

**S-Monovette® 4.9 ml IH**

Revision date: 20.07.2021

Art. no. 04.1950.xxx

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

**1.1. Product identifier**

S-Monovette® 4.9 ml IH

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

**Use of the substance/mixture**

For glucose determination.

**Uses advised against**

See instructions for use - SARSTEDT S-Monovette® Blood collection system at [www.sarstedt.com](http://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:	<a href="mailto:info@sarstedt.com">info@sarstedt.com</a>	
Contact person:	Dr. Daniel Will	Telephone: +49 (0)2293 / 305 - 4500
	Jochen Hoffmann	
e-mail:	<a href="mailto:sicherheitsdatenblatt@sarstedt.com">sicherheitsdatenblatt@sarstedt.com</a>	
Internet:	<a href="http://www.sarstedt.com">www.sarstedt.com</a>	
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:	<a href="mailto:info.gb@sarstedt.com">info.gb@sarstedt.com</a>	
Internet:	<a href="http://www.sarstedt.com">www.sarstedt.com</a>	

**1.4. Emergency telephone number:**

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

Hazard categories:

Acute toxicity: Acute Tox. 4

Acute toxicity: Acute Tox. 4

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Resp. Sens. 1

Respiratory or skin sensitisation: Skin Sens. 1

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Harmful if swallowed.

Harmful in contact with skin.

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Harmful if inhaled.  
Causes skin irritation.  
Causes serious eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause an allergic skin reaction.  
May cause respiratory irritation.

**2.2. Label elements**

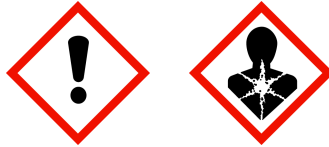
**Regulation (EC) No. 1272/2008**

**Hazard components for labelling**

Iodessigsäure Lithiumsalz  
Lithium heparin

**Signal word:** Danger

**Pictograms:**



**Hazard statements**

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H335 May cause respiratory irritation.

**Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 Wash hands thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
  
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.  
P330 Rinse mouth.  
P302+P352 IF ON SKIN: Wash with plenty of soap and water.  
P312 Call a POISON CENTER/doctor if you feel unwell.  
P333 If skin irritation or rash occurs:  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P312 Call a POISON CENTER/doctor if you feel unwell.  
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337+P313 If eye irritation persists: Get medical advice/attention.

**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**

The product contains up to 27.2 I.U. lithium heparin and up to 1.1 mg lithium iodoacetate per ml nominal volume.

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
65749-30-6	Iodessigsäure Lithiumsalz			70 - < 75 %
	265-905-7			
	Acute Tox. 4, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H332 H312 H302 H315 H319 H335			
9045-22-1	Lithium heparin			10 - < 15 %
	232-681-7			
	Acute Tox. 4, Resp. Sens. 1, Skin Sens. 1; H302 H334 H317			

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	
65749-30-6	265-905-7	Iodessigsäure Lithiumsalz	70 - < 75 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: ATE = 1100 mg/kg; oral: ATE = 500 mg/kg	
9045-22-1	232-681-7	Lithium heparin	10 - < 15 %
		oral: LD50 = 1950 mg/kg	

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

**After inhalation**

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

**After contact with eyes**

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

**After ingestion**

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. The granules can cause a blockage in the stomach and intestinal area. Do not administer laxative. Do not induce vomiting unless instructed by a physician.

**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.

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**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.

**Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**General measures**

Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

**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**

**Advice on safe handling**

Avoid dust formation. Do not breathe dust. 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**

Store light protected. Store in a place accessible by authorized persons only.

**Hints on joint storage**

No special measures are necessary.

**7.3. Specific end use(s)**

For glucose determination.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**8.2. Exposure controls**



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**Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.  
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

**Eye/face protection**

Wear eye 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.

**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 boiling range:	not determined
Flash point:	not applicable

**Flammability**

Solid/liquid:	not determined
Gas:	not applicable

**Explosive properties**

No data available.

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

**Self-ignition temperature**

Solid:	not determined
Gas:	not applicable

Decomposition temperature:	not determined
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**Oxidizing properties**

No data available.

Vapour pressure:	not determined
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Density:	1,135 g/cm <sup>3</sup>
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Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.
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**Solubility in other solvents**

not determined

Partition coefficient n-octanol/water:

not determined

Relative vapour density:

not determined

Evaporation rate:

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**

Avoid high temperatures or direct sunlight.

**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**

Harmful if swallowed.

Harmful in contact with skin.

Harmful if inhaled.

**ATEmix calculated**

ATE (oral) 648,6 mg/kg; ATE (dermal) 1482,7 mg/kg; ATE (inhalation vapour) 14,83 mg/l; ATE (inhalation aerosol) 2,022 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
65749-30-6	Iodessigsäure Lithiumsalz				
	oral	ATE 500 mg/kg			
	dermal	ATE 1100 mg/kg			
	inhalation vapour	ATE 11 mg/l			
	inhalation aerosol	ATE 1,5 mg/l			
9045-22-1	Lithium heparin				
	oral	LD50 1950 mg/kg	Rat	ChemIDplus - Database	

**Irritation and corrosivity**

Causes skin irritation.

Causes serious eye irritation.

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**Sensitising effects**

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Lithium heparin)  
May cause an allergic skin reaction. (Lithium heparin)

**Carcinogenic/mutagenic/toxic effects for reproduction**

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

**STOT-single exposure**

May cause respiratory irritation. (Iodessigsäure Lithiumsalz)

**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 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**

No data available.

**12.7. Other adverse effects**

No information available.

**Further information**

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

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. 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)**

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

**Marine transport (IMDG)**

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

**Air transport (ICAO-TI/IATA-DGR)**

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

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: Permeates easily through outer skin and causes poisoning. 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**

First issue.

**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



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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
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H312	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Resp. Sens. 1; H334	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method

**Relevant H and EUH statements (number and full text)**

H302	Harmful if swallowed.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled .
H335	May cause respiratory irritation.

**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.



**SARSTEDT**  
Aktiengesellschaft & Co. KG  
D - 51588 Nümbrecht

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according to Regulation (EC) No 1907/2006

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