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.

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 Jochen Hoffmann	Telephone: +49 (0)2293 / 305 - 4500
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.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Acute toxicity: Acute Tox. 4
Serious eye damage/eye irritation: Eye Irrit. 2
Hazard Statements:
Harmful if inhaled.
Causes serious eye irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Tris (2-ethylhexyl) trimellitate
Ethylenediaminetetraacetic acid dipotassium salt

Signal word: Warning

Pictograms:

Hazard statements

H319	Causes serious eye irritation.
H332	Harmful if inhaled.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Additional advice on labelling

none

2.3. Other hazards

No information available.

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.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
3319-31-1	Tris (2-ethylhexyl) trimellitate			40 - < 45 %
	222-020-0			
	Acute Tox. 4, Acute Tox. 4, Eye Irrit. 2; H332 H312 H319			
25102-12-9	Ethylenediaminetetraacetic acid dipotassium salt			1 - < 5 %
	217-895-0			
	Acute Tox. 4, STOT RE 2; H332 H373			
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		
3319-31-1	222-020-0	Tris (2-ethylhexyl) trimellitate	40 - < 45 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = > 2,6 mg/l (dusts or mists); dermal: LD50 = > 1977 mg/kg; oral: LD50 = > 2000 mg/kg		
25102-12-9	217-895-0	Ethylenediaminetetraacetic acid dipotassium salt	1 - < 5 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 = > 2000 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 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.

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 measures

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.

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/m³	fibres/ml	Category	Origin
872-50-4	1-Methyl-2-pyrrolidone	10	40		TWA (8 h)	WEL
		20	80		STEL (15 min)	WEL

8.2. Exposure controls


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

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
pH-Value:	No data available

Changes in the physical state

Melting point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flash point:	No data available

Flammability

Solid/liquid:	No data available
Gas:	No data available

Explosive properties

No data available.

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

Self-ignition temperature

Solid:	No data available
Gas:	No data available
Decomposition temperature:	No data available

Oxidizing properties

No data available

Vapour pressure:	No data available
Density:	No data available
Water solubility:	Preparation partially soluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	No data available
Relative vapour density:	No data available
Evaporation rate:	No data available

9.2. Other information

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 Regulation (EC) No 1272/2008

Acute toxicity

Harmful if inhaled.

ATEmix calculated

ATE (inhalation aerosol) 3,350 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
3319-31-1	Tris (2-ethylhexyl) trimellitate				
	oral	LD50 > 2000 mg/kg	Rat		
	dermal	LD50 > 1977 mg/kg	Rabbit		
	inhalation vapour	ATE 11 mg/l			
	inhalation (4 h) aerosol	LC50 > 2,6 mg/l	Rat		
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			
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

Causes serious eye irritation.

Skin corrosion/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

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
3319-31-1	Tris (2-ethylhexyl) trimellitate						
	Acute fish toxicity	LC50	> 100 mg/l	96 h	Oryzias latipes		
	Acute algae toxicity	ErC50	> 100 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50	> 180 mg/l	48 h	Daphnia magna (Big water flea)		
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone						
	Acute fish toxicity	LC50	832 mg/l	96 h	Lepomis macrochirus (Bluegill)	IUCLID	
	Acute algae toxicity	ErC50	> 500 mg/l	72 h	Scenedesmus quadricauda	IUCLID	
	Acute crustacea toxicity	EC50	ca. 4897 mg/l	48 h	Daphnia magna (Big water flea)	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
3319-31-1	Tris (2-ethylhexyl) trimellitate	8,8
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	-0,54

BCF

CAS No	Chemical name	BCF	Species	Source
3319-31-1	Tris (2-ethylhexyl) trimellitate	< 2,7		

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. Endocrine disrupting properties

The product has not been tested.

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.
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

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

2010/75/EU (VOC):	0,29 %
2004/42/EC (VOC):	0,29 %

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

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
VOC: Volatile Organic Compounds

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

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method
Eye Irrit. 2; H319	Calculation method

Relevant H and EUH statements (number and full text)

H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H373	May cause damage to organs (Respiratory tract) through prolonged or repeated exposure if inhaled.

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.)