

## 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

### 1.1 PRODUCT IDENTIFIER

#### PRODUCT NAME:

Serazym<sup>®</sup> Anti-Cardiolipin-β2-GP-1 GAM  
Serazym<sup>®</sup> Anti-Cardiolipin-β2-GP-1 IgG/IgM  
Serazym<sup>®</sup> Anti-Cardiolipin-β2-GP-1 IgA  
Serazym<sup>®</sup> Anti-β2-GP-1 IgG/IgM  
Serazym<sup>®</sup> Anti-Phosphatidylserine-β2-GP-1 IgG/IgM  
Serazym<sup>®</sup> Anti-Phosphatidylserine-Prothrombin IgG/IgM  
Serazym<sup>®</sup> Anti-β2-GP-1 GAM  
Serazym<sup>®</sup> Anti-Phospholipid screen IgG/IgM

#### CATALOG NUMBER:

E-077  
E-054  
E-078  
E-055  
E-084  
E-085  
E-086  
E-089

Serazym<sup>®</sup> Anti-TPO IgG  
Serazym<sup>®</sup> Anti-TG IgG  
Serazym<sup>®</sup> Anti-Nucleosome IgG  
Serazym<sup>®</sup> Anti-dsDNA IgG  
Serazym<sup>®</sup> ENA screen  
Serazym<sup>®</sup> ENA profile  
Serazym<sup>®</sup> ANA screen  
Serazym<sup>®</sup> ANA profile  
Serazym<sup>®</sup> Anti-MPO (pANCA) IgG  
Serazym<sup>®</sup> Anti-PR3 (cANCA) IgG  
Serazym<sup>®</sup> Anti-PR3 (cANCA) IgG enhanced  
Serazym<sup>®</sup> Anti-ASGPR IgG  
Serazym<sup>®</sup> Anti-Insulin IgG  
Serazym<sup>®</sup> Nucleo ANAScreen plus

E-052  
E-053  
E-035  
E-058  
E-062  
E-064  
E-065  
E-066  
E-087  
E-088  
E-091  
E-056  
E-080  
E-100

Serazym<sup>®</sup> RF IgM  
Serazym<sup>®</sup> RF IgA  
Serazym<sup>®</sup> RF IgG  
Serazym<sup>®</sup> RF IgA/IgG/IgM  
Serazym<sup>®</sup> Anti-CCP IgG

E-012  
E-060  
E-083  
E-105  
E-095

Serazym<sup>®</sup> Anti-Gliadin IgA  
Serazym<sup>®</sup> Anti-Gliadin IgG  
Serazym<sup>®</sup> ASCA IgA  
Serazym<sup>®</sup> ASCA IgG  
Serazym<sup>®</sup> Anti-Transglutaminase IgA  
Serazym<sup>®</sup> Anti-Transglutaminase IgG  
Serazym<sup>®</sup> Anti-Intrinsic Factor IgG  
Serazym<sup>®</sup> Anti-GP2 IgG  
Serazym<sup>®</sup> Anti-Gliadin deamid IgA  
Serazym<sup>®</sup> Anti-Gliadin deamid IgG  
Serazym<sup>®</sup> Anti-GP2 IgG

E-025  
E-026  
E-032  
E-033  
E-047  
E-050  
E-082  
E-090  
E-101  
E-102  
E-104

Serazym<sup>®</sup> Anti-Borrelia IgG  
Serazym<sup>®</sup> Anti-Borrelia IgM  
Serazym<sup>®</sup> Anti-Francisella tularensis GAM


E-021  
E-023  
E-049

Serazym<sup>®</sup> Human IgG  
Serazym<sup>®</sup> Human IgM  
Serazym<sup>®</sup> Human IgA  
Serazym<sup>®</sup> Human Cu/Zn SOD

E-003  
E-004  
E-007  
E-002

Serazym<sup>®</sup> Ovalbumin ELISA  
Serazym<sup>®</sup> Bovine Serum Albumin  
Serazym<sup>®</sup> Bovine Serum Albumin sensitive

E-041 a-1, a-2,b, c-1, c-2  
E-048 / b  
E-108

	<p><b>optional Safety data sheet</b>  <b>according to EG 1907/2006, article 32</b></p> <p>Enzyme Immunoassays  Anti-Phospholipid Syndrome / Systemic  Autoimmune Disease / Rheumatic Diseases /  Gastrointestinal Autoimmune Diseases / Infectious  Diseases / Human Proteins and Antibodies /  Vaccine Control</p>	<p>File:  SDBR_E_ELISA-01_v05.docx  Version: 05 last version: 04  date: 2013-11-01  Revision: 2013-11-01  valid from: 2013-11-11</p> <p>page 2 of 12</p>
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## 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

All products are test kits for immunological determination of different antigens by ELISA principle.

