

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: DIAQUICK Mononucleosis Cassette

Version: 07

Date: May 13, 2025



Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

DIAQUICK Mononucleosis Cassette

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

Relevant identified use

In-vitro diagnostic medical device for human samples.

For professional use only.

Uses advised against

None

1.3. Details of the supplier of the safety data sheet

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Hondastrasse, Objekt M55, IZ-NOE Sued, 2351 Wr. Neudorf, Austria

Phone / e-mail: +43 2236 660 910 0 / office@dialab.at

Responsible person:

saftey@dialab.at

1.4. Emergency telephone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

Section 2. Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) 1272/2008 (CLP):

No hazardous substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2. Label elements

Regulation (EC) 1272/2008 (CLP):

The product does not need to be labelled in accordance with EC directives or respective national laws.

Pictogram(s) and signal words:

No

Hazard-determining components of labelling:

No

Hazard statements:

No

Safety statements:

No

2.3. Other hazards

The mixture does not contain PBT/vPvB substance.

The mixture does not contain endocrine disruptor.

Section 3. Composition / information on ingredients

3.1. Substances

Cassette and Buffer are mixtures.

3.2. Mixtures

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Composition/information on ingredients:

Chemical name	CAS No.	EINECS No.	REACH Registration No.	Classification	Concentration
cellulose nitrate membrane	9004-70-0	N/A	Not available	Not Classified	0.07 %
PS	9003-53-6	N/A	Not available	Not Classified	2.45%
glass fiber filter paper	65997-17-3	266-046-0	Not available	Not Classified	0.30%
Polyester film	113669-97-9	N/A	Not available	Not Classified	0.13%
HOPE	9002-88-4	N/A	Not available	Not Classified	96.62%
Cellulose	9004-34-6	N/A	Not available	Not Classified	0.43%

Buffer composition

Volume of buffer: 3 mL

Buffer

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification	Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)
Purified water	N/A	7732-18-5	231-791-2	97.755~97.955%	Not Classified	N/A
Sodium chloride	N/A	7647-14-5	231-598-3	0.8~0.9%	Not Classified	N/A
Disodium hydrogenorthophosphate	N/A	7558-79-4	231-448-7	0.7~0.8%	Not Classified	N/A
Caseins.sodium complexes	N/A	9005-46-3	N/A	0.5%	Not Classified	N/A
Kanamycin	N/A	25389-94-0	246-933-9	0.025%	H360	N/A
Sodium azide	N/A	26628-22-8	247-852-1	0.02%	H300; H400; H410	N/A

Components with EU occupational exposure limits

None

The wording of the listed hazard warnings can be found in Section 16.

Substances that are on the "Candidate List of Substances of Very High Concern (SVHC) for authorization by the European Chemicals Agency (ECHA) are not intended to be part of this product. It is therefore not to be expected that these substances are contained in the product in quantities of > 0.1 %.

Section 4. First aid measures

4.1. Description of first aid measures

General notes:

In all cases of doubt, or when symptoms persist, seek medical attention.

Following inhalation:

None expected to require first aid measures. If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

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Following skin contact:

None expected to require first aid measures. Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

Following eye contact:

None expected to require first aid measures. Flush with running water for at least 15 minutes. If irritation persists get medical attention.

Following ingestion:

Immediate first aid is not likely to be required. A physician or poison control center can be contacted for advice.

4.2. Most important symptoms and effects, both acute and delayed

The product is not classified as harmful to human health effect.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Use extinguishing agents appropriate for surrounding fire.

Unsuitable extinguishing media:

Not investigated.

5.2. Special hazards arising from the substance or mixture

Not found yet.

5.3. Advice for firefighters

Wear self-contained breathing apparatus for fire fighting if necessary.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Use personal protective equipment. Ensure adequate ventilation. Evacuate personnel to safe areas.

For emergency responders:

Avoid skin and eye contact. Refer to section 8 of MSDS for personal protection details.

6.2. Environmental precautions

Avoid disposing into drainage/sewer system or directly into the aquatic environment.

6.3. Methods and material for containment and cleaning up

Cassette: Sweep up and shovel into suitable containers. Clean up affected area

Buffer: with liquid-binding material (sand, diatomite, acid binders, universal, binders, sawdust).

