
- Enzyme conjugate: red
- Washing buffer (10x concentrate): clear
- Sample diluent: blue
- Substrate: clear
- Stop solution: clear

9.2. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

PH: Microtiter strips: Not applicable
- Calibrators: 6-8
- Enzyme conjugate: 6-8
- Washing buffer (10x concentrate): 6-8
- Sample diluent: 6-8
- Substrate: 3-4
- Stop solution: <1

BOILING POINT:
- Microtiter strips: Not applicable
- Calibrators
- Enzyme conjugate
- Washing buffer (10x concentrate): Lowest known value (water): 100°C/212°F
- Sample diluent
- Substrate
- Stop solution
### Melting Point:
- **Microtiter strips**: Not applicable
- **Calibrators**
- **Enzyme conjugate**
- **Washing buffer (10x concentrate)**: May melt at 0°C/32°F
- **Sample diluent**
- **Substrate**
- **Stop solution**

### Solubility:
- **Microtiter strips**: Not applicable
- **Calibrators**
- **Enzyme conjugate**
- **Washing buffer (10x concentrate)**: Complete solubility in cold and hot water.
- **Sample diluent**
- **Substrate**
- **Stop solution**

### Vapor Pressure:
- **Microtiter strips**: Not applicable
- **Calibrators**
- **Enzyme conjugate**
- **Washing buffer (10x concentrate)**: 23.4 mbar at 20°C/68°F
- **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 (10x 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 (10x 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.
11. TOXICOLOGICAL INFORMATION

INHALATION:
- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x 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 (10x 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 (10x 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 (10x 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.
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
- Calibrators
- Enzyme conjugate
- Washing buffer (10x concentrate)
- Sample diluent
- Substrate
- Stop solution

This product is not classified according to European laws.

R34: Causes burns.

**S-PHRASES:**
- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x concentrate)
- Sample diluent
- Substrate
- Stop solution

S 36: Wear suitable protective clothing.

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).
16. OTHER INFORMATION

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

- Microtiter strips
- Calibrators
- Enzyme conjugate
- Washing buffer (10x concentrate)
- Sample diluent
- Substrate
- Stop solution

Not applicable.
R34: Causes burns.
R35: Causes severe burns.

DOCUMENT HISTORY:
Version 1: 2009-12-23 (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.