

Seramun® Wash buffer B

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Seramun® Wash buffer B
Article number: WB-002-01
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

QC ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreehagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
E-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

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Labelling of packages where the contents do not exceed 125 ml
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2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.
Remove contact lenses, if present and easy to do. Continue rinsing.

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After ingestion

Rinse mouth thoroughly with water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Foam
Dry extinguishing powder
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated:
Carbon monoxide
Carbon dioxide (CO₂)
Nitrogen oxides (NO_x)
Ambient fire may liberate hazardous vapours.

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Use personal protection equipment.

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Take up mechanically.

For cleaning up

Wipe up with absorbent material (eg. cloth, fleece).

Other information

Wipe up with absorbent material (eg. cloth, fleece). Wash with plenty of water.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling

Observe instructions for use.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.

Wash hands before breaks and after work.

Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Keep cool.

Keep/Store only in original container.

Never return spills in original containers for re-use.

Hints on joint storage

Keep away from: Food and feedingstuffs

Further information on storage conditions

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

QC ELISA

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
7647-01-0	Hydrogen chloride	5	8		TWA (8 h)	
		10	15		STEL (15 min)	

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye protection: not required.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing.

Respiratory protection

Usually no personal respiratory protection necessary.

Thermal hazards

No special handling advices are necessary.

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Environmental exposure controls
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	odourless

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	120 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value (at 20 °C):	7.3-7.5 Experimental data
Viscosity / kinematic:	not determined
Water solubility: (at 20 °C)	completely miscible

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not applicable
Vapour pressure: (at 20 °C)	not determined
Vapour pressure: (at 50 °C)	not determined
Density (at 20 °C):	1.1100 g/cm³ Experimental data
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
The product is not: oxidising.

Other safety characteristics

Solid content:	not applicable
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Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

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10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

No information available.

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

12.2. Persistence and degradability

Part of the components is biodegradable.

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12.3. Bioaccumulative potential

On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

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14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation)

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intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Seramun® Sample diluent J

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Seramun® Sample diluent J
Article number: DIL-010-01
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

QC ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreehagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
E-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Sens. 1; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing.
P302+P352 IF ON SKIN: Wash with plenty of Water and soap.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Pictograms:



Seramun® Sample diluent J

Hazard statements

H317-H412

Precautionary statements

P280-P302+P352-P333+P313

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
-	hydrochloric acid ... %			< 0.1 %
	231-595-7	017-002-01-X		
	Skin Corr. 1B, STOT SE 3; H314 H335			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			<0.06 %
	-	613-167-00-5	01-2120764691-48	
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
-	231-595-7	hydrochloric acid ... %	< 0.1 %
		Skin Corr. 1B; H314: >= 25 - 100 Skin Irrit. 2; H315: >= 10 - < 25 Eye Irrit. 2; H319: >= 10 - < 25 STOT SE 3; H335: >= 10 - 100	
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	<0.06 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: LC50 = 0.171 mg/l (dusts or mists); dermal: LD50 = 87.12 mg/kg; oral: LD50 = 64 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=100	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

Remove contact lenses, if present and easy to do. Continue rinsing.

Seramun® Sample diluent J**After ingestion**

Rinse mouth thoroughly with water.
Let water be drunk in little sips (dilution effect).

4.2. Most important symptoms and effects, both acute and delayed

Allergic reactions

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Foam
Dry extinguishing powder
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated:
Carbon monoxide
Carbon dioxide (CO₂)
Nitrogen oxides (NO_x)
Ambient fire may liberate hazardous vapours.

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Use personal protection equipment.

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up**For containment**

Take up mechanically.

For cleaning up

Wipe up with absorbent material (eg. cloth, fleece).

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Seramun® Sample diluent J

Advice on safe handling

Observe instructions for use.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.

Wash hands before breaks and after work.

Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Keep cool.

Keep/Store only in original container.

Never return spills in original containers for re-use.