## 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Seramun Diagnostica GmbH  
Spreenhagener Straße 1  
15754 Heidesee  
GERMANY  
Phone: +49 33767-791 10  
Fax: +49 33767-791 99  
E-mail: info@seramun.com

## 1.4 EMERGENCY TELEPHONE NUMBER

Phone: +49 33767-791-10 available only during office hours.

# 2. HAZARDS IDENTIFICATION

## 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Although it is **not classified as hazardous** according to the European Regulations 1999/45/EG and (EC) 1272/2008 the product should be handled with the usual care for all chemicals, in order to avoid synergistic effects.

Because of the preservative it may be dangerous for water organisms.

## 2.2 LABEL ELEMENTS

Labels according European regulation (EC) 1272/2002 (CLP)

Pictogram	none
Signal word	none
Hazard Statement(s)	none
Precautionary Statement(s)	none
Supplemental Hazard Statements	none

Safety data sheet available for professional users on request.

## 2.3 OTHER HAZARDS

None of the components is listed as PBT or vPvB relevant


# 3. COMPOSITION / INFORMATION ON INGREDIENTS

## 3.1 SUBSTANCES

All products are mixtures.





























## 3.2 MIXTURES


Wash Buffer	Tris-buffer, preservatives
Incubation Buffer	Tris-buffer, bovine serum albumin, preservatives
Standard solution	Tris-buffer, bovine serum albumin, preservatives , as active substances IgG (goat or sheep)
Conjugate solution	Tris-buffer, bovine serum albumin, preservatives , as active substances IgG (goat or sheep) and horseradish peroxidase (EC1.11.1.7)
substrate solution	aqueous solution of TMB, hydrogen peroxide, containing citrate and preservative
stop solution	diluted sulfuric acid






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The bovine serum albumin was derived from bovine blood collected at USDA licensed establishment.

Dangerous components according to 67/548/EWG; 1999/45/EG and EG 1272/2008:

REACH registration number	EINECS	CAS-No.	name	percent age	symbol/ signal word	R-phrases / H-phrases
<u>Wash buffer</u>						
not available	201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	< 0.9	X <sub>i</sub>  <b>Warning</b>	R36/38 H315, H319
not available	200-210-4	54-64-8	Thiomersal	< 0.01	T+, N    <b>Danger</b>	R26/27/28-33-50/53 H373, H330 H300, H310, H410
<u>Incubation buffer</u>						
not available	201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	< 0.9	X <sub>i</sub>  <b>Warning</b>	R36/38 H315, H319
not available	200-210-4	54-64-8	Thiomersal	< 0.03	T+, N    <b>Danger</b>	26/27/28-33-50/53 / H373, H330 H300, H310, H410
<u>Conjugate solution</u>						
not available	201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	< 0.15	X <sub>i</sub>  <b>Warning</b>	R36/38 H315, H319
not available	247-500-7	26172-55-4	5-Chlor-2-methyl-4-isothiazolin-3-on	< 0.01	T, N     <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
not available	220-239-6	2682-20-4	2-Methyl-4-isothiazolin-3-on	< 0.005	T, N     <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
<u>Standard solution</u>						
not available	201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	< 0.15	X <sub>i</sub>  <b>Warning</b>	R36/38 H315, H319
not available	247-500-7	26172-55-4	5-Chlor-2-methyl-4-isothiazolin-3-on	< 0.01	T, N     <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
not available	220-239-6	2682-20-4	2-Methyl-4-isothiazolin-3-on	< 0.005	T, N     <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
not available	247-852-1	26628-22-8	sodium azid	< 0.1	T+, N   <b>Danger</b>	R28-50/53 H300, H400, H410

