

Material Safety Data Sheet
ELISA Kits
– Food Intolerance (1) –
(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: Enzyme immunoassays (various) for the determination of human IgG and/or IgG₄ antibodies against food and other antigens

CATALOGUE NUMBER: ILE-SCGxx (various)

COMPONENTS: Microtiter strips
Calibrators/Controls
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 IgG and/or IgG₄ antibodies against food and other antigens in serum or plasma; in-vitro diagnostic

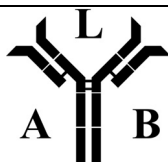
1.3. COMPANY / UNDERTAKING IDENTIFICATION

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.



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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/Controls	Not classified
	Enzyme conjugate	Not classified
	Washing buffer (10x concentrate)	Not classified
	Sample diluent	Not classified
	Substrate	Irritant, Xi, R36/38
	Stop solution	Corrosive, C, R34
HEALTH HAZARDS:	Microtiter strips	Not applicable
	Calibrators/Controls	Not applicable
	Enzyme conjugate	Not applicable
	Washing buffer (10x concentrate)	Not applicable
	Sample diluent	Not applicable
	Substrate	Causes Irritations
	Stop solution	Causes burns

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

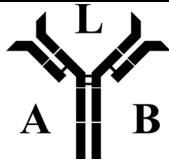
3. COMPOSITION / INFORMATION ON INGREDIENTS

SUBSTANCE / COMPONENT:	Microtiter strips	Commodity
	Calibrators/Controls	Preparation
	Enzyme conjugate	Preparation
	Washing buffer (10x concentrate)	Preparation
	Sample diluent	Preparation
	Substrate	Preparation; contains Trizma Base
	Stop solution	Sodium hydroxide solution (NaOH), 1 M

Hazardous substance	Concentration	CAS No.	EC No.	Classification
Trizma Base	6%	77-86-1	201-064-4	Xi; R36/38
Sodium hydroxide solution	2-5%	1310-73-2	215-185-5	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.

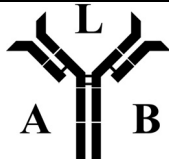


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4. FIRST AID MEASURES

INHALATION:	Microtiter strips Calibrators/Controls 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/Controls 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.
SKIN CONTACT:	Microtiter strips Calibrators/Controls 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/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} Rinse thoroughly with plenty of water for at least 15 minutes. Remove contact lenses. In case of severe disturbance consult a physician.
PROTECTION OF FIRST AIDER:	Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} 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.



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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/Controls	Not applicable
	Enzyme conjugate	Not applicable
	Washing buffer (10x concentrate)	Not applicable
	Sample diluent	Not applicable
	Substrate	Not applicable
	Stop solution	Not applicable

SUITABLE EXTINGUISHING MEDIA: Water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Consider adjacent fires when choosing the extinguishing medium.

DANGEROUS COMBUSTION

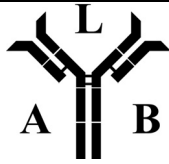
PRODUCTS: No data available.

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/Controls 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/Controls 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).



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METHODS FOR CLEANING:	Microtiter strips	Sweep material and dispose in an appropriate labeled container. Dispose via an approved waste disposal company.
	Calibrators/Controls Enzyme conjugate Washing buffer (10x 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.

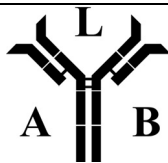
7. HANDLING AND STORAGE

HANDLING:	Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate	After handling wash hands thoroughly.
	Stop solution	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 food and other antigens. Do not use reagents for other purposes.	

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. EXPOSURE LIMIT VALUES

Microtiter strips	Not applicable
Calibrators/Controls	Not applicable
Enzyme conjugate	Not applicable
Washing buffer (10x concentrate)	Not applicable
Sample diluent	Not applicable
Substrate	Not applicable
Stop solution	At present no limit defined. Comment: according to TRGS900 a MAK value of 2 mg/m ³ (maximum exposure category 1, exceeding factor 1) was defined till 2005.



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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

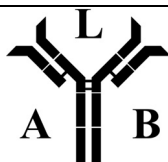
9.1. GENERAL INFORMATION

PHYSICAL STATE:

Microtiter strips	plastic plate
Calibrators/Controls	liquid
Enzyme conjugate	liquid
Washing buffer (10x concentrate)	liquid
Sample diluent	liquid
Substrate	liquid
Stop solution	liquid

COLOR:

Microtiter strips	white/clear
Calibrators/Controls	blue
Enzyme conjugate	red
Washing buffer (10x concentrate)	clear
Sample diluent	blue
Substrate	clear to slight yellow
Stop solution	clear

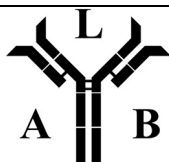


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9.2. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