Hints on joint storage

Keep away from: Food and feedingstuffs

Further information on storage conditions

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

QC ELISA

Restricted to professional users.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
7647-01-0	Hydrogen chloride	5	8		TWA (8 h)	
		10	15		STEL (15 min)	

DNEL/DMEL values

CAS No	Name of agent	Exposure route	Effect	Value
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
Worker DNEL, long-term		inhalation	systemic	0.02 mg/m ³
Worker DNEL, acute		inhalation	systemic	0.04 mg/m ³

PNEC values

CAS No	Name of agent	Value
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	
Freshwater		3.39 mg/kg
Marine water		3.39 mg/kg
Freshwater sediment		0.027 mg/kg
Marine sediment		0.027 mg/kg
Micro-organisms in sewage treatment plants (STP)		0.23 mg/l
Soil		0.01 mg/kg

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection. Eye glasses Eye glasses with side protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing.

Respiratory protection

Usually no personal respiratory protection necessary.

Thermal hazards

No special handling advices are necessary.

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	pink-red
Odour:	characteristic

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	380 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value (at 20 °C):	7.3-7.5 Experimental data
Viscosity / kinematic:	not determined

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Water solubility: (at 20 °C)	completely miscible
Solubility in other solvents not determined	
Partition coefficient n-octanol/water:	not applicable
Vapour pressure: (at 20 °C)	not determined
Vapour pressure: (at 50 °C)	not determined
Density (at 20 °C):	1.0240 g/cm ³ Experimental data
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
The product is not: oxidising.

Other safety characteristics

Solid content: not determined

Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Seramun® Sample diluent J

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	LD50 64 mg/kg	Rat	European Chemicals Agency	OECD 401
	dermal	LD50 87.12 mg/kg	Rabbit	European Chemicals Agency	OECD 402
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) dust/mist	LC50 0.171 mg/l	Rat	European Chemicals Agency	OECD 403

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

No information available.

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Seramun® Sample diluent J

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
-	hydrochloric acid ... %					
	Acute fish toxicity	LC50 862 mg/l	96 h	Leuciscus idus		
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)					
	Acute fish toxicity	LC50 0.19 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	European Chemicals Agency	EPA OPP 72-1
	Acute algae toxicity	ErC50 0.0052 mg/l	72 h	Skeletonema costatum	European Chemicals Agency	OECD 201
	Acute crustacea toxicity	EC50 0.10 mg/l	48 h	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Fish toxicity	NOEC 0.02 mg/l	38 d	Danio rerio (zebrafish)	European Chemicals Agency	OECD 210
	Algae toxicity	NOEC 0.00049 mg/l	2 d	Skeletonema costatum	European Chemicals Agency	OECD 201
	Crustacea toxicity	NOEC 0.0036 mg/l	21 d	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Acute bacteria toxicity	(EC50 0.91 mg/l)	3 h	Activated sludge	European Chemicals Agency	OECD 209

12.2. Persistence and degradability

Part of the components is biodegradable.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
	OECD 301B	<50 %	28	European Chemicals Agency
	Part of the components is biodegradable.			

12.3. Bioaccumulative potential

On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.401

BCF

CAS No	Chemical name	BCF	Species	Source
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.12	Lepomis macrochirus (Bluegill)	European Chemicals Agency

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

Seramun® Sample diluent J

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU
(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

3 - highly hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Seramun® Sample diluent J

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control
Article number: KST-1-108-3001 (STD 1)
KST-1-108-3002 (STD 2)
KST-1-108-3003 (STD 3)
KST-1-108-3004 (STD 4)
KST-1-108-3005 (STD 5)
KST-1-108-3006 (STD 6)
KST-1-108-3007 (STD 7)
KST-1-108-1001 (CONTROL)
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

QC ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreehagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
E-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Sens. 1A; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Labelling of packages where the contents do not exceed 125 ml

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

Signal word: Warning
Pictograms:



Hazard statements

H317-H412

Precautionary statements

P280-P302+P352-P333+P313

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			<0.06 %
	-	613-167-00-5	01-2120764691-48	
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	<0.06 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: LC50 = 0.171 mg/l (dusts or mists); dermal: LD50 = 87.12 mg/kg; oral: LD50 = 64 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=100	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

Remove contact lenses, if present and easy to do. Continue rinsing.

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

After ingestion

Rinse mouth thoroughly with water.
Let water be drunken in little sips (dilution effect).

4.2. Most important symptoms and effects, both acute and delayed

Allergic reactions

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Foam
Dry extinguishing powder
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated:
Carbon monoxide
Carbon dioxide (CO₂)

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Take up mechanically.

