

**S-Monovette® cfDNA Exact**

Revision date: 30.07.2021

Art. no. 01.2040.001

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

**1.1. Product identifier**

S-Monovette® cfDNA Exact

**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: [info@sarstedt.com](mailto:info@sarstedt.com)  
Contact person: Dr. Daniel Will  
Telephone: +49 (0)2293 / 305 - 4500  
Jochen Hoffmann  
e-mail: [sicherheitsdatenblatt@sarstedt.com](mailto:sicherheitsdatenblatt@sarstedt.com)  
Internet: [www.sarstedt.com](http://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](mailto:info.gb@sarstedt.com)  
Internet: [www.sarstedt.com](http://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:  
Respiratory or skin sensitisation: Skin Sens. 1  
Hazard Statements:  
May cause an allergic skin reaction.

**2.2. Label elements**

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

**Hazard components for labelling**

methenamine; hexamethylenetetramine

**Signal word:** Warning

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**Pictograms:**



**Hazard statements**

H317 May cause an allergic skin reaction.

**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.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P321 Specific treatment (see remarks 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.  
P501 Dispose of contents/container to waste disposal site according to legal regulations.

**2.3. Other hazards**

No information available.

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

**3.2. Mixtures**

**Chemical characterization**

The S-Monovette® cfDNA Exact contains 0.84 ml of an aqueous stabilizer solution.

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
100-97-0	methenamine; hexamethylenetetramine			10 - < 15 %
	202-905-8	612-101-00-2		
	Flam. Sol. 2, Skin Sens. 1; H228 H317			
5949-29-1	Citric acid monohydrate			1 - < 5 %
	201-069-1		01-2119457026-42	
	Eye Irrit. 2; H319			

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	
100-97-0	202-905-8	methenamine; hexamethylenetetramine	10 - < 15 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >20000 mg/kg	
5949-29-1	201-069-1	Citric acid monohydrate	1 - < 5 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = 11700 mg/kg	

**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.

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**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**

Observe risk of aspiration if vomiting occurs. 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**

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**

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**

**7.1. Precautions for safe handling**

**Advice on safe handling**

See instructions for use - SARSTEDT S-Monovette® Blood collection system at [www.sarstedt.com](http://www.sarstedt.com). Wear suitable protective gloves when taking blood samples and handling potentially infectious material.

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**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 at room temperature. Store light protected.

**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**

**8.2. Exposure controls**



**Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. When using do not eat, drink, smoke, sniff.

**Eye/face protection**

Avoid contact with eyes. If necessary, use suitable protective 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.

**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:	slight inherent smell
pH-Value (at 25 °C):	5,95

**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**

Solid/liquid:	not applicable
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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: 1,105 g/cm<sup>3</sup>

Water solubility: Preparation 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**

If the preparation dries up, there is a risk of explosion with regard to: acetic anhydride, halogenated hydrocarbons, iodine and nitric acid. With dried preparations exothermic reactions are possible with regard to: oxidizing agents, peroxides.

**10.4. Conditions to avoid**

Heating. exposure to light.

**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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
100-97-0	methenamine; hexamethylenetetramine				
	oral	LD50 >20000 mg/kg	Rat	ECHA	
	dermal	LD50 >2000 mg/kg	Rat	ECHA	
5949-29-1	Citric acid monohydrate				
	oral	LD50 11700 mg/kg	Rat		OECD 402
	dermal	LD50 >2000 mg/kg	Rat		OECD 402

**Irritation and corrosivity**

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

**Sensitising effects**

May cause an allergic skin reaction. (methenamine; hexamethylenetetramine)

**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.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
5949-29-1	Citric acid monohydrate					
	Acute fish toxicity	LC50 440 - 760 mg/l	96 h	Leuciscus idus (golden orfe)	(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
5949-29-1	Citric acid monohydrate	-1,72

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**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.

**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

**Other applicable information**

For safe transport, SARSTEDT offers a complete packaging system for the S-Monovette® that has been

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tested and meets the requirements of packaging regulation P 650 of the ADR, RID, ICAO and IATA.

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

**Additional information**

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

**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.

**SECTION 16: Other information**

**Changes**

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,7,8,9,10,11,12,13,14,15,16.

**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



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(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>

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

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method

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

H228 Flammable solid.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye 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.

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