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REACH registration number	EINECS	CAS-No.	name	percent age	symbol/ signal word	R-phrases / H-phrases
<u>Substrate solution</u>						
not available	259-364-6	54827-17-7	3,3',5,5'-Tetramethylbenzidine	< 0,04	X <sub>n</sub>  <b>Warning</b>	R20/21/22-36/37/38-40 H301, H311, H330, H341
not available	247-500-7	26172-55-4	5-Chlor-2-methyl-4-isothiazolin-3-on	< 0.0001	T,N  <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
not available	220-239-6	2682-20-4	2-Methyl-4-isothiazolin-3-on	< 0.0001	T,N  <b>Danger</b>	R23/24/25-34-43-50/53 H272, H314, H317, H334
not available	231-765-0	7722-84-1	hydrogen peroxyde	< 0,005	X <sub>n</sub> , X <sub>i</sub>  <b>Danger</b>	R22-41 H302, H318
<u>Stop solution</u>						
Not available	231-639-5	7664-93	sulphuric acid	2.5	C  <b>Warning</b>	R35 H290, H314

The full text of R-phrases and H-statements is in article 16

## 4. FIRST AID MEASURES

### 4.1 DESCRIPTION OF FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration.

Consult a physician.

In case of skin contact

Wash off with plenty of water. Consult a physician.

In case of eye contact

Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

If swallowed

Never give anything by mouth to an unconscious person.


Rinse mouth with water, drink about 300 ml water, consult a physician.

### 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No data available

### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

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## 5. FIREFIGHTING MEASURES

### 5.1 EXTINGUISHING MEDIA

Suitable extinguishing media

Use water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire.

In case of fire toxic vapors, e.g. nitric oxide and carbon monoxide, can be released.

### 5.3 ADVICE FOR FIREFIGHTERS

Wear breath protective mask and protective clothes if necessary during fire fighting.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

### 6.2 ENVIRONMENTAL PRECAUTIONS

Keep away from drains. Avoid contamination of water or soil.

### 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Suck up with inert absorbance material and dispose as hazardous waste. Keep in a suitable, closed container.

### 6.4 REFERENCE TO OTHER SECTIONS

For personal protection see chapter 8.

For disposal considerations see chapter 13.

## 7. HANDLING AND STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING

No smoking, eating, drinking, chewing gum or storage of food or beverages in the working laboratories. Wash hands after work. Remove safety clothing before entering a refreshment room.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store tightly closed at a cool dry place. Reseal opened bottles carefully and store in an upright position.


Recommended storage temperature: 2-8 °C

Storage classification: 12 (non flammable liquids)

segregate from: class1 (explosives)  
class 4.1A (flammable solids)  
class 4.3 (dangerous when wet)  
class 6.2 (infectious)  
class 7 (radioactive)

### 7.3 SPECIFIC END USE(S)

Use only in accordance to the manual.

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 CONTROL PARAMETERS

EINECS	name	limit value according to MAK (TRGS 900)	limit value according to BGW (TRGS 903)
200-210-4	Thiomersal	not listed	100 µg/ml blood
247-500-7	5-Chlor-2-methyl-4-isothiazolin-3-on	0.05 mg/m <sup>3</sup>	not listed
220-239-6	2-Methyl-4-isothiazolin-3-on	0.05 mg/m <sup>3</sup>	not listed
201-064-4	Tris(hydroxymethyl)-aminomethan	not listed	not listed
247-852-1	sodium azid	0.2 mg/m <sup>3</sup>	not listed
259-364-6	3,3',5,5'-Tetramethylbenzidine	not listed	not listed
231-765-0	Hydrogen Peroxide	not listed	not listed

By using the product according with the requirements, no air pollution is to be expected.

### 8.2 EXPOSURE CONTROLS

Consider the usual good hygiene and safety practice by handling chemicals.

#### Personal protective equipment

**Eye/face protection:** Safety glasses with side shields conforming to EN 166 (EU), NIOSH (US)

**Skin protection:** protective gloves of nitril rubber (thickness min. 0.28 mm, AQL1,5) or nature latex (thickness min. 0.22 mm, AQL 1,5), satisfying the norm EN 374

**Body protection:** impenetrable protective clothing, the kind of protective equipment has to be selected depending from concentration and amount of dangerous substance at the specific workplace.