For cleaning up

Wipe up with absorbent material (eg. cloth, fleece).

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe instructions for use.

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Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.

Wash hands before breaks and after work.

Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Keep cool.

Keep/Store only in original container.

Never return spills in original containers for re-use.

Hints on joint storage

Keep away from: Food and feedingstuffs

Further information on storage conditions

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

QC ELISA

Restricted to professional users.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Name of agent			
DNEL type		Exposure route	Effect	Value
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
Worker DNEL, long-term		inhalation	systemic	0.02 mg/m³
Worker DNEL, acute		inhalation	systemic	0.04 mg/m³

PNEC values

CAS No	Name of agent		
Environmental compartment	Value		
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)		
Freshwater	3.39 mg/kg		
Marine water	3.39 mg/kg		
Freshwater sediment	0.027 mg/kg		
Marine sediment	0.027 mg/kg		
Micro-organisms in sewage treatment plants (STP)	0.23 mg/l		
Soil	0.01 mg/kg		

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

Eye/face protection

Eye protection: not required.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing

Respiratory protection

Usually no personal respirative protection necessary.

Thermal hazards

No special handling advices are necessary.

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	pink-red
Odour:	characteristic

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	380 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value (at 20 °C):	7.3-7.5 Experimental data
Viscosity / kinematic:	not determined
Water solubility: (at 20 °C)	completely miscible

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not applicable
Vapour pressure: (at 20 °C)	not determined

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Vapour pressure: (at 50 °C)	not determined
Density (at 20 °C):	1.0027 g/cm ³ Experimental data
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
The product is not: oxidising.

Other safety characteristics

Solid content: not determined

Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	LD50 64 mg/kg	Rat	European Chemicals Agency	OECD 401
	dermal	LD50 87.12 mg/kg	Rabbit	European Chemicals Agency	OECD 402
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) dust/mist	LC50 0.171 mg/l	Rat	European Chemicals Agency	OECD 403

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

No information available.

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)					
	Acute fish toxicity	LC50 0.19 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	European Chemicals Agency	EPA OPP 72-1
	Acute algae toxicity	ErC50 0.0052 mg/l	72 h	Skeletonema costatum	European Chemicals Agency	OECD 201
	Acute crustacea toxicity	EC50 0.10 mg/l	48 h	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Fish toxicity	NOEC 0.02 mg/l	38 d	Danio rerio (zebrafish)	European Chemicals Agency	OECD 210
	Algae toxicity	NOEC 0.00049 mg/l	2 d	Skeletonema costatum	European Chemicals Agency	OECD 201
	Crustacea toxicity	NOEC 0.0036 mg/l	21 d	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Acute bacteria toxicity	(EC50 0.91 mg/l)	3 h	Activated sludge	European Chemicals Agency	OECD 209

12.2. Persistence and degradability

Part of the components is biodegradable.

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
	OECD 301B	<50 %	28	European Chemicals Agency
	Part of the components is biodegradable.			

12.3. Bioaccumulative potential

On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.401

BCF

CAS No	Chemical name	BCF	Species	Source
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.12	Lepomis macrochirus (Bluegill)	European Chemicals Agency

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

Serazym® Bovine Serum Albumin (BSA) sensitive Standards and Control

UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Sens. 1A; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate
Article number: KJG-1-108-0001
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

QC ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreehagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
E-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Sens. 1; H317
Repr. 1B; H360D
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

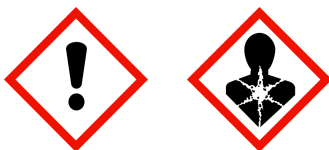
Regulation (EC) No 1272/2008

Hazard components for labelling

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Signal word: Danger

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P501 Dispose of contents/container to in accordance with local regulations.

Special labelling of certain mixtures

Restricted to professional users.

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

Pictograms:



Hazard statements

H317-H360D-H412

Precautionary statements

P280-P308+P313-P501

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			1 - < 3 %
	212-828-1	606-021-00-7		
	Repr. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H360D H315 H319 H335			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			<0.06 %
	-	613-167-00-5	01-2120764691-48	
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
872-50-4	212-828-1	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	1 - < 3 %
		dermal: LD50 = 8000 mg/kg; oral: LD50 = 3600 mg/kg STOT SE 3; H335: >= 10 - 100	
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	<0.06 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: LC50 = 0.171 mg/l (dusts or mists); dermal: LD50 = 87.12 mg/kg; oral: LD50 = 64 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=100	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.
Remove contact lenses, if present and easy to do. Continue rinsing.

