

according to UK REACH Regulation

Microvettes K2E

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

1.1. Product identifier

Microvettes K2E

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

Use of the substance/mixture

For haematological testing.

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 Call NHS 111 or a doctor (public). NPIS: 0344 892 0111 (healthcare

<u>number:</u> 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 STOT RE 2; H373

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

Ethylenediaminetetraacetic acid dipotassium salt dihydrate

Signal word: Warning



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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.
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.

P501 Dispose of contents/container to waste disposal site according to legal regulations.

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 Microvette® contains EDTA-K2 in the usual amount for anticoagulation of human blood.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt dihydrate			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 dihydrate	100 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 = 2800 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

If the user comes into contact with the preparation of the product, please note the following:



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After inhalation

Provide fresh air. Medical treatment necessary. Get medical advice/attention if you feel unwell.

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. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink 1 glass of 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

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

Use personal protection equipment. Wear suitable protective gloves when taking blood samples and handling potentially infectious material.

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

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) or take up mechanically.

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

Observe the instructions for use and handling. Wear suitable protective gloves when taking blood samples and



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handling potentially infectious material.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special measures are necessary.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

For haematological testing.

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

Required in case of formation of dust.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid

Colour: colourless / white Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

No data available

No data available

boiling range:

Flammability: No data available
Lower explosion limits: No data available
Upper explosion limits: No data available
Flash point: No data available
Auto-ignition temperature: No data available



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Decomposition temperature:

pH-Value:

No data available

No data available

Water solubility:

easily soluble

Solubility in other solvents

There are no data available on the mixture itself.

Partition coefficient n-octanol/water:

Vapour pressure:

Density:

No data available

No data available

No data available

No data available

Relative vapour density:

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

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 GB CLP Regulation

Acute toxicity

Harmful if inhaled.

ATEmix calculated

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



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CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt dihydrate					
	oral	LD50 mg/kg	2800		(external safety data sheet)	OECD 401
	inhalation vapour	ATE	11 mg/l			
	inhalation dust/mist	ATE	1,5 mg/l			

Irritation and corrosivity

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

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

May cause damage to organs through prolonged or repeated exposure. (Ethylenediaminetetraacetic acid dipotassium salt dihydrate)

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.

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 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.

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 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

Information according to 2012/18/EU Not subject to 2012/18/EU (SEVESO III) (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): 3 - highly 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): 2,7,9,11,12,16.



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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 (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
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.



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