**Respiratory protection:** by using according to the intended use, not required. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

**Environmental exposure controls:** Keep away from drains.


## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

component	description	colour	odour
Wash buffer	liquid product	colourless	odourless
Incubation buffer	liquid product	coloured	odourless
Conjugate solution	liquid product	IgG: red IgA: violet IgM: green	odourless
Standard solution	liquid product	coloured	odourless
Substrate solution	liquid product	colourless	characteristic
Stopp solution	liquid product	colourless	odourless

component	pH-value	boiling point	Flash point	Explosive properties
Wash buffer	7.3 – 7.5	101 °C	not applicable	non
Incubation buffer	7.3 – 7.5	102 °C	not applicable	non
Conjugate solution	7.3 – 7.5	102 °C	not applicable	non
Standard solution	7.3 – 7.5	102 °C	not applicable	non
Substrate solution	3.5 – 3.7	102 °C	not applicable	non
Stopp solution	1	103 °C	not applicable	non

component	Oxidising properties	Vapour pressure	relative density
Wash buffer	non	not measured	1.11 g/ml
Incubation buffer	non	not measured	1.0026 g/ml
Conjugate solution	non	not measured	1.043 g/ml
Standard solution	non	not measured	1.0026 – 1.007 g/ml

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Substrate solution	non	not measured	1.013 g/ml
Stopp solution	non	not measured	1.02 g/ml

component	solubility	Water solubility	Viscosity
Wash buffer	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Incubation buffer	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Conjugate solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Standard solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Substrate solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Stopp solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured

## 9.2 OTHER INFORMATION

No further dangerous properties known.

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY

No data available.

### 10.2 CHEMICAL STABILITY

store at 2 – 8 °C

### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4 CONDITIONS TO AVOID

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the product)  
See storage conditions chapter 7.2.

### 10.5 INCOMPATIBLE MATERIALS

Oxidizing agents, metals (will not cause a dangerous reaction, but destroys the quality of the product)

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS


Dangerous decomposition products are not known.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

(a) acute toxicity

Component	valuation	value	species
Thimerosal	LD <sub>50</sub> (oral)	75 mg/kg	rat
	LD <sub>50</sub> (oral)	91 mg/kg	mouse
5-Chlor-2-methyl-4-isothiazolin-3-on	LD <sub>50</sub> (oral)	3350 mg/kg	rat
2-Methyl-4-isothiazolin-3-on	LD <sub>50</sub> (oral)	550 mg/kg	rat
Tris(hydroxymethyl)-aminomethan	LD <sub>50</sub> (oral)	5900 mg/kg	rat
sodium azid	LD <sub>50</sub> (oral)	27 mg/kg	rat
3,3',5,5'-Tetramethylbenzidine	no data available		
hydrogen peroxide	LD <sub>50</sub> (oral)	1232 mg/kg	rat

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(b) skin corrosion/irritation

Component	valuation	value	species
hydrogen peroxide	LD <sub>50</sub> (dermal)	3000 mg/kg	rabbit

(c) serious eye damage/irritation

Possible damages: slight irritation for sulfuric acid

(d) respiratory or skin sensitization

No information available

(e) germ cell mutagenicity

Suspicion of carcinogenicity for 3,3',5,5'-Tetramethylbenzidine (Muta. 2)

(f) carcinogenicity

Suspicion of carcinogenicity for 3,3',5,5'-Tetramethylbenzidine (Muta. 2)

(g) reproductive toxicity

Suspicion of carcinogenicity for 3,3',5,5'-Tetramethylbenzidine (Muta. 2)

(h) STOT-single exposure

No specific target organ toxicant because no component is known as specific target organ toxicant.

(i) STOT-repeated exposure

No specific target organ toxicant because no component is known as specific target organ toxicant.