After ingestion

Rinse mouth thoroughly with water.
Let water be drunken in little sips (dilution effect).

4.2. Most important symptoms and effects, both acute and delayed

Allergic reactions

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Foam
Dry extinguishing powder
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated:
Carbon monoxide
Carbon dioxide (CO₂)
Nitrogen oxides (NO_x)

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation.
Do not breathe gas/fumes/vapour/spray.
Avoid contact with skin, eyes and clothes.
Use personal protection equipment.

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Take up mechanically.

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

- Observe instructions for use.
- If handled uncovered, arrangements with local exhaust ventilation have to be used.
- Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

- No special fire protection measures are necessary.

Advice on general occupational hygiene

- When using do not eat, drink, smoke, sniff.
- Wash hands before breaks and after work.
- Take off contaminated clothing.

Further information on handling

- Use only in accordance with instructions for use.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

- Keep container tightly closed.
- Keep cool.
- Keep/Store only in original container.
- Never return spills in original containers for re-use.
- Keep locked up.
- Store in a place accessible by authorized persons only.
- Provide adequate ventilation as well as local exhaustion at critical locations.

Hints on joint storage

- Keep away from: Food and feedingstuffs

Further information on storage conditions

- storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

- QC ELISA
- Restricted to professional users.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
872-50-4	n-Methyl-2-pyrrolidone	10	40		TWA (8 h)	
		20	80		STEL (15 min)	

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

DNEL/DNEL values

CAS No	Name of agent	Exposure route	Effect	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			
Worker DNEL, long-term		inhalation	systemic	14,4 mg/m³
Worker DNEL, long-term		inhalation	local	40,0 mg/m³
Worker DNEL, long-term		dermal	systemic	4,8 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	3,6 mg/m³
Consumer DNEL, long-term		inhalation	local	4,5 mg/m³
Consumer DNEL, long-term		dermal	systemic	2,5 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,85 mg/kg bw/day
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
Worker DNEL, long-term		inhalation	systemic	0.02 mg/m³
Worker DNEL, acute		inhalation	systemic	0.04 mg/m³

PNEC values

CAS No	Name of agent	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	
Freshwater		0,25 mg/l
Freshwater (intermittent releases)		5 mg/l
Marine water		0,025 mg/l
Freshwater sediment		1,09 mg/kg
Marine sediment		0,109 mg/kg
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	
Freshwater		3.39 mg/kg
Marine water		3.39 mg/kg
Freshwater sediment		0.027 mg/kg
Marine sediment		0.027 mg/kg
Micro-organisms in sewage treatment plants (STP)		0.23 mg/l
Soil		0.01 mg/kg

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

Suitable material: NBR (Nitrile rubber)
Thickness of the glove material ≥ 0.4 mm
Breakthrough time: > 480 min
Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Thermal hazards

No special handling advices are necessary.

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	red
Odour:	characteristic

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	380 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value (at 20 °C):	6.5-7.1 Experimental data
Viscosity / kinematic:	not determined
Water solubility: (at 20 °C)	completely miscible

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not applicable
Vapour pressure: (at 20 °C)	not determined
Vapour pressure: (at 50 °C)	not determined
Density (at 20 °C):	1.020 g/cm ³ Experimental data
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Solid content:

not determined

Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone				
	oral	LD50 3600 mg/kg	Rat	IUCLID	
	dermal	LD50 8000 mg/kg	Rabbit	IUCLID	
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	LD50 64 mg/kg	Rat	European Chemicals Agency	OECD 401
	dermal	LD50 87.12 mg/kg	Rabbit	European Chemicals Agency	OECD 402
	inhalation vapour	ATE 0.5 mg/l			
	inhalation (4 h) dust/mist	LC50 0.171 mg/l	Rat	European Chemicals Agency	OECD 403

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

May cause an allergic skin reaction. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))

Carcinogenic/mutagenic/toxic effects for reproduction

May damage the unborn child. (N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone)
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone H: skin resorptive

