



## Declaration

EUROIMMUN AG declares that all diagnostics for indirect immunofluorescence are not classified as hazardous material according to directive 88/379/EEC.

That's why no Safety Data Sheeds (SDS) according to directive 91/155/EEC are necessary.

Lübeck, 10.08.2004

---

E. Müller-Kunert, PhD  
Head Immunofluorescencetechnique



## Declaration

EUROIMMUN declares that all diagnostics for ELISA test systems, apart from the exceptions mentioned below, are not classified as hazardous materials according to the directive 88/379/EEC.

Exceptions:

- Chromogen/substrate solution
- Stop solution for Anti-CCP ELISA

For these exceptions Safety Data Sheets (SDS) are provided by EUROIMMUN in accordance with directive 91/155/EEC.

Luebeck, 18. December 2002

---

W. Schlumberger, PhD  
Head Immunobiochemical Diagnostics

**Safety Data Sheet**

according to EC Directive 91/155/EEC

Printed at: 23.02.04

Page: 1 of 2

**1. Identification of the substance/preparation and of the company***Identification of the substance/preparation:*

Product name: Chromogen/substrate solution

Order No.: corresponding to the test kit

*Identification of the company:*

EUROIMMUN AG • D-23560 Lübeck • Seekamp 31 • Tel.: ++49 (0)451-5855-0

Emergency telephone No.: ++49 (0)451-5855-0, Telefax: ++49 (0)4509/8743-391

**2. Composition/information on ingredients**

Aquarious solution with organic and inorganic compounds.

*Hazardous compounds:*

Dimethyl Sulfoxid:	Concentration:	9%
	Symbol:	Xi
	R-phrase:	36/38 Irritating to eyes and skin
N,N-Dimethylformamid:	Concentration:	8%
	Symbol:	T
	R-Phrase:	61-E20/21-36 May cause harm to the unborn child Also harmful by inhalation and in contact with skin Irritating to eyes

**3. Hazards identification**

May cause harm to the unborn child - Irritating to eyes and skin.

**4. First aid measures**

- Inhalation: Move to fresh air.
- Skin contact: Immediately wash skin with soap and copious amount of water.
- Eye contact: Immediately flush eyes with copious amounts of water for at least 15 minutes.
- Ingestion: Wash out mouth with water provided person is conscious. Call a physician.

**5. Fire-fighting measures**

suitable extinguishing media: Noncombustible. Use water spray to cool exposed containers, use extinguishing media appropriate to surrounding fire conditions.

**6. Accidental release measures**

Evacuate area and ventilate area, wear self-contained breathing apparatus, rubber boots and heavy rubber gloves, absorb on sand or vermiculite and place in closed containers for waste disposal, avoid splashing.

**7. Handling and storage**

- Storage: Store closed at +2°C to +8°C
- Handling: No further requirements

**8. Exposure controls/personal protection***Personal protection:*

- Respiratory Protection: Necessary, if vapour/aerosols appears.
- Eye protection: Necessary
- Hand protection: Necessary

Protection material is suit to the concentration and the quantity of the hazardous material.

Working hygiene: Remove contaminated clothes. Wash and disinfect hands after end of work.



## Safety Data Sheet

according to EC Directive 91/155/EEC

Printed at:	23.02.04
Page:	2 of 2

### 9. Physical and chemical properties

- Appearance:	liquid	- Flash point:	not available
- Colour:	yellow	- Explosive properties	lower upper not available
- Odour:	not available	- Vapour pressure:	not available
- pH value:	not available	- Relative density:	not available
- Melting point:	< 0°C (water)	- Water solubility:	dilutable in water
- Boiling point:	> 100°C (water)		
- Ignition temperature:	not available		

### 10. Stability and reactivity

*Conditions to avoid:* Stability can only be ensured if the product is stored unopened at +2°C to +8°C.

*Materials to avoid:* Acid anhydrides, acid halides, boron hydrides, oxidizing agents, chloroformates, reducing agents, halogens

*Hazardous decomposition products:* Data not available

### 11. Toxicological information

May cause harm to the unborn child.

After contact with skin: Irritant

After contact to eyes: Irritant

### 12. Ecological information

No ecological problems are to be expected when the product is handled and used due care and attention.

### 13. Disposal considerations

*Product:*

There are no harmonised regulations on the disposal of chemicals in the member states of the EU. Contact your competent body for further information.

*Packaging:*

Handle contaminated packaging like the substance itself.

### 14. Transport information

No additional labelling required in Germany (Take care for possible different classifications in other countries).

### 15. Regulatory information

Labelling according to the Directive 67/548/EEC and 88/379/EEC:

Symbol:	T	toxic
R-phrases:	61- 36/38	May cause harm to the unborn child Irritating to eyes and skin
S-phrases:	53	Avoid exposure - obtain special instructions before use - Restricted to professional users
Compounds:	N,N-Dimethylformamid, Dimethylsulfoxid	

### 16. Other information

Date of issue: 01.10.2002                      replace edition of: 24.01.2000

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. All chemicals may have unknown hazardous potentials and should be handled with care.



