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

1.1 PRODUCT IDENTIFIER

PRODUCT NAME:

Serazym® Bovine Serum Albumin sensitive

CATALOG NUMBER:

E-108

10-fold Standard concentrates for
 Serazym® Bovine Serum Albumin sensitive

E-108-S0-2, E-108-S50-2, E-108-S100-2,
 E-108-S150-2, E-108-S200-2, E-108-S250-2,
 E-108-S300-2

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

RELEVANT IDENTIFIED USES:

For immunological determination of BSA by ELISA principle [PROC 15].
 Reserved for industrial and professional use.

RESTRICTIONS ON USE:

None identified

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

Classification in accordance with Regulation (EG) No 1272/2008 [CLP]

Part of the test kit	Hazard class	Hazard class and category	Hazard statement
substrate solution	reproductive toxicity	category 1B (Repr. 1B)	H360D
conjugate solution	reproductive toxicity	category 1B (Repr. 1B)	H360D
conjugate solution	skin sensitization	category 1 (Skin Sens. 1)	H317
sample diluent	skin sensitization	category 1 (Skin Sens. 1)	H317
standard solutions	skin sensitization	category 1 (Skin Sens. 1)	H317
control solution	skin sensitization	category 1 (Skin Sens. 1)	H317

2.2 LABEL ELEMENTS

Information: According to EU Regulation (EC) 1272/2008, Article 1 (5) (d), in vitro diagnostic medical devices (IVDs) within the meaning of Directive 98/79 / EC are exempt from the labeling requirement.

Labelling as specified by the Regulation (EC) Nr. 1272/2008 [CLP]

Substrate solution:

Hazard pictogram(s)




Signal word

Danger

Hazard statement(s)

H360D

May damage the unborn child.

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Precautionary statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 If exposed or concerned: Get medical advice/attention.

Conjugate solution:

Hazard pictogram(s)



Signal word

Danger

Hazard Statement(s)

H360D May damage the unborn child.
H317 May cause an allergic skin reaction.
EUH208 Contains 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one. May produce an allergic reaction.

Precautionary Statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 If exposed or concerned: Get medical advice/attention.

Sample diluent, conjugate, standards and control solutions:

Hazard pictogram(s)



Signal word

Warning

Hazard Statement(s)

H317 May cause an allergic skin reaction.
EUH208 Contains 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one. May produce an allergic reaction.

Precautionary Statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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 with inorganic salts and preservatives (thimerosal 0.01%).
Concentrations of dangerous components according to (EC) 1272/2008 are below the concentration limits mentioned in the law.

Sample diluent:


TRIS-buffer with inorganic salts, stabilizing agents and preservative.
Dangerous components according to (EC) 1272/2008:

REACH No.	EINECS	CAS-No.	name	percentage	pictogram(s)	H-statements
not available	613-167-00-5	55965-84-9	Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one	0.008		H302, H314, H317, H410

Standard solutions:

TRIS-buffer with inorganic salts, stabilizer, specific antigen BSA and preservative.
The bovine serum Albumin is derived from bovine blood collected at a USDA licensed establishment.



Dangerous components according to (EC) 1272/2008:

REACH No.	EINECS	CAS-No.	name	percentage	pictogram(s)	H-statements
not available	613-167-00-5	55965-84-9	Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one	0.015		H302, H314, H317, H410

Conjugate solution:

TRIS-buffer with inorganic salts, protein free stabilizer and supplements and preservative, as active substances IgG (rabbit) and horseradish peroxidase (EC1.11.1.7).


Dangerous components according to (EC) 1272/2008:

REACH No.	EINECS	CAS-No.	name	percentage	pictogram(s)	H-statements
not available	613-167-00-5	55965-84-9	Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one	0.008		H302, H314, H317, H410
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	2.5		H315, H319, H360D, H335

Substrate solution:

aqueous solution of TMB, hydrogen peroxide, containing citrate and preservative.


Dangerous components according to (EC) 1272/2008:

REACH No.	EINECS	CAS-No.	name	percentage	pictogram(s)	H-statements
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	5.0		H315, H319, H360D, H335

Stop solution:

diluted sulfuric acid.

