

**Monovettes K2E-Gel**

Revision date: 04.04.2024

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

**1.1. Product identifier**

Monovettes K2E-Gel

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

**Use of the substance/mixture**

For molecular virus diagnostics.

**Uses advised against**

See instructions for use - SARSTEDT S-Monovette® Blood collection system at [www.sarstedt.com](http://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:	<a href="mailto:info@sarstedt.com">info@sarstedt.com</a>	
Contact person:	Dr. Daniel Will	Telephone: +49 (0)2293 / 305 - 4500
	Jochen Hoffmann	
E-mail:	<a href="mailto:sicherheitsdatenblatt@sarstedt.com">sicherheitsdatenblatt@sarstedt.com</a>	
Internet:	<a href="http://www.sarstedt.com">www.sarstedt.com</a>	
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:	<a href="mailto:info.gb@sarstedt.com">info.gb@sarstedt.com</a>	
Internet:	<a href="http://www.sarstedt.com">www.sarstedt.com</a>	

**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.

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

**GB CLP Regulation**

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

**2.2. Label elements**

**GB CLP Regulation**

**Special labelling of certain mixtures**

EUH210 Safety data sheet available on request.

**Additional advice on labelling**

none

**2.3. Other hazards**

No information available.

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**SECTION 3: Composition/information on ingredients**

**3.2. Mixtures**

**Chemical characterization**

The Monovette® K2E contains separating gel and 1.6 mg H4EDTA / ml nominal volume.

**Relevant ingredients**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt dihydrate			1 - < 5 %
	217-895-0			
	Acute Tox. 4; H332			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			< 1 %
	212-828-1	606-021-00-7		
	Repr. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H360D H315 H319 H335			

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	1 - < 5 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 = 2800 mg/kg	
872-50-4	212-828-1	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	< 1 %
		dermal: LD50 = 8000 mg/kg; oral: LD50 = 3600 mg/kg STOT SE 3; H335: >= 10 - 100	

**SECTION 4: First aid measures**

**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. If skin irritation or rash 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 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.

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**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**

Wear a self-contained breathing apparatus and chemical protective clothing.

**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.

**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.

**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**

Wear suitable protective gloves when taking blood samples and handling potentially infectious material.

**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. Store at room temperature.

**Hints on joint storage**

No special measures are necessary.

**7.3. Specific end use(s)**

For molecular virus diagnostics.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
872-50-4	1-Methyl-2-pyrrolidone	10	40		TWA (8 h)	WEL
		20	80		STEL (15 min)	WEL

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**8.2. Exposure controls**



**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

Wear eye 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:	Separating gel: pasty / liquid	
Colour:	white / colourless	
Odour:	characteristic	
Melting point/freezing point:		No data available
Boiling point or initial boiling point and boiling range:		No data available
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
Decomposition temperature:		No data available
pH-Value:		No data available
Viscosity / kinematic:		No data available
Water solubility:	Preparation partially soluble	
Solubility in other solvents		
There are no data available on the mixture itself.		
Partition coefficient n-octanol/water:		No data available
Vapour pressure:		No data available
Density:		No data available
Relative vapour density:		No data available
Particle characteristics:		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

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Gas: No data available  
Oxidizing properties  
There are no data available on the mixture itself.

**Other safety characteristics**

Evaporation rate: No data available  
Solid content: No data available

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

No data available.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

No data available.

**10.4. Conditions to avoid**

Heating.

**10.5. Incompatible materials**

Oxidizing agents. Fluorine. Acids. Alkalis (alkalis).

**10.6. Hazardous decomposition products**

No data available.

**SECTION 11: Toxicological information**

**11.1. Information on hazard classes as defined in GB CLP Regulation**

**Acute toxicity**

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

**ATEmix calculated**

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) 876,1 mg/l; ATE (inhalation dust/mist) 119,5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt dihydrate				
	oral	LD50 2800 mg/kg	Rat	(external safety data sheet)	OECD 401
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1,5 mg/l			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone				
	oral	LD50 3600 mg/kg	Rat	IUCLID	
	dermal	LD50 8000 mg/kg	Rabbit	IUCLID	

**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**

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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.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone					
	Acute fish toxicity	LC50	832 mg/l	96 h	Lepomis macrochirus	IUCLID
	Acute algae toxicity	ErC50	> 500 mg/l	72 h	Scenedesmus subspicatus	IUCLID
	Acute crustacea toxicity	EC50	ca. 4897 mg/l	48 h	Daphnia magna	IUCLID

**12.2. Persistence and degradability**

The product has not been tested.

**12.3. Bioaccumulative potential**

The product has not been tested.

**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	-0,54 (25° C)

**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**

There are no data available on the mixture itself.

**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**

Dispose of waste according to applicable legislation.

**SECTION 14: Transport information**

**Land transport (ADR/RID)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	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**

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):  
N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Restrictions on use (REACH, annex XVII):

Entry 30, Entry 75

Directive 2010/75/EU on industrial emissions: 0,29 %

Directive 2004/42/EC on VOC in paints and varnishes: 0,29 %

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**National regulatory information**

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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**

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

First issue.

**Abbreviations and acronyms**

Acute Tox: Acute toxicity

Skin Irrit: Skin irritation

Eye Irrit: Eye irritation

Repr: Reproductive toxicity

STOT SE: Specific target organ toxicity - single exposure

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>

VOC: Volatile Organic Compounds



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**Relevant H and EUH statements (number and full text)**

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
EUH210	Safety data sheet available on request.

**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.)*