

according to UK REACH Regulation

## Monovettes LH (Blood gas)

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

### 1.1. Product identifier

Monovettes LH (Blood gas)

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

## Use of the substance/mixture

For near-patient (POCT), immediate determination of blood gases, pH or electrolytes.

### 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

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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

number: 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

#### **GB CLP Regulation**

Resp. Sens. 1; H334 Skin Sens. 1; H317

Full text of hazard statements: see SECTION 16.

## 2.2. Label elements

## **GB CLP Regulation**

### Hazard components for labelling

Lithium heparin Calcium heparin

Signal word: Danger



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### Pictograms:



#### **Hazard statements**

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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

protection.

P284 Wear respiratory protection.

P302+P352 IF ON SKIN: Wash with plenty of Water.

P321 Specific treatment (see Precautionary statements on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
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. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P501 Dispose of contents/container to waste disposal site according to legal regulations.

#### Additional advice on labelling

none

#### 2.3. Other hazards

No information available.

### **SECTION 3: Composition/information on ingredients**

## 3.2. Mixtures

### **Chemical characterization**

The Monovette® contains a calcium-balanced heparin solution (50 I.U./mL nominal volume).

## **Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
9045-22-1	Lithium heparin			5 - < 10 %
	232-681-7			
	Resp. Sens. 1, Skin Sens. 1; H334 H317			
37270-89-6	Calcium heparin			1 - < 5 %
	Resp. Sens. 1, Skin Sens. 1; 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		
9045-22-1	232-681-7	Lithium heparin	5 - < 10 %
	oral: LD50 = 1950 mg/kg		
37270-89-6		Calcium heparin	1 - < 5 %
	oral: LD50 = 1950 mg/kg		

### **SECTION 4: First aid measures**



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### 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

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

### After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

### 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.

## 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 advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. 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

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**



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### 7.1. Precautions for safe handling

#### Advice on safe handling

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

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.

### 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)

For near-patient (POCT), immediate determination of blood gases, pH or electrolytes.

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

### 8.1. Control parameters

### 8.2. Exposure controls





#### 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. 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: Liquid
Colour: colourless
Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

No data available

No data available

boiling range:



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No data available Flammability: Lower explosion limits: No data available Upper explosion limits: No data available Flash point: No data available Auto-ignition temperature: No data available Decomposition temperature: No data available pH-Value: No data available Water solubility: Preparation soluble

Solubility in other solvents

There are no data available on the mixture itself.

Partition coefficient n-octanol/water:

Vapour pressure:

Density:

No data available

No data available

No data available

No data available

Relative vapour density:

No data available

## 9.2. Other information

## Information with regard to physical hazard classes

Explosive properties

There are no data available on the mixture itself.

Self-ignition temperature

Solid: No data available
Gas: No data available

Oxidizing properties

There are no data available on the mixture itself.

Other safety characteristics

Evaporation rate: No data available Solid content: No data available

## **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 information available.

## 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 GB CLP Regulation

#### **Acute toxicity**

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



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CAS No	Chemical name					
	Exposure route	Dose	Species	Source	Method	
9045-22-1	Lithium heparin					
	oral	LD50 1950 mg/kg	Rat	ChemIDplus - Database		
37270-89-6	Calcium heparin					
	oral	LD50 1950 mg/kg	Rat	ChemIDplus - Database		

#### Irritation and corrosivity

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

#### Sensitising effects

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

#### 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 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 substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

## 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.

The product has not been tested.

### 12.7. Other adverse effects

No information available.

#### **Further information**

Avoid release to the environment.



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### **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

#### **Disposal recommendations**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

## **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

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

Information according to 2012/18/EU

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

(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): 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.



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### **SECTION 16: Other information**

#### Changes

This data sheet contains changes from the previous version in section(s): 2,9,11.

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
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 GB CLP Regulation

Classification	Classification procedure
Resp. Sens. 1; H334	Calculation method
Skin Sens. 1; H317	Calculation method

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

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### **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.



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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.)