Dangerous components according to (EC) 1272/2008:

REACH No.	EINECS	CAS-No.	name	percentage	pictogram(s)	H-statements
01-2119458838-20-XXXX	231-639-5	7664-93	sulphuric acid	2.5		H290, H314

Full text of H-phrases: see section 16.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

4.1.1 General information:

When in doubt or if symptoms are observed, get medical advice (show safety data sheet if possible).

4.1.2 Following inhalation:

Provide fresh air.

4.1.3 Following skin contact:

After contact with skin, wash immediately with plenty of water.

4.1.4 Following eye contact:

In case of contact with eyes flush immediately with plenty water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

4.1.5 Following ingestion:

Never pour anything into the mouth if an unconscious person!
Rinse mouth immediately and drink plenty of water. When in doubt or if symptoms are observed, get medical advice.

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.

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media:
water spray jet, alcohol resistant foam, dry extinguishing powder or carbon dioxide (CO₂).

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The components of product itself are not combustible; Fire extinguishing method of surrounding areas must be discussed.

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

5.3 ADVICE FOR FIREFIGHTERS

In case of combustion wear a suitable respirator and special protective clothing if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protection equipment. Do not inhale vapours/ fumes/ gases. Provide adequate ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Do not allow to enter into surface water, soil or drains.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Soak up inert absorbent and dispose as waste. Collect in closed and suitable containers for disposal.

6.4 REFERENCE TO OTHER SECTIONS

Personal protection equipment see under section 8.

See section 13 for waste disposal information.

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING


When using do not eat, drink and smoke. Wash hand before breaks and after work. Used working clothes should not be worn outside the working area.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a cool dry place. Containers which are opened must be carefully resealed and store upright.

The recommended storage temperature: 2-8 °C

Storage category: 12 (non-combustible liquids)
stored separately from: class 1 (explosive hazardous substances)
class 4.1A (other potentially explosive hazardous substances)
class 4.3 (hazardous substances that release flammable gases when in contact with water)
class 6.2 (infectious substances)
class 7 (radioactive substances)

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Further information: Store far from foodstuffs.
Protect from unauthorised access.

7.3 SPECIFIC END USE(S)

Use only in accordance to the manual and instructions for use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

EINECS	substance	TRGS 900-MAK-values	TRGS 903-BGW-values
212-828-1	N-Methyl-2-pyrrolidone	82 mg/m ³	150 mg/l (urine at the end of a shift) parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 EXPOSURE CONTROLS

Please follow the usual instructions when dealing with chemicals.
Pregnant women should strictly avoid inhalation or skin contact.

Personal protective equipment

Eye/face protection: use safety glasses with side shields according to EN 166 (EC), NIOSH (US).

Skin protection: use safety gloves made of nitrile (thickness min. 0.28 mm, AQL1,5) or natural latex (thickness min. 0.22 mm, AQL 1,5) as per EN 374

Body protection: personal protective equipment must comply with the requirements of the specified standards appropriate for chemical hazards.

Respiratory protection: not required, if handled according to the intended use. 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: Do not allow to enter into surface water, soil or 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
Sample diluent	liquid product	pink	odourless
Conjugate solution	liquid product	red	odourless
Standard solutions	liquid product	pink	odourless
Substrate solution	liquid product	colourless	characteristic
Stop 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
Sample diluent	7.3 – 7.5	102 °C	not applicable	non
Conjugate solution	7.3 – 7.5	102 °C	not applicable	non
Standard solutions	7.3 – 7.5	102 °C	not applicable	non
Substrate solution	3.6 – 3.8	102 °C	not applicable	non
Stop solution	1	103 °C	not applicable	non

component	oxidising properties	vapour pressure	relative density
Wash buffer	non	not measured	1.11 g/ml
Sample diluent	non	not measured	1.0026 g/ml
Conjugate solution	non	not measured	1.017 g/ml
Standard solutions	non	not measured	1.0026 g/ml
Substrate solution	non	not measured	1.003 g/ml
Stop 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
Sample diluent	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 solutions	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Substrate solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Stop 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

If the products are used according to the instructions, 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 products).
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 products).
The stop solution may be corrosive to metals.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Dangerous decomposition products are not known.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS


Acute Toxicity: Quantitative data on the toxicity of the mixture are not available.