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone					
	Acute fish toxicity	LC50 832 mg/l	96 h	Lepomis macrochirus	IUCLID	
	Acute algae toxicity	ErC50 > 500 mg/l	72 h	Scenedesmus subspicatus	IUCLID	
	Acute crustacea toxicity	EC50 ca. 4897 mg/l	48 h	Daphnia magna	IUCLID	
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)					
	Acute fish toxicity	LC50 0.19 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	European Chemicals Agency	EPA OPP 72-1
	Acute algae toxicity	ErC50 0.0052 mg/l	72 h	Skeletonema costatum	European Chemicals Agency	OECD 201
	Acute crustacea toxicity	EC50 0.10 mg/l	48 h	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Fish toxicity	NOEC 0.02 mg/l	38 d	Danio rerio (zebrafish)	European Chemicals Agency	OECD 210
	Algae toxicity	NOEC 0.00049 mg/l	2 d	Skeletonema costatum	European Chemicals Agency	OECD 201
	Crustacea toxicity	NOEC 0.0036 mg/l	21 d	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Acute bacteria toxicity	(EC50 0.91 mg/l)	3 h	Activated sludge	European Chemicals Agency	OECD 209

12.2. Persistence and degradability

Part of the components is biodegradable.

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			
	OECD 301B	<50 %	28	European Chemicals Agency
	Part of the components is biodegradable.			

12.3. Bioaccumulative potential

On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	-0,54 (25° C)
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.401

BCF

CAS No	Chemical name	BCF	Species	Source
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.12	Lepomis macrochirus (Bluegill)	European Chemicals Agency

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160508 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 30, Entry 75

Information according to 2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

3 - highly hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,15.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Repr. 1B; H360D	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H310	Fatal 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.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Serazym® Bovine Serum Albumin (BSA) sensitive Conjugate

EUH071 Corrosive to the respiratory tract.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

SeramunBlau® fast

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: SeramunBlau® fast
Article number: SUB-002-01
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

QC ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Sprenhagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
E-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Repr. 1B; H360D

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Signal word: Danger

Pictograms:



Hazard statements

H360D May damage the unborn child.

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/protective clothing/eye protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P501 Dispose of contents/container to in accordance with local regulations.

Special labelling of certain mixtures

Restricted to professional users.

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Pictograms:



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Hazard statements

H360D

Precautionary statements

P202-P280-P308+P313-P501

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			5 - < 10 %
	212-828-1	606-021-00-7		
	Repr. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H360D H315 H319 H335			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
872-50-4	212-828-1	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	5 - < 10 %
		dermal: LD50 = 8000 mg/kg; oral: LD50 = 3600 mg/kg STOT SE 3; H335: >= 10 - 100	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

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

Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

Remove contact lenses, if present and easy to do. Continue rinsing.

After ingestion

Rinse mouth thoroughly with water.

Let water be drunken in little sips (dilution effect).

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

SeramunBlau® fast**Suitable extinguishing media**

Foam
Dry extinguishing powder
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated:
Carbon monoxide
Carbon dioxide (CO₂)
Nitrogen oxides (NO_x)

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.
In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Provide adequate ventilation.
Do not breathe gas/fumes/vapour/spray.
Avoid contact with skin, eyes and clothes.
Use personal protection equipment.

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up**For containment**

Take up mechanically.

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Observe instructions for use.
If handled uncovered, arrangements with local exhaust ventilation have to be used.
Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.
Wash hands before breaks and after work.

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Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

- Keep container tightly closed.
- Keep cool. Protect from sunlight.
- Keep/Store only in original container.
- Never return spills in original containers for re-use.
- Keep locked up.
- Store in a place accessible by authorized persons only.
- Provide adequate ventilation as well as local exhaust at critical locations.

Hints on joint storage

Keep away from: Food and feedingstuffs

Further information on storage conditions

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

- QC ELISA
- Restricted to professional users.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
872-50-4	n-Methyl-2-pyrrolidone	10	40		TWA (8 h)	
		20	80		STEL (15 min)	

DNEL/DMEL values

CAS No	Name of agent	Exposure route	Effect	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			
Worker DNEL, long-term		inhalation	systemic	14,4 mg/m³
Worker DNEL, long-term		inhalation	local	40,0 mg/m³
Worker DNEL, long-term		dermal	systemic	4,8 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	3,6 mg/m³
Consumer DNEL, long-term		inhalation	local	4,5 mg/m³
Consumer DNEL, long-term		dermal	systemic	2,5 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,85 mg/kg bw/day

PNEC values

CAS No	Name of agent	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	
Freshwater		0,25 mg/l
Freshwater (intermittent releases)		5 mg/l
Marine water		0,025 mg/l
Freshwater sediment		1,09 mg/kg
Marine sediment		0,109 mg/kg

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection. Eye glasses with side protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Thermal hazards

No special handling advices are necessary.

