

Seramun® Wash and Incubation Buffer (5x)

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

1.1. Product identifier

Product name: Seramun® Wash and Incubation Buffer (5x)
Article number: LSG-0-000-4255
REACH Registration Number: not applicable

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

Use of the substance/mixture

For use in in vitro test systems.
Restricted to professional users.

Uses advised against

None identified.

1.3. Details of the supplier of the safety data sheet

Company name: Seramun Diagnostica GmbH
Street: Spreenhagener 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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Regulation (EC) No 1272/2008

Special labelling of certain mixtures

EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
EUH210 Safety data sheet available on request.

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

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)			<0.0015 %
	-	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.

Seramun® Wash and Incubation Buffer (5x)

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)	<0.0015 %
		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 M acute; H400: M=100 M chron.; 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.

If skin irritation occurs: Get medical advice/attention.

After contact with eyes

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

After ingestion

Rinse mouth thoroughly with water.

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.

Seramun® Wash and Incubation Buffer (5x)

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.

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)

For use in in vitro test systems.

Restricted to professional users.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Seramun® Wash and Incubation Buffer (5x)

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
64-19-7	Acetic acid	10	25		TWA (8 h)	
		20	50		STEL (15 min)	
7664-38-2	Orthophosphoric acid	-	1		TWA (8 h)	
		-	2		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

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

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:	light yellow-white
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:	120 °C Calculated flash point.

Flammability

Solid/liquid:	not determined
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):	6.2-6.4 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
Density (at 20 °C):	1.1100 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 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.

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

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

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.

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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 ecotoxicological properties of this mixture are determined by the ecotoxicological properties of the single components (see section 3).

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 mg/l	0.19	96 h	Oncorhynchus mykiss (Rainbow trout)	European Chemicals Agency EPA OPP 72-1
	Acute algae toxicity	ErC50 mg/l	0.0052	72 h	Skeletonema costatum	European Chemicals Agency OECD 201
	Acute crustacea toxicity	EC50 mg/l	0.10	48 h	Daphnia magna (Big water flea)	European Chemicals Agency OECD 202
	Fish toxicity	NOEC mg/l	0.02	38 d	Danio rerio (zebrafish)	European Chemicals Agency OECD 210
	Algae toxicity	NOEC mg/l	0.00049	2 d	Skeletonema costatum	European Chemicals Agency OECD 201
	Crustacea toxicity	NOEC mg/l	0.0036	21 d	Daphnia magna (Big water flea)	European Chemicals Agency OECD 202
	Acute bacteria toxicity	(EC50 mg/l)	0.91	3 h	Activated sludge	European Chemicals Agency OECD 209

12.2. Persistence and degradability

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

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.

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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)

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

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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

2010/75/EU (VOC):	0,025 % (0,281 g/l)
2004/42/EC (VOC):	0,025 % (0,281 g/l)
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
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): 1,8,9.

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

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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>
VOC: Volatile Organic Compounds

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.
EUH071	Corrosive to the respiratory tract.
EUH208	Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
EUH210	Safety data sheet available on request.

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.)

Seraline® Anti-Helicobacter-6 IgA Conjugate

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

1.1. Product identifier

Product name: Seraline® Anti-Helicobacter-6 IgA Conjugate
Article number: LIA-007-6 A
REACH Registration Number: not applicable

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

Use of the substance/mixture

For use in in vitro test systems.
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

-

Regulation (EC) No 1272/2008

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

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

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
616-45-5	2-Pyrrolidone			0.3 - < 1 %
	210-483-1		01-2119475471-37	
	Repr. 1B, Eye Irrit. 2; H360 H319			

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

Seraline® Anti-Helicobacter-6 IgA Conjugate

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
616-45-5	210-483-1	2-Pyrrolidone	0.3 - < 1 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg Repr. 1B; H360: >= 3 - 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.

After contact with eyes

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

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

Non-flammable. In case of fire may be liberated:
Carbon dioxide (CO₂)
Carbon monoxide
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

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.

Seraline® Anti-Helicobacter-6 IgA Conjugate

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.

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)

For use in in vitro test systems.

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)	

Seraline® Anti-Helicobacter-6 IgA Conjugate

DNEL/DMEL values

CAS No	Name of agent		
DNEL type	Exposure route	Effect	Value
616-45-5	2-Pyrrolidone		
Worker DNEL, long-term	inhalation	systemic	29.62 mg/m ³
Worker DNEL, long-term	dermal	systemic	4.2 mg/kg bw/day

PNEC values

CAS No	Name of agent	
Environmental compartment	Value	
616-45-5	2-Pyrrolidone	
Freshwater	0.5 mg/l	
Marine water	0.05 mg/l	
Freshwater sediment	0.4205 mg/kg	
Micro-organisms in sewage treatment plants (STP)	10 mg/l	
Soil	0.0612 mg/kg	

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:	violet
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.

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Sublimation point:	not determined
Softening point:	not determined
Flash point:	120 °C Calculated flash point.
Flammability	
Solid/liquid:	not determined
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):	6.5-7.1 Experimental data
Viscosity / dynamic:	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):	1.0179 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 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.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

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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.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
616-45-5	2-Pyrrolidone					
	oral	LD50 >2000 mg/kg		Rat	European Chemicals Agency	OECD 401
	dermal	LD50 >2000 mg/kg		Rabbit	European Chemicals Agency	

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.

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.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
616-45-5	2-Pyrrolidone					
	Acute fish toxicity	LC50 10000 mg/l	96 h	Danio rerio (zebrafish)	European Chemicals Agency	OECD 203
	Acute algae toxicity	ErC50 >500 mg/l	72 h	Desmodesmus subspicatus	European Chemicals Agency	
	Acute crustacea toxicity	EC50 >500 mg/l	48 h	Daphnia magna (Big water flea)	European Chemicals Agency	

12.2. Persistence and degradability

Biodegradable.

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12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
616-45-5	2-Pyrrolidone	-0,71

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.

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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 75

2004/42/EC (VOC): 0 % (0,002 g/l)

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): 1,2,8,9.

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

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(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
VOC: Volatile Organic Compounds
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)

H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.
EUH210	Safety data sheet available on request.

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® prec

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

1.1. Product identifier

Product name: SeramunBlau® prec
Article number: SUB-0-200-0020
REACH Registration Number: not applicable

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

Use of the substance/mixture

For use in in vitro test systems.
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

Regulation (EC) No 1272/2008

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

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

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			0.1 - < 0.3 %
	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.

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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	0.1 - < 0.3 %
		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

Wash with plenty of water.

After contact with eyes

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

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

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

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.

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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. Protect from sunlight.

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)

For use in in vitro test systems.

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
872-50-4	n-Methyl-2-pyrrolidone	10	40		TWA (8 h)	
		20	80		STEL (15 min)	

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DNEL/DMEL values

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

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 - light yellow

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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
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):	4.9-5.3 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):	1.013 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 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.

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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.

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	

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

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 not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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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

The single components are biodegradable.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

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

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.

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<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.
<u>14.5. Environmental hazards</u>	
ENVIRONMENTALLY HAZARDOUS:	No
<u>14.6. Special precautions for user</u>	
No dangerous good in sense of this transport regulation.	
<u>14.7. Maritime transport in bulk according to IMO instruments</u>	
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 30, Entry 75

2010/75/EU (VOC): 0,102 % (1,032 g/l)

2004/42/EC (VOC): 0,102 % (1,032 g/l)

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

(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): 1,8.

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

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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>
VOC: Volatile Organic Compounds

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.
EUH210	Safety data sheet available on request.

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.)