(j) aspiration hazard

No information available

## 11.2 FURTHER TOXICOLOGICAL INFORMATION

Quantitative data on the toxicity of the mixtures are not available. Calculation of ATE according to EC 1272/2008, Appendix I: see section 15.1

Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY

Preservatives 5-chlor-2-methyl-4-isothiazoline-3-on and 2-methyl-4-isothiazoline-3-on:

species	valuation	value
trout	LC <sub>50</sub> (mg/l)	0.19
bass	LC <sub>50</sub> (mg/l)	0.28
marine algae (Skeletonema costatum)	EC <sub>50</sub> (mg/l)	0.003
algae (Selenastrum capricornutum)	EC <sub>50</sub> (mg/l)	0.018
invertebrates (Daphnia magna)	EC <sub>50</sub> (mg/l)	0,16

Preservative Thimerosal:

species	valuation	value
trout	LC <sub>50</sub> (mg/l)	21.2

Preservative sodium azid:

species	valuation	value
sunfish	LC <sub>50</sub> (mg/l/96h)	0.7
invertebrates (Daphnia pulex)	EC <sub>50</sub> (mg/l/48h)	4.2
green algae	IC <sub>50</sub> (mg/l)	272



Hydrogen peroxide:

species	valuation	value
fathead minnow	LC <sub>50</sub> (mg/l)	16.4
invertebrates (Daphnia magna)	EC <sub>50</sub> (mg/l)	2.4
microorganisms (activated sludge)	EC <sub>50</sub> (mg/l)	466

Sulfuric acid:

species	valuation	value
invertebrates (Daphnia magna)	EC <sub>50</sub> (mg/l/24h)	29

For Tris(hydroxymethyl)-aminomethane are no data available.

## 12.2 PERSISTENCE AND DEGRADABILITY

substance	t ½ anerob (h)
5-chlor-2-methyl-4-isothiazolin-3-one	4.8
2-methyl-4-isothiazolin-3-one	9.1
Tris(hydroxymethyl)-aminomethane	89% / 28 d
hydrogen peroxide	99% / 0.02 d

## 12.3 BIOACCUMULATIVE POTENTIAL

5-Chlor-2-methyl-4-isothiazolin-3-on und 2-Methyl-4-isothiazolin-3-on:

log P(o/w) = 0.401 no bioaccumulation expected

Tris(hydroxymethyl)-aminomethane: log P(o/w) = - 1.56 no bioaccumulation expected

Hydrogen peroxide log P(o/w) = - 1.57 no bioaccumulation expected

## 12.4 MOBILITY IN SOIL

No data available.

## 12.5 RESULTS OF PBT AND vPvB ASSESSMENT

None of the components is listed as PBT or vPvB relevant.

## 12.6 OTHER ADVERSE EFFECTS

Herbicide and nematicide effects known.

Keep away from drains. Avoid contamination of water or soil.

If used properly, no ecological problems are to be expected.

# 13. DISPOSAL CONSIDERATIONS

## 13.1 WASTE TREATMENT METHODS

Product:

May not be discarded together with the normal waste. May not be discarded into sewerage.


Chemicals or remaining residues have to be treated as special waste and should be discarded, according to the appropriate legislation. Information can be collected from the responsible public authorities.

Recommended waste classification: 18 02 06 Chemicals from research and diagnosis in animals

18 02 07 Chemicals from diagnosis in humans

15 02 03 Absorbents, filter materials, wiping cloths and protective clothing

Packaging:

	<p align="center"><b>optional Safety data sheet</b>  <b>according to EG 1907/2006, article 32</b></p> <p align="center">Enzyme Immunoassays  Anti-Phospholipid Syndrome / Systemic  Autoimmune Disease / Rheumatic Diseases /  Gastrointestinal Autoimmune Diseases / Infectious  Diseases / Human Proteins and Antibodies /  Vaccine Control</p>	<p>File:  SDBR_E_ELISA-01_v05.docx  Version: 05 last version: 04  date: 2013-11-01  Revision: 2013-11-01  valid from: 2013-11-11</p> <p align="right">page 10 of 12</p>
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Disposal according to the instructions of the public authorities. Contaminated packages have to be treated like the substance itself. Packaging, that is not contaminated, can be recycled or treated like normal house garbage.