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless-pale blue
Odour:	characteristic

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	91 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined

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pH-Value (at 25 °C):	3.5-4.0	Experimental data
Viscosity / kinematic:	not determined	
Water solubility: (at 20 °C)	completely miscible	
Solubility in other solvents not determined		
Partition coefficient n-octanol/water:	not applicable	
Vapour pressure: (at 20 °C)	not determined	
Vapour pressure: (at 50 °C)	not determined	
Density (at 20 °C):	1.0030 g/cm³	Experimental data
Relative vapour density:	not determined	
Particle characteristics:	not applicable	

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
The product is not: oxidising.

Other safety characteristics

Solid content: not applicable

Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.
Protect from sunlight.

10.5. Incompatible materials

metals
Oxidising agent

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone				
	oral	LD50 mg/kg 3600	Rat	IUCLID	
	dermal	LD50 mg/kg 8000	Rabbit	IUCLID	

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

May damage the unborn child. (N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone H: skin resorptive

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone					
	Acute fish toxicity	LC50 832 mg/l	96 h	Lepomis macrochirus	IUCLID	
	Acute algae toxicity	ErC50 mg/l > 500	72 h	Scenedesmus subspicatus	IUCLID	
	Acute crustacea toxicity	EC50 mg/l ca. 4897	48 h	Daphnia magna	IUCLID	

12.2. Persistence and degradability

Biodegradable.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

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Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	-0,54 (25° C)

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160508 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 30, Entry 75

2010/75/EU (VOC): 5,15 % (51,655 g/l)

2004/42/EC (VOC): 5,15 % (51,655 g/l)

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,15.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

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EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Repr. 1B; H360D	Calculation method

Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

SeramunBlau® stop

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: SeramunBlau® stop
Article number: STO-001-01
REACH Registration Number: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

ELISA
Restricted to professional users.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreehagener Str. 1
Place: D-15754 Heidesee
Telephone: +49 33767 791-10
e-mail: quality@seramun.com

1.4. Emergency telephone number: +49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Met. Corr. 1; H290

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

sulphuric acid 2.5 %

Signal word: Warning

Pictograms:



Hazard statements

H290 May be corrosive to metals.

Labelling of packages where the contents do not exceed 125 ml

-

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

SeramunBlau® stop

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
7664-93-9	sulphuric acid			1 - < 3 %
	231-639-5	016-020-00-8		
	Met. Corr. 1, Skin Corr. 1A; H290 H314			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
7664-93-9	231-639-5	sulphuric acid	1 - < 3 %
	inhalation: LC50 = 0.375 mg/l (dusts or mists); oral: LD50 = 2140 mg/kg Skin Corr. 1A; H314: >= 15 - 100 Skin Irrit. 2; H315: >= 5 - < 15 Eye Irrit. 2; H319: >= 5 - < 15		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Water mist
Water spray
Dry extinguishing powder
Carbon dioxide (CO2)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable. In case of fire may be liberated:
Sulphur oxides

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Provide adequate ventilation.
Do not breathe gas/fumes/vapour/spray.
Avoid contact with skin, eyes and clothes.
Use personal protection equipment.

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

Use personal protective equipment as required.

6.2. Environmental precautions

No special environmental measures are necessary.

6.3. Methods and material for containment and cleaning up**For containment**

Take up mechanically.

For cleaning up

Wipe up with absorbent material (eg. cloth, fleece).

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Observe instructions for use.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.
Wash hands before breaks and after work.
Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.
Keep cool.
Keep/Store only in original container.
Never return spills in original containers for re-use.
Unsuitable container/equipment material: Metal.

Hints on joint storage

Keep away from: Food and feedingstuffs

Further information on storage conditions

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

ELISA
Restricted to professional users.