(a) acute toxicity

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD ₅₀ (oral)	3514 mg/kg	rat
	LC ₅₀ (inhalativ)	>5,1 mg/l	rat
Mixture of: 5-chloro-2- methyl-4- isothiazolin-3-one and 2-methyl-2H - isothiazol-3- one	LD ₅₀ (oral)	457 mg/kg	rat
	LC ₅₀ (inhalativ)	>1,23 mg/l	rat

(b) skin corrosion/irritation

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD ₅₀ (dermal)	8000 mg/kg	rabbit
Mixture of: 5-chloro-2- methyl-4- isothiazolin-3-one and 2-methyl-2H - isothiazol-3- one	(dermal)	in concentrations >0,75%	rabbit

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Risk of skin resorption (substrate, conjugate solution).

May cause an allergic skin reaction (sample diluent, conjugate, standards and controls)

(c) serious eye damage/irritation

Irritation effect (stop solution).

(d) respiratory or skin sensitization

No information available.

(e) germ cell mutagenicity

No information available.

(f) carcinogenicity

No information available.

(g) reproductive toxicity

For substrate and conjugate solution: May damage the unborn child: N-Methyl-2-pyrrolidone; Repr. 1B

(h) STOT-single exposure

For substrate and conjugate solution: May cause respiratory irritation.

Other components: No specific target organ toxicant, because no component is known as specific target organ toxicant.

(i) STOT-repeated exposure

No specific target organ toxicant, repeated exposure.

(j) aspiration hazard

No information available.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

N-Methyl-2-pyrrolidone:

species	valuation	value
bluegill (<i>Lepomis macrochirus</i>)	LC ₅₀ (mg/l/96h)	832
gold orfe (<i>Leuciscus idus</i>)	LC ₅₀ (mg/l/96h)	> 500
green alga (<i>Desmodesmus subspicatus</i>)	IC ₅₀ (mg/l/72h)	> 500
invertebrates (<i>Daphnia magna</i>)	EC ₅₀ (mg/l/48h)	4897

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-on and 2-Methyl-2H-isothiazol-3-on:

species	valuation	value
rainbow trout	LC ₅₀ (mg/l/96h)	0.19
green alga	IC ₅₀ (mg/l/72h)	0.027
invertebrates (<i>Daphnia magna</i>)	EC ₅₀ (mg/l/48h)	0.16

12.2 PERSISTENCE AND DEGRADABILITY

substance	value	evaluation
N-Methyl-2-pyrrolidone	> 90%/20d	easily biologically degradable
Mixture of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one	< 50%/10d	not easily biodegradable

12.3 BIOACCUMULATIVE POTENTIAL

N-Methyl-2-pyrrolidone	log P(o/w): ≤ 4	there is no Bioaccumulation expected.
Mixture of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3- one	log P(o/w): = 0,401	there is 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.

Do not allow to enter into surface water, soil or drains.

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

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Products:

Disposal should be made in accordance with national and local regulations and laws.

Packaging:

Emptied packaging can be given to local recycling or waste disposal.

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

IMDG: 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.

Reference:

ADR: limited quantities LQ:
excepted quantities EQ


5 L
Code E1

maximum net quantity per inner packaging: 30 ml
maximum net quantity per outer packaging: 1000 ml

IMDG: limited quantities LQ
excepted quantities EQ

5 L
Code E1

maximum net quantity per inner packaging: 30 ml
maximum net quantity per outer packaging: 1000 ml

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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) 1907/2006 in the current version.

Water endangering class according to VwVwS (Germany): Water endangering class 1.

Employment limitations:

Reference is made to the restrictions of employment specified in the Youth Employment Act and the Maternity Protection Act.

Other regulations, limitations and prohibitive regulations:

Substance of very high concern (SVHC) according (EC) 1907/2006 (REACH), Artikel 57: N-Methyl-2-pyrrolidone (CAS 872-50-4)

15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

16. OTHER INFORMATION

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

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

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.

A newly created safety data sheet