Recommended waste classification: 15 01 02 Plastic packaging

## 14. TRANSPORT INFORMATION

The following classification is due to the stop solution

### 14.1 UN NUMBER

ADR/RID: UN 3264

IMDG: UN 3264

IATA: UN 3264

### 14.2 UN PROPER SHIPPING NAME

ADR/RID: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

IMDG: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

IATA: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

### 14.3 TRANSPORT HAZARD CLASS(ES)

ADR/RID: 8

IMDG: 8

IATA: 8

### 14.4 PACKING GROUP

ADR/RID: III

IMDG: III

IATA: III

### 14.5 ENVIRONMENTAL HAZARDS

ADR/RID: No

IMDG: Marine pollutant no

IATA: No

### 14.6 SPECIAL PRECAUTIONS FOR USER

ADR/RID: tunnel restriction code E

IMGD: EmS-numbers: F-A, S-B

IATA: no

### 14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE

These products will be shipped only in approved card boxes.

## 15. REGULATORY INFORMATION

### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet meets the requirements of the Regulation (EC) 453/2010 to amending Regulation (EC) 1907/2006.

The calculated toxicity (ATE) of the mixture according EC 1272/2008, Annex I (mg/kg body weight)


Wash buffer	910,000	category	without rating
Incubation buffer	53,000	category	without rating
Standard solution	26,700	category	without rating
Conjugate Solution	3.500,000	category	without rating
Substrate Solution	69,000	category	without rating
Stop solution	non toxic component		

According EC 1272/2008, Annex I: no classification not hazardous to water.

Water endangering class according to VwVwS (Germany): 1

### 15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

	<p align="center"><b>optional Safety data sheet</b>  <b>according to EG 1907/2006, article 32</b></p> <p align="center">Enzyme Immunoassays  Anti-Phospholipid Syndrome / Systemic  Autoimmune Disease / Rheumatic Diseases /  Gastrointestinal Autoimmune Diseases / Infectious  Diseases / Human Proteins and Antibodies /  Vaccine Control</p>	File: SDBR_E_ELISA-01_v05.docx Version: 05 last version: 04 date: 2013-11-01 Revision: 2013-11-01 valid from: 2013-11-11  page 11 of 12
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## 16. OTHER INFORMATION

Fully text to the R-Phrases mentioned in heading 3:

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.  
R22 Harmful if swallowed.  
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.  
R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.  
R28 Very toxic if swallowed.  
R33 Danger of cumulative effects.  
R34 Causes burns.  
R35 Causes severe burns.  
R36/38 Irritating to eyes and skin.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R40 Possible risk of cancer.  
R41 Risk of serious damage to eyes.  
R43 May cause sensitization by skin contact.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Fully text to the H-Sentences mentioned in heading 3:

H272 May intensify fire; oxidiser.  
H290 May be corrosive to metals.  
H300 Fatal if swallowed.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H310 Fatal in contact with skin.  
H311 Toxic in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H330 Fatal if inhaled.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H341 Suspected of causing genetic defects.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Categories of the Acute Toxicity (ATE) according EC 1272/2008:

Category 1	0< ATE ≤5	(oral in mg/kg body weight)
Category 2	5< ATE ≤50	(oral in mg/kg body weight)
Category 3	50< ATE ≤300	(oral in mg/kg body weight)
Category 4	300< ATE ≤2.000	(oral in mg/kg body weight)

Further information:


The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action.

The REACH registration numbers in heading 3 is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration is envisaged for a later registration deadline.

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Changes with respect to the previous version:

- Changes in articles 1, addition of E-041 a-1, 1-2, c-1, c-2

	<p><b>optional Safety data sheet</b>  <b>according to EG 1907/2006, article 32</b></p> <p>Enzyme Immunoassays  Anti-Phospholipid Syndrome / Systemic  Autoimmune Disease / Rheumatic Diseases /  Gastrointestinal Autoimmune Diseases / Infectious  Diseases / Human Proteins and Antibodies /  Vaccine Control</p>	<p>File:  SDBR_E_ELISA-01_v05.docx  Version: 05 last version: 04  date: 2013-11-01  Revision: 2013-11-01  valid from: 2013-11-11</p> <p>page 12 of 12</p>
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- Actualization in articles 2.2, 3, 8, 11.1, 12, 13, 14 and 15