

according to UK REACH Regulation

End-to-End Capillary 20µl K2E

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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 capillary blood collection.

Uses advised against

See instructions for use at www.sarstedt.com.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: Vitrex Medical A/S
Street: Vasekær 6-8
Place: DK-2730 Herlev
Telephone: +45 44947011
e-mail: vitrex@vitrex.dk
Internet: www.vitrexmedical.com

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

Signal word: Warning

Pictograms:





Hazard statements

H332 Harmful if inhaled.



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

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.

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 End-to-End Capillary 20µl is made of glass and 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 | |
| | 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

| opeome cone: Limite, in factore 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

Please note that the product is made of glass and therefore glass breakage may occur.

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

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



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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 advice

Observe the instructions for use and handling. Please note that the product is made of glass and therefore glass breakage may occur. 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

For cleaning up

Take up mechanically. Pay attention to broken pieces. 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

Avoid dust formation. Do not breathe dust. Please note that the product is made of glass and therefore glass breakage may occur. Observe the instructions for use and handling. 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.

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 capillary blood collection.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



Appropriate engineering controls

Do not breathe dust.

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

Use of protective clothing.

Respiratory protection

Required in case of formation of dust. Not required if used as intended.

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/freezing point: not determined



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Boiling point or initial boiling point and

not determined

boiling range:

Flash point: not applicable

Flammability

Solid/liquid: not determined
Gas: not applicable

Explosive properties

The product is not: Explosive. No data available.

Lower explosion limits:

Upper explosion limits:

Auto-ignition temperature:

not determined

not determined

not determined

not determined

Oxidizing properties

No data available.

Vapour pressure:

Density:

not determined

not determined

Water solubility:

easily soluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

Relative vapour density:

Evaporation rate:

not determined
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 GB CLP Regulation

Acute toxicity

Harmful if inhaled.



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ATEmix calculated

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

| 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 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)

Aspiration hazard

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

11.2. Information on other hazards

Other information

No data available

Further information

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 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.



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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

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: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. 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

(SEVESO III):

National regulatory information

Not subject to 2012/18/EU (SEVESO III)



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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

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%

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

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).



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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.
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.)