

according to Regulation (EC) No 1907/2006

Minivettes POCT K3E

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

1.1. Product identifier

Minivettes POCT K3E

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

Use of the substance/mixture

For collection and dispensing of diagnostic blood samples for Point-of-Care tests.

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. Dagmar Flach 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.

Beaumont Leys

Street: 68 Boston Road
Place: GB-LE4 1AW Leicester

Telephone: +44 (0) 116 235 9023 Telefax: +44 (0) 116 236 6099

e-mail: info@sarstedt.co.uk Internet: www.sarsedt.com

1.4. Emergency telephone Call NHS 111 or a doctor.

number:

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:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Ethylenediaminetetraacetic acid tripotassium salt



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Signal word: Warning

Pictograms:



Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P321 Specific treatment (see remarks on this label).
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Minivettes POCT K3E contain 2.1 mg H4EDTA / ml nominal volume.

Hazardous components

| CAS No | Chemical name | | Quantity | |
|------------|---|----------|----------|--|
| | EC No | Index No | REACH No | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 65501-24-8 | Ethylenediaminetetraacetic acid tripotassium salt | | 100 % | |
| | 241-543-5 | | | |
| | Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335 | | | |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

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

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. 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 plenty of water. Get medical advice/attention if you feel unwell.



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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

Use personal protection equipment. Wear suitable protective gloves during blood collection and if handling potentially infectious meterial.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

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

Observe instructions for use. Wear suitable protective gloves during blood collection and if handling potentially infectious meterial.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Advice on storage compatibility

No special measures are necessary.

7.3. Specific end use(s)

For collection and dispensing of diagnostic blood samples for Point-of-Care tests.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



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Protective and hygiene measures

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

Eye/face protection

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

Hand protection

Wear suitable protective gloves during blood collection and if handling potentially infectious meterial . 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.

Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid

Colour: colourless / white Odour: characteristic

pH-Value: not determined

Changes in the physical state

Melting point:

Initial boiling point and boiling range:

Flash point:

not determined

not determined

not determined

Flammability

Solid: not applicable
Gas: not applicable

Explosive properties

No data available.

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

Auto-ignition temperature

Solid: not applicable
Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidizing.

Vapour pressure: not determined

Density: not determined

Water solubility: easily soluble

Solubility in other solvents

not determined



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Partition coefficient: not determined 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 toxicological effects

Acute toxicity

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

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

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

May cause respiratory irritation. (Ethylenediaminetetraacetic acid tripotassium salt)

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

This 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



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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.

12.6. 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

Advice on disposal

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. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture



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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 juvenils according to the 'juvenile

work protection guideline' (94/33/EC).

Water contaminating class (D): 3 - highly water contaminating

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

First issue.

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%

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

| Classification | Classification procedure |
|---------------------|--------------------------|
| Skin Irrit. 2; H315 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |
| STOT SE 3; H335 | Calculation method |

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singulary 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.)