

**S-Monovette® 2,7ml ThromboExact**

Revision date: 29.04.2021

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

**1.1. Product identifier**

S-Monovette® 2,7ml ThromboExact

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

**Use of the substance/mixture**

The S-Monovette® ThromboExact is used for platelet counting in case of suspected anticoagulant -induced pseudothrombocytopenia.

**Uses advised against**

Use S-Monovette® only for blood collection. Do not use for injection. Use only with S-Monovette® needle / adapter.

**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. When used as intended, there is no contact with the 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**

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**3.2. Mixtures**

**Chemical characterization**

The S-Monovette® ThromboExact contains an aqueous, magnesium-based stabilizer solution that prevents the formation of platelet aggregates.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

**After inhalation**

Provide fresh air.

**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 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**

Non-flammable.

**5.3. Advice for firefighters**

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

**Additional information**

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**

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**

Observe the instructions for use and handling. Avoid contact with the preparation. 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)**

The S-Monovette® ThromboExact is used for platelet counting in case of suspected anticoagulant -induced pseudothrombocytopenia.

**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.

**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:	Liquid
Colour:	colourless
Odour:	characteristic
pH-Value:	4,90 - 8,00

**Changes in the physical state**

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

**Flammability**

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Solid/liquid: not applicable  
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 applicable

Gas: not applicable

Decomposition temperature: not determined

**Oxidizing properties**

No data available.

Vapour pressure: not determined

Density: 1,256 g/cm<sup>3</sup>

Water solubility: easily soluble

**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**

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 Regulation (EC) No 1272/2008**

**Acute toxicity**

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

**Irritation and corrosivity**

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

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**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**

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:**

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.

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**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 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**

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**

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%

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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>

**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.)*