PH:	Microtiter strips	Not applicable
	Calibrators/Controls	6-8
	Enzyme conjugate	6-8
	Washing buffer (10x concentrate)	6-8
	Sample diluent	6-8
	Substrate	9-10
	Stop solution	>13
BOILING POINT:	Microtiter strips	Not applicable
	Calibrators/Controls	} Lowest known value (water): 100°C/212°F
	Enzyme conjugate	
	Washing buffer (10x concentrate)	
	Sample diluent	
	Substrate	
	Stop solution	
MELTING POINT:	Microtiter strips	Not applicable
	Calibrators/Controls	} May melt at 0°C/32°F This specification is based on the ingredient water.
	Enzyme conjugate	
	Washing buffer (10x concentrate)	
	Sample diluent	
	Substrate	
	Stop solution	
SOLUBILITY:	Microtiter strips	Not applicable
	Calibrators/Controls	} Complete solubility in cold and hot water.
	Enzyme conjugate	
	Washing buffer (10x concentrate)	
	Sample diluent	
	Substrate	
	Stop solution	
VAPOR PRESSURE:	Microtiter strips	Not applicable
	Calibrators/Controls	} 23.4 mbar at 20°C/68°F This specification is based on the ingredient water.
	Enzyme conjugate	
	Washing buffer (10x concentrate)	
	Sample diluent	
	Substrate	
	Stop solution	
NO AVAILABLE DATA:	To flash point, explosion limits, ignition temperatures, viscosity, oxidizing properties, density, partition coefficient (octanol/water).	



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10. STABILITY AND REACTIVITY

10.1. CONDITIONS TO AVOID

Microtiter strips Calibrators/Controls 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.
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10.2. MATERIALS TO AVOID

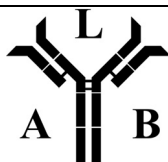
Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} When handled according to the intended use no hazardous reactions are to be expected.
	Strong oxidants, strong acids, organic compounds.

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/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate	} No health effects known.
	Stop solution	May cause irritation of the upper respiratory tract May be harmful. Material acts extremely damaging to mucosas or the upper respiratory tract. May cause lung oedema.
INGESTION:	Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} No health effects known.
		May cause nausea or stomach ache. May cause burns in mouth or throat.



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SKIN CONTACT:	Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} No health effects known. May cause irritation of the skin. May be harmful when absorbed through the skin. Causes burns of the skin.
EYE CONTACT:	Microtiter strips Calibrators/Controls Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	} No health effects known. May cause irritation of the eyes. May cause burns of the eyes.

The following information are based on Trizma Base as component of the substrate and sodium hydroxide solution as ingredient of the stop solution:

Component	LD50	Sensitization	Carcinogenicity
Sodium hydroxide solution	2000 mg/kg (rat, oral)	No sensitizing effect known.	No component of these products with a concentration $\geq 0.1\%$ were identified as expected, possible or carcinogenic product for humans by the IARC.
Trizma Base	5900 mg/kg (Rat, oral)		

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

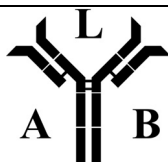
12. ECOLOGICAL INFORMATION

The following information is based on Trizma Base as component of the substrate. For all other components no data are available.

MOBILITY:	Trizma Base is water soluble and therefore spreads in aquatic systems easily.
PERSISTENCE AND DEGRADABILITY:	According to computer simulations a good biodegradability of Trizma Base is expected.
BIOACCUMULATIONPOTENIAL:	Trizma Base: $\text{Log}K_{\text{OW}} < 1$ – no significant bioaccumulating effect according to computer simulations.

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. Dissolve or mix the stop solution with a combustible solvent and burn in a chemical incinerator with an afterburner and scrubber.
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HAZARDOUS WASTE: According to our current knowledge no hazardous waste in the sense of the European directive 91/689/EC.

14. TRANSPORT INFORMATION

The following information is based on sodium hydroxide as ingredient of the stop solution. All other components are not hazardous in the sense of the mentioned regulations:

STREET TRAFFIC / RAIL TRAFFIC: ADR (directive 94/55/EC) / RID (directive 96/49/EC)
UN Number: 1824
Class 8
Packing group III
Proper shipping name: sodium hydroxide solution

SEA TRAFFIC: IMDG
UN Number: 1824
Class 8
Packing group III
EMS-No: F-A, S-B
Proper shipping name: sodium hydroxide solution
Marine pollutant: no

AIR TRAFFIC: IATA
UN Number: 1824
Class 8
Packing group III
Proper shipping name: sodium hydroxide solution

15. REGULATORY INFORMATION

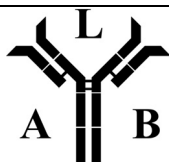
IDENTIFICATION ACCORDING TO EUROPEAN DIRECTIVES:

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/Controls
Enzyme conjugate
Washing buffer (10x concentrate)
Sample diluent
Substrate
Stop solution

} This product is not classified according to European laws.
R36: Irritating to eyes
R38: Irritating to skin
R35: Causes severe burns.



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S-PHRASES:

Microtiter strips
Calibrators/Controls
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).

EUROPEAN INVENTORY:

Sodium hydroxide as ingredient of the stop solution and Trizma Base as component of the substrate not listed.

NATIONAL RULES:

German administrative rule for substances harmful to water (VwVwS): WGK 2 (according to annex 2): harmful to water for Trizma Base as component of the substrate and WGK 1: weakly harmful to water for sodium hydroxide as ingredient of the stop solution.

16. OTHER INFORMATION

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

Microtiter strips
Calibrators/Controls
Enzyme conjugate
Washing buffer (10x concentrate)
Sample diluent
Substrate

Not applicable.

Stop solution

R36: Irritating to eyes.

R38: Irritating to skin.

R35: Causes severe burns.

DOCUMENT HISTORY:

Version 1: 2010-11-30 (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.