

Monovettes LH-Gel

Revision date: 21.07.2021

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

1.1. Product identifier

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

Use of the substance/mixture

For plasma separation.

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 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
Serious eye damage/eye irritation: Eye Irrit. 2
Hazard Statements:
Harmful if inhaled.
Causes serious eye irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Tris (2-ethylhexyl) trimellitate

Signal word: Warning

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Pictograms:



Hazard statements

H319 Causes serious eye irritation.
H332 Harmful if inhaled.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTER/doctor if you feel unwell.
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.

Special labelling of certain mixtures

EUH208 Contains Lithium heparin. May produce an allergic reaction.

Additional advice on labelling

none

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

The article contains separating gel and a preparation carrier coated with lithium heparin (up to 30 I.U./mL nominal volume).

Hazardous components

| CAS No | Chemical name | | | Quantity |
|-----------|--|--------------|----------|-----------|
| | EC No | Index No | REACH No | |
| | GHS Classification | | | |
| 3319-31-1 | Tris (2-ethylhexyl) trimellitate | | | 40 - 60 % |
| | 222-020-0 | | | |
| | Acute Tox. 4, Acute Tox. 4, Eye Irrit. 2; H332 H312 H319 | | | |
| 9045-22-1 | Lithium heparin | | | < 1 % |
| | 232-681-7 | | | |
| | Acute Tox. 4, Resp. Sens. 1, Skin Sens. 1; H302 H334 H317 | | | |
| 872-50-4 | N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone | | | < 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 | |
| 3319-31-1 | 222-020-0 | Tris (2-ethylhexyl) trimellitate | 40 - 60 % |
| | | inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = > 2,6 mg/l (dusts or mists); dermal: LD50 = > 1977 mg/kg; oral: LD50 = > 2000 mg/kg | |
| 9045-22-1 | 232-681-7 | Lithium heparin | < 1 % |
| | | oral: LD50 = 1950 mg/kg | |
| 872-50-4 | 212-828-1 | N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone | < 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

After inhalation

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

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.

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. 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.

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. Full protection suit.

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

Observe the instructions for use and handling.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

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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

Do not breathe dust.

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)

For plasma separation.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|----------|------------------------|-----|-------------------|-----------|---------------|--------|
| 872-50-4 | 1-Methyl-2-pyrrolidone | 10 | 40 | | TWA (8 h) | WEL |
| | | 20 | 80 | | STEL (15 min) | WEL |

8.2. Exposure controls



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/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.

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Skin protection

Wear suitable 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: | Separating gel: pasty / solid | |
| Colour: | white | |
| Odour: | characteristic | |
| pH-Value: | | No data available |

Changes in the physical state

| | |
|---|-------------------|
| Melting point: | No data available |
| Boiling point or initial boiling point and boiling range: | No data available |
| Flash point: | No data available |

Flammability

| | |
|---------------|-------------------|
| Solid/liquid: | No data available |
| Gas: | No data available |

Explosive properties

No data available.

| | |
|----------------------------|-------------------|
| Lower explosion limits: | No data available |
| Upper explosion limits: | No data available |
| Auto-ignition temperature: | No data available |

Self-ignition temperature

| | |
|--------|-------------------|
| Solid: | No data available |
| Gas: | No data available |

| | |
|----------------------------|-------------------|
| Decomposition temperature: | No data available |
|----------------------------|-------------------|

Oxidizing properties

No data available

| | |
|------------------|-------------------|
| Vapour pressure: | No data available |
|------------------|-------------------|

| | |
|----------|-------------------|
| Density: | No data available |
|----------|-------------------|

| | |
|-------------------|-------------------------------|
| Water solubility: | Preparation partially soluble |
|-------------------|-------------------------------|

Solubility in other solvents

not determined

| | |
|--|-------------------|
| Partition coefficient n-octanol/water: | No data available |
|--|-------------------|

| | |
|--------------------------|-------------------|
| Relative vapour density: | No data available |
|--------------------------|-------------------|

| | |
|-------------------|-------------------|
| Evaporation rate: | No data available |
|-------------------|-------------------|

9.2. Other information

| | |
|----------------|-------------------|
| Solid content: | No data available |
|----------------|-------------------|

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

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The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Heating.

10.5. Incompatible materials

Oxidizing agents. Fluorine. Acids. Alkalis (alkalis).

10.6. Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

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

Acute toxicity

Harmful if inhaled.

ATEmix calculated

ATE (inhalation aerosol) 3,344 mg/l

| CAS No | Chemical name | | | | |
|-----------|--|-------------------|---------|-----------------------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 3319-31-1 | Tris (2-ethylhexyl) trimellitate | | | | |
| | oral | LD50 > 2000 mg/kg | Rat | | |
| | dermal | LD50 > 1977 mg/kg | Rabbit | | |
| | inhalation vapour | ATE 11 mg/l | | | |
| | inhalation (4 h) aerosol | LC50 > 2,6 mg/l | Rat | | |
| 9045-22-1 | Lithium heparin | | | | |
| | oral | LD50 1950 mg/kg | Rat | ChemIDplus - Database | |
| 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

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Contains Lithium heparin. 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.

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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 additive carrier can cause mechanical side effects if swallowed by waterbirds or aquatic organisms.

| CAS No | Chemical name | | | | | |
|-----------|--|--------------------|-----------|---------------------------------|--------|--------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 3319-31-1 | Tris (2-ethylhexyl) trimellitate | | | | | |
| | Acute fish toxicity | LC50 > 100 mg/l | 96 h | Oryzias latipes | | |
| | Acute algae toxicity | ErC50 > 100 mg/l | 72 h | Pseudokirchneriella subcapitata | | |
| | Acute crustacea toxicity | EC50 > 180 mg/l | 48 h | Daphnia magna (Big water flea) | | |
| 872-50-4 | N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone | | | | | |
| | Acute fish toxicity | LC50 832 mg/l | 96 h | Lepomis macrochirus (Bluegill) | IUCLID | |
| | Acute algae toxicity | ErC50 > 500 mg/l | 72 h | Scenedesmus quadricauda | IUCLID | |
| | Acute crustacea toxicity | EC50 ca. 4897 mg/l | 48 h | Daphnia magna (Big water flea) | IUCLID | |

12.2. Persistence and degradability

The product is expected to be environmentally inert. In sunlight, a photochemical degradation of the surface is expected. Significant biodegradation is not expected.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|-----------|--|---------|
| 3319-31-1 | Tris (2-ethylhexyl) trimellitate | 8,8 |
| 872-50-4 | N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone | -0,54 |

BCF

| CAS No | Chemical name | BCF | Species | Source |
|-----------|----------------------------------|-------|---------|--------|
| 3319-31-1 | Tris (2-ethylhexyl) trimellitate | < 2,7 | | |

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.

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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. |

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

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

2010/75/EU (VOC): 0,299 %

2004/42/EC (VOC): 0,299 %

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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):

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

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

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>

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

| Classification | Classification procedure |
|--------------------|--------------------------|
| Acute Tox. 4; H332 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |

Relevant H and EUH statements (number and full text)

| | |
|--------|---|
| H302 | Harmful if swallowed. |
| 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. |
| H360D | May damage the unborn child. |
| EUH208 | Contains Lithium heparin. May produce an allergic reaction. |

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.)