

**S-Monovettes Serum Express CAT**

Revision date: 28.01.2022

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

**1.1. Product identifier**

S-Monovettes Serum Express CAT

**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](http://www.sarstedt.com).

**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>	
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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**

**GB CLP Regulation**

Acute Tox. 4; H332  
Eye Irrit. 2; H319  
Resp. Sens. 1; H334

Full text of hazard statements: see SECTION 16.

**2.2. Label elements**

**GB CLP Regulation**

**Hazard components for labelling**

Tris (2-ethylhexyl) trimellitate  
Thrombin

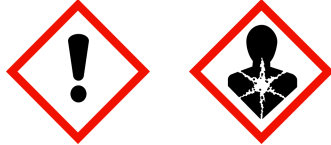
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**Signal word:** Danger

**Pictograms:**



**Hazard statements**

- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H334 May cause allergy or asthma symptoms or breathing difficulties 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.
- P284 Wear respiratory protection.
- 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.
- 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.
- 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 product contains separating gel and plastic granules coated with up to 28 U thrombin per 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	30 - < 35 %
	222-020-0	
	Acute Tox. 4, Acute Tox. 4, Eye Irrit. 2; H332 H312 H319	
9002-04-4	Thrombin	1 - < 5 %
	232-648-7	
	Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, STOT SE 3; H315 H319 H334 H335	
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	< 1 %
	212-828-1	
	606-021-00-7	
	Repr. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H360D H315 H319 H335	
556-67-2	octamethylcyclotetrasiloxane; [D4]	< 0.1 %
	209-136-7	
	014-018-00-1	
	Repr. 2, Aquatic Chronic 1; H361f H410	

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	30 - < 35 %
		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	
872-50-4	212-828-1	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	< 1 %
		dermal: LD50 = 8000 mg/kg; oral: LD50 = 3600 mg/kg STOT SE 3; H335: >= 10 - 100	
556-67-2	209-136-7	octamethylcyclotetrasiloxane; [D4]	< 0.1 %
		M chron.; H410: M=10	

**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**

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. 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. 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. Get immediate medical advice/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**

In case of fire: Wear self-contained breathing apparatus.

**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**

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**General advice**

Provide adequate ventilation. 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**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. 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)**

See instructions for use - SARSTEDT S-Monovette® Blood collection system at [www.sarstedt.com](http://www.sarstedt.com).

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

**8.1. Control parameters**

**Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	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**



**Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust.

**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.

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**Eye/face protection**

Suitable eye protection: goggles.

**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, as well as when handling the article.

**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:	white	
Odour:	characteristic	
pH-Value:		not determined
<b>Changes in the physical state</b>		
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flash point:		not applicable
<b>Flammability</b>		
Solid/liquid:		not determined
Gas:		not applicable
<b>Explosive properties</b>		
No data available.		
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Auto-ignition temperature:		not determined
<b>Self-ignition temperature</b>		
Solid:		not determined
Gas:		not applicable
Decomposition temperature:		not determined
<b>Oxidizing properties</b>		
No data available.		
Vapour pressure:		not determined
Density:		not determined
Water solubility:		practically insoluble
<b>Solubility in other solvents</b>		
not determined		
Partition coefficient n-octanol/water:		not determined
Relative vapour density:		not determined

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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**

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**

Harmful if inhaled.

**ATEmix calculated**

ATE (inhalation dust/mist) 4,287 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) dust/mist	LC50 > 2,6 mg/l	Rat		
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**

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Thrombin)

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

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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.

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 has not been tested.

**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**

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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.  
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)**

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

**Inland waterways transport (ADN)**

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

**Marine transport (IMDG)**

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

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

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



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**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; octamethylcyclotetrasiloxane; [D4]

Restrictions on use (REACH, annex XVII):

Entry 30, Entry 70, Entry 75

2010/75/EU (VOC): 0,295 %

2004/42/EC (VOC): 0,295 %

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

**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

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)

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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>

**Classification for mixtures and used evaluation method according to GB CLP Regulation**

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method
Eye Irrit. 2; H319	Calculation method
Resp. Sens. 1; H334	Calculation method

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

H312	Harmful in contact with skin.
H315	Causes skin irritation.
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.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.

**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.)*