

according to Regulation (EC) No 1907/2006

S-Monovettes Hirudin

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

1.1. Product identifier

S-Monovettes Hirudin

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

Use of the substance/mixture

See instructions for use - SARSTEDT S-Monovette® Blood collection system at www.sarstedt.com.

Uses advised against

See instructions for use - SARSTEDT S-Monovette® Blood collection system at www.sarstedt.com.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: SARSTEDT AG & Co. KG

Street: Sarstedtstraße 1
Place: D-51588 Nümbrecht

Post-office box: 1220

D-51582 Nümbrecht

Telephone: +49 (0)2293 / 305 - 0 Telefax: +49 (0)2293 / 305 - 2470

e-mail: info@sarstedt.com

Contact person: Dr. Daniel Will Telephone: +49 (0)2293 / 305 - 4500

Jochen Hoffmann

e-mail: sicherheitsdatenblatt@sarstedt.com

Internet: www.sarstedt.com
Responsible Department: R & D Center

Supplier

Company name: SARSTEDT Ltd.

Street: Optimus Way, Optimus Point Place: GB-LE3 8JR Leicester

Telephone: +44 (0) 116 235 9023 Telefax: +44 (0) 116 236 6099

e-mail: info.gb@sarstedt.com Internet: www.sarstedt.com

1.4. Emergency telephone Call NHS 111 or a doctor (public). NPIS: 0344 892 0111 (healthcare

<u>number:</u> professionals).

Further Information

All information in this safety data sheet refers to the unused product and its preparation.

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

Additional advice on labelling

none

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures



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Chemical characterization

S-Monovettes Hirudin contain > 525 ATU hirudin / ml blood.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. Get medical advice/attention if you feel unwell.

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 immediately and drink 1 glass of of water. Get medical advice/attention if you feel unwell.

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.

5.2. Special hazards arising from the substance or mixture

In case of fire, the smoke may contain, in addition to the base material, combustion products with not definable toxic and / or irritant compositions. Combustion products may i.a. contain: carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

Wear personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. 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



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Advice on safe handling

Observe the instructions for use and handling. Wear suitable protective gloves when taking blood samples and handling potentially infectious material.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

See instructions for use - SARSTEDT S-Monovette® Blood collection system at www.sarstedt.com.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls





Protective and hygiene measures

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

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. Wear suitable protective gloves when taking blood samples and handling potentially infectious material.

Skin protection

Use of protective clothing.

Respiratory protection

Not required if used as intended.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid
Colour: colourless
Odour: characteristic

pH-Value: not determined

Changes in the physical state

Melting point: not determined
Boiling point or initial boiling point and not determined

boiling range:



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Flash point: not applicable

Flammability

Solid/liquid: not determined
Gas: not applicable

Explosive properties

No data available.

Lower explosion limits:

Upper explosion limits:

not determined

not determined

Auto-ignition temperature:

not determined

Self-ignition temperature

Solid: not determined Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

No data available.

Vapour pressure: not determined

Density: not determined

Water solubility: Preparation soluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

Relative vapour density:

Evaporation rate:

not determined
not determined

9.2. Other information

Solid content: not determined

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

No data available.

10.5. Incompatible materials

No data 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.



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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.

Additional information on tests

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

11.2. Information on other hazards

Endocrine disrupting properties

No data available

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Endocrine disrupting properties

The product has not been tested.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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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Inland waterways transport (ADN)

14.1. UN 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: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: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 information available.

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

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

(SEVESO III):

National regulatory information

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

First issue.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging



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REACH: Registration, Evaluation and Authorization of Chemicals

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

UN: United Nations

DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate 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

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)

EmS: Emergency Schedules MFAG: Medical First Aid Guide

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.)