<b>Safety Data Sheet</b> according to EC Directive 91/155/EEC	Printed at: 27.04.04
	Page: 1 of 2

## 1. Substance/preparation and company description

*Substance/preparation description:*

Product name: Stop solution for the Anti -CCP- ELISA from Euroimmun

Order No.: corresponds to the test kit

*Description of the company:*

EUROIMMUN AG • D-23560 Lübeck • Seekamp 31 • Tel.: ++49 (0)451-5855-0

*Emergency telephone No.:* ++49 (0)451-5855-0, Telefax: ++49 (0)4509/8743-391

## 2. Composition/information of ingredients

Preparation with inorganic compounds.

*Hazardous compounds:*

Sodium hydrogen	Concentration:	≥ 2-5 %
	Symbol:	C
	R-phrase:	35
		Causes serious burns.

## 3. Hazard identification

- Causes serious burns.

## 4. First aid measures

- Inhalation: Move to fresh air, consult doctor.  
 - Skin contact: Rinse generously with water. Dab with Polyethylenglycol 400. Remove contaminated clothes immediately.  
 - Eye contact: Immediately flush eyes with generous amounts of water for at least 15 minutes. Consult eye doctor.  
 - Ingestion: Allow to drink large amount of water (if necessary several liters), avoid vomiting (Danger of perforation!). Consult doctor immediately. No neutralization attempts.

## 5. Fire-fighting measures

Suitable fire-fighting means: Should correspond to surroundings.

Special dangers: Not combustible. Contact with light alloys can cause hydrogen gas to form (danger of explosion!). Surrounding fire can create dangerous vapours.

## 6. Accidental measures

Personal precautionary measures:	Do not inhale vapour/ aerosols. Avoid substance contact. Ventilate closed areas (rooms) with fresh air.
Environmental protection measures:	Do not allow to get in the sewerage.
Cleaning procedures:	Use liquid-binding material, e.g., Chemizorb ®. Dispose. Do follow up cleaning.
Additional indications:	Render harmless: Neutralize with diluted sulfuric acid.

## 7. Handling and storage

- *Storage:* Close tightly. Store dry between +15 °C to +25 °C. Do not store aluminium, tin, or zinc containers.  
 - *Handling:* Not storable for an unlimited period. No other requirements.

## 8. Exposure control/person protection

*Personal protection:*

- Respiratory Protection: Necessary, if vapour/aerosols appears.  
 - Eye protection: Necessary.  
 - Hand protection: Necessary.  
 Other preventive measures: Corresponding protective clothing.



## Safety Data Sheet

according to EC Directive 91/155/EEC

Printed at:	27.04.04
Page:	2 of 2

Working hygiene: Remove contaminated clothes. Wash and disinfect hands after end of work.

### 9. Physical and chemical properties

- Appearance:	liquid	- Flash point:	not available
- Colour:	colourless	- Explosive properties	lower not available
- Odour:	odourless		upper not available
- pH value:	13,7 (20°C)	- Vapour pressure:	not available
- Melting point:	not available	- Relative density:	1,05 g/cm <sup>3</sup> (20°C)
- Boiling point:	not available	- Water solubility:	Solubly (20°C)
- Ignition temperature:	not available		

### 10. Stability and reactivity

*Conditions to avoid:*

No information exists.

*Materials to avoid:*

Metals, light alloys, hydrogen gas (can develop!); ammonium compounds: It can develop ammonia; acids.

*Hazardous decomposition products:* No information exist.

### 11. Toxicological information

- Inhalation:	Mucous membrane burns, coughing and breathlessness
- Skin contact:	Burns.
- Eye contact:	Burns. Danger of blindness!
- Ingestion:	Burns in the mouth, pharynx, gullet and stomach-intestine-tract.

### 12. Ecological information

- With proper handling and application, no ecological hazards are to be expected.
- Do not allow to get in waters, waste water or earth.

### 13. Disposal procedure

*Product:*

*Chemicals must be disposed in observance of national regulation. No standardized regulations at present in the EU for the disposal of chemicals.*

*Packaging:*

Disposal in accordance with the official rules. Contaminated packagings are to be treated as potentially hazard. Unless otherwise officially regulated, contaminated packagings are not to be treated as normal waste or recycled.

### 14. Transport information

No additional labelling required in Germany (observe possible classifications for other countries).

### 15. Regulatory information

Labelling according to the directive 67/548/EEC and 88/379/EEC:

Symbol:	C	Corroding.
R-phrases:	34	Causes burns
S-phrases:	26-36/37/39-45	On contact with eyes immediately rinse thoroughly with water and consult doctor. Suitable protective clothing, protection gloves, goggles, face protection are required. Should an accident or nausea occur immediately consult doctor (show this label if possible).

Compounds: Sodium hydrogen

### 16. Other information

Date of issue: 13.02.2003                      replace edition of: ---

The above information is in accordance with current standards and is a guideline for the careful handling of hazardous products. All chemicals may have unknown hazardous potential and should be handled with care.