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
7664-93-9	Sulphuric acid (mist)	-	0.05		TWA (8 h)	

DNEL/DMEL values

CAS No	Name of agent			
DNEL type	Exposure route	Effect	Value	
7664-93-9	sulphuric acid			
Worker DNEL, long-term	inhalation	local	0.05 mg/m ³	
Worker DNEL, acute	inhalation	local	0.1 mg/m ³	

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye protection: not required.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing

Respiratory protection

Usually no personal respirative protection necessary.

Thermal hazards

No special handling advices are necessary.

Environmental exposure controls

No special environmental measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	odourless

Test method

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C Calculation method.
Flash point:	120 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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SeramunBlau® stop

Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature: not determined

Decomposition temperature: not determined

pH-Value (at 20 °C): 1 Experimental data

Viscosity / kinematic: not determined

Water solubility:
(at 20 °C) completely miscible

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not applicable

Vapour pressure: not determined

Vapour pressure: not determined

Density (at 20 °C): 1.02 g/cm³ Experimental data

Relative vapour density: not determined

Particle characteristics: not applicable

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Solid content: not applicable

Further Information

No known hazardous decomposition products.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

Corrosive to metals.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

metals

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

SeramunBlau® stop

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7664-93-9	sulphuric acid				
	oral	LD50 mg/kg 2140	Rat	European Chemicals Agency	OECD 401
	inhalation (4 h) dust/mist	LC50 mg/l 0.375	Rat	European Chemicals Agency	OECD 403

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

No information available.

Additional information on tests

There are no data available on the preparation/mixture itself.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
7664-93-9	sulphuric acid					
	Acute fish toxicity	LC50 >16 mg/l	96 h	Lepomis macrochirus (Bluegill)	European Chemicals Agency	
	Acute algae toxicity	ErC50 100 mg/l	72 h	Desmodesmus subspicatus	European Chemicals Agency	OECD 201
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia magna (Big water flea)	European Chemicals Agency	OECD 202
	Algae toxicity	NOEC 100 mg/l	3 d	Desmodesmus subspicatus	European Chemicals Agency	OECD 201

12.2. Persistence and degradability

The single components are biodegradable.

12.3. Bioaccumulative potential

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Does not bioaccumulate.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

060199 WASTES FROM INORGANIC CHEMICAL PROCESSES; wastes from the manufacture, formulation, supply and use (MFSU) of acids; wastes not otherwise specified

List of Wastes Code - used product

060199 WASTES FROM INORGANIC CHEMICAL PROCESSES; wastes from the manufacture, formulation, supply and use (MFSU) of acids; wastes not otherwise specified

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

UN 3264

14.2. UN proper shipping name:

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)

14.3. Transport hazard class(es):

8

14.4. Packing group:

III

Hazard label:

8



Classification code:

C1

Special Provisions:

274

Limited quantity:

5 L

Excepted quantity:

E1

Transport category:

3

Hazard No:

80

Tunnel restriction code:

E

Inland waterways transport (ADN)

14.1. UN number or ID number:

UN 3264

14.2. UN proper shipping name:

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)

14.3. Transport hazard class(es):

8

14.4. Packing group:

III

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Hazard label: 8



Classification code: C1
 Special Provisions: 274
 Limited quantity: 5 L
 Excepted quantity: E1

Marine transport (IMDG)

14.1. UN number or ID number: UN 3264
14.2. UN proper shipping name: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)
14.3. Transport hazard class(es): 8
14.4. Packing group: III
 Hazard label: 8



Special Provisions: 223, 274
 Limited quantity: 5 L
 Excepted quantity: E1
 EmS: F-A, S-B
 Segregation group: 1 - acids

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 3264
14.2. UN proper shipping name: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)
14.3. Transport hazard class(es): 8
14.4. Packing group: III
 Hazard label: 8



Special Provisions: A3 A803
 Limited quantity Passenger: 1 L
 Passenger LQ: Y841
 Excepted quantity: E1
 IATA-packing instructions - Passenger: 852
 IATA-max. quantity - Passenger: 5 L
 IATA-packing instructions - Cargo: 856
 IATA-max. quantity - Cargo: 60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

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National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,4,5,6,7,8,9,10,11,12,13,14,16.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant H and EUH statements (number and full text)

H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible

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for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)