

S-Monovettes K2E (without separating gel)

Revision date: 12.08.2020

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

1.1. Product identifier

S-Monovettes K2E (without separating gel)

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

Use of the substance/mixture

For blood collection. For haematological testing.

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

Hazard categories:

Acute toxicity: Acute Tox. 4

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements:

Harmful if inhaled.

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Regulation (EC) No. 1272/2008

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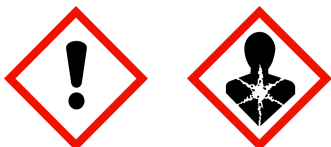
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Hazard components for labelling

Ethylenediaminetetraacetic acid dipotassium salt

Signal word: Warning

Pictograms:



Hazard statements

H332 Harmful if inhaled.
H373 May cause damage to organs (Respiratory tract) through prolonged or repeated exposure if inhaled.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTER/doctor if you feel unwell.
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

S-Monovettes K2E contain 1.6 mg H4EDTA / ml nominal volume.

Hazardous components

CAS No	Chemical name	Quantity
	EC No	Index No
	REACH No	
	GHS Classification	
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt	100 %
	217-895-0	
	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

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
25102-12-9	217-895-0	Ethylenediaminetetraacetic acid dipotassium salt	100 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 = > 2000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice. Get medical advice/attention if you feel unwell.

After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical

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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

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. 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

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

Avoid contact with the preparation. 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 (e.g. sand, diatomaceous earth, acid- or universal binding agents) or 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

Do not open Monovette®. Avoid contact with the preparation. Observe the instructions for use and handling. Use S-Monovette® only for blood collection. Do not use for injection. Use only with S-Monovette® needle / adapter. 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.

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7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Do not open Monovette®.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

For blood collection. For haematological testing.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



Appropriate engineering controls

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

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.

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 work protective clothing.

Respiratory protection

Required in case of formation of vapours/aerosols.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid / solid
Colour:	colourless / white
Odour:	characteristic
pH-Value:	not determined

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

The product is not: Explosive. No data available.

Lower explosion limits: not determined
Upper explosion limits: not determined

Self-ignition temperature

Solid: not applicable
Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure: not determined

Density: not determined

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

Heating.

10.5. Incompatible materials

Strong oxidizing agents.

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

ATEmix calculated

ATE (inhalation vapour) 11,00 mg/l; ATE (inhalation aerosol) 1,500 mg/l

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Acute toxicity

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt				
	oral	LD50 > 2000 mg/kg			
	inhalation vapour	ATE 11 mg/l			
	inhalation aerosol	ATE 1,5 mg/l			

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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.

12.7. 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

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.

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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.

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

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)

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

Changes

This data sheet contains changes from the previous version in section(s): 2,3,4,5,6,7,8,9,11,13,16.

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

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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 Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method
STOT RE 2; H373	Calculation method

Relevant H and EUH statements (number and full text)

H332 Harmful if inhaled.
H373 May cause damage to organs (Respiratory tract) through prolonged or repeated exposure 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.

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