

according to UK REACH Regulation

Monovettes FE

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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 glucose determination.

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 lnternet: www.sarstedt.com

<u>1.4. Emergency telephone</u> Call NHS 111 or a doctor (public). NPIS: 0344 892 0111 (healthcare

number: 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

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

potassium fluoride

Ethylene dinitrilo tetraacetic acid disodium salt

Signal word: Warning



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Pictograms:



Hazard statements

H332 Harmful if inhaled.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P271 Use only outdoors or in a well-ventilated area.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

Additional advice on labelling

none

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Pictograms:



2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

The product contains up to 1.8 mg H4EDTA and up to 1.2 mg potassium fluoride per ml nominal volume.

Relevant ingredients

CAS No	Chemical name				
	EC No	Index No	REACH No		
	Classification (GB CLP Regulation)				
7789-23-3	potassium fluoride			10 - < 15 %	
	232-151-5	009-005-00-2			
	Acute Tox. 3, Acute Tox. 3, H331 H311 H301				
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt				
	Acute Tox. 4, STOT RE 2; H332 H373				

Full text of H and EUH statements: see section 16.

Specific Conc. Limits. M-factors and ATE

opecine ou	iic. Liiiiits, ivi-ia	Citors and ATE	
CAS No	EC No	Chemical name	Quantity
	Specific Conc	Limits, M-factors and ATE	
7789-23-3	232-151-5	potassium fluoride	10 - < 15 %
	I	E = 3 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: ATE = al: LD50 = 245 mg/kg	
6381-92-6		Ethylene dinitrilo tetraacetic acid disodium salt	5 - < 10 %
	inhalation: AT 2800 mg/kg	E = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 =	

SECTION 4: First aid measures



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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

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. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink 1 glass of of water.

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

General advice

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

Do not breathe gas/fumes/vapour/spray. 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. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

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 glucose determination.

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

Wear eye protection/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.

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: Liquid
Colour: colourless
Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

No data available

No data available

boiling range:

Flammability:

Lower explosion limits:

No data available

Upper explosion limits:

No data available

Flash point:

No data available



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Auto-ignition temperature:

Decomposition temperature:

PH-Value:

Viscosity / kinematic:

No data available

Preparation soluble

Solubility in other solvents

There are no data available on the mixture itself.

Partition coefficient n-octanol/water:

Vapour pressure:

Density:

Relative vapour density:

Particle characteristics:

No data available

No data available

No data available

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:

Solid content:

No data available

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

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 (oral) 2061 mg/kg; ATE (dermal) 2523 mg/kg; ATE (inhalation vapour) 22,10 mg/l; ATE (inhalation dust/mist) 3,585 mg/l



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CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
7789-23-3	potassium fluoride					
	oral	LD50 mg/kg	245	Rat	(IUCLID)	
	dermal	ATE mg/kg	300			
	inhalation vapour	ATE	3 mg/l			
	inhalation dust/mist	ATE	0,5 mg/l			
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt					
	oral	LD50 mg/kg	2800	Rat	(external safety data sheet)	OECD 401
	inhalation vapour	ATE	11 mg/l			
	inhalation dust/mist	ATE	1,5 mg/l			

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

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

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.



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CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt						
	Acute fish toxicity	LC50	320 mg/l		Poecilia reticulata (Guppy)	(external safety data sheet)	(IUCLID)
	Acute algae toxicity	ErC50	60 mg/l		Desmodesmus subspicatus (green alga)	(external safety data sheet)	OECD 201
	Acute crustacea toxicity	EC50	140 mg/l	I	Daphnia magna (Big water flea)	(external safety data sheet)	DIN 38412
	Crustacea toxicity	NOEC	25 mg/l		Daphnia magna (Big water flea)	(external safety data sheet)	ECHA
	Acute bacteria toxicity	EC50	640 mg/l	3 h	Activated sludge	(external safety data sheet)	OECD 301D

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt				
	OECD 301D 2 % 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
7789-23-3	potassium fluoride	-0,77
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt	-11,7

BCF

CAS No	Chemical name	BCF	Species	Source
6381-92-6	Ethylene dinitrilo tetraacetic acid disodium salt	1,8		

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.

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



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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)

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.

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 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

2012/18/EU (SEVESO III):

Restrictions on use (REACH, annex XVII):

Entry 3

Information according to Directive

...

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): 2 - obviously hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information



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Changes

This data sheet contains changes from the previous version in section(s): 7,9.

First issue.

Abbreviations and acronyms

Acute Tox: Acute toxicity

STOT RE: Specific target organ toxicity - repeated exposure

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

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

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

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H332	Harmful if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

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.



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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.)