

S-Monovette® cfDNA Exact

Revision date: 04.04.2024

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

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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.

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

GB CLP Regulation

Skin Sens. 1; H317

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

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.

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
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			5 - < 10 %
	201-069-1		01-2119457026-42	
	Eye Irrit. 2, STOT SE 3; H319 H335			

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	5 - < 10 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = 5400 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 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

7.1. Precautions for safe handling

Advice on safe handling

See instructions for use - SARSTEDT S-Monovette® Blood collection system at 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.

Advice on general occupational hygiene

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

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.

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

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

Test method

Melting point/freezing point: No data available
Boiling point or initial boiling point and boiling range: No data available
Flammability: No data available
Lower explosion limits: No data available
Upper explosion limits: No data available
Flash point: No data available

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Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Value (at 25 °C):	5,95
Viscosity / kinematic:	No data available
Water solubility:	Preparation soluble OECD 105
Solubility in other solvents	
There are no data available on the mixture itself.	
Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	1,105 g/cm ³
Relative vapour density:	No data available
Particle characteristics:	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

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 GB CLP Regulation

Acute toxicity

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

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
100-97-0	methenamine; hexamethylenetetramine				
	oral	LD50 mg/kg	>20000	Rat	(external safety data sheet)
	dermal	LD50 mg/kg	>2000	Rat	(external safety data sheet) OECD 402
5949-29-1	Citric acid monohydrate				
	oral	LD50 mg/kg	5400	Mouse	(external safety data sheet) OECD 401
	dermal	LD50 mg/kg	>2000	Rat	OECD 402

Irritation and corrosivity

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

Serious eye damage/eye irritation: 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

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

Reproductive toxicity: 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
100-97-0	methenamine; hexamethylenetetramine					
	Acute fish toxicity	LC50 mg/l	49000	96 h Cyprinodon variegatus (desert carp)	(external safety data sheet)	OECD 203
5949-29-1	Citric acid monohydrate					
	Acute fish toxicity	LC50 760 mg/l	440 -	96 h Leuciscus idus (golden orfe)	(IUCLID)	

12.2. Persistence and degradability

The product has not been tested.

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CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
100-97-0	methenamine; hexamethylenetetramine			
	OECD 301D aerob	35 %	28	
	Not easily biodegradable			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
100-97-0	methenamine; hexamethylenetetramine	-2,18
5949-29-1	Citric acid monohydrate	-1,72

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.

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.

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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 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 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, Entry 40, Entry 75

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

2012/18/EU (SEVESO III):

Marketing and use of explosives precursors (Regulation (EU) 2019/1148):

This product is regulated by Regulation (EU) 2019/1148: all suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point.

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): 7,9.

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Abbreviations and acronyms

Flam. Sol: Flammable solids
 Eye Irrit: Eye irritation
 Skin Sens: Skin sensitisation
 STOT SE: Specific target organ toxicity - single exposure
 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>

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

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.
 H335 May cause respiratory 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.



SARSTEDT

Aktiengesellschaft & Co. KG

D - 51588 Nümbrecht

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according to UK REACH Regulation

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