6.4. Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

Section 7. Handling and storage

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7.1. Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Wash thoroughly after handling.
Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

7.3. Specific end use(s):

Not available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure limits:

Cassette: Not available.

Buffer:

Substance	EC No.	CAS No.	Occupational Exposure Limit Value (8-hours reference period)		Occupational Exposure Limit Value (15-minutes reference period)	
			ppm	mg/m ³	ppm	mg/m ³
Sodium chloride	231-598-3	7647-14-5	-	5	-	-
Sodium azide (as NaN ₃)	247-852-1	26628-22-8	-	0.1	-	0.3

8.1.2 Additional exposure limits under the conditions of use:

Not available.

8.1.3 DNEUDMEL and PNEC-Values:

Not available.

8.2. Exposure controls

Appropriate engineering controls

Use adequate ventilation to keep airborne concentrations low.

Individual protection measures, such as personal protective equipment

Eye/face protection: No special requirements.

Hand protection: No special requirements. Wear gloves if necessary.

Body protection: No special requirements.

Respiratory protection: No special requirements.

Thermal hazards: Wear suitable protective clothing to prevent heat.

Environmental exposure controls

Avoid discharge into the environment. Dispose of rinse water in accordance with local and national regulations

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Parameter	<u>Cassette:</u>	<u>Buffer:</u>
	Value / test method / remarks	Value / test method / remarks
Physical State	Solid	Liquid
Colour	White	Colorless transparent
Odour	Odourless	Weak odor
Melting point / freezing point	Not available	Not available
Boiling point or initial boiling point and boiling range	Not available	Not available
Flammability	Not available	Not available

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Lower and upper explosion limit	Not explosive	Not explosive
Flash point	Not established	Not established
Auto-ignition temperature	Product is not known to be self-igniting.	Product is not known to be self-igniting.
Decomposition temperature	Not established	Not established
pH-value at 20 °C	Not established	Not established
Kinematic viscosity	Not established	Not established
Solubility in water / in other solvents	Not available	Not available
Partition coefficient n-octanol/water (log value)	Not established	Not established
Vapour pressure	Not established	Not established
Density and/or relative density (20 °C)	Not established	Not established
Relative vapour density	Not established	Not established
Particle characteristics	Not established	Not relevant, liquid

9.2. Other information

Information with regard to physical hazard classes:

None

Other safety characteristics:

None

Section 10. Stability and reactivity

10.1. Reactivity

The substance is stable under normal storage and handling conditions.

10.2. Chemical stability

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon oxides.

Section 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Summaries of the information derived from the test conducted:

Not available

Relevant toxicological properties:

Not available

Information on likely routes of exposure:

Not available

Symptoms related to the physical, chemical and toxicological characteristics:

Not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure:

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Not available

Interactive effects:

Not available

Absence of specific data:

Not available

11.2. Information on other hazards

Endocrine disrupting properties: The mixture does not contain endocrine disruptor.

Other information: Not applicable

Section 12. Ecological information

12.1. Toxicity

Cassette: Not available

Buffer: Sodium chloride (CAS# 7647-14-5)

Acute toxicity:

LC50(96h, Fish): 5840 mg/L

LC50(48h, Crustacea): 874 mg/L

EC50(72h, Algae/aquatic plants): Not available

Chronic (long-term) toxicity: Buffer

NOEC(Fish): 252 mg/L

NOEC(Crustacea): 314 mg/L

EC50(Algae/aquatic plants): Not available

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

Section 13. Disposal considerations

13.1. Waste treatment methods

The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

Information regarding the disposal of the product:

Not available

Information regarding the disposal of the packaging:

Not available

Physical/chemical properties that may affect waste treatment options shall be specified:

Not available

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Sewage disposal:

Not available

Special precautions for any recommended waste treatment:

Not available

Section 14. Transport information

14.1. UN number or ID number

Not regulated

14.2. UN proper shipping name

Not regulated

14.3. Transport hazard class(es)

Not regulated

14.4. Packing group

Not regulated

14.5. Environmental hazards

no

14.6. Special precautions for user

See sections 2.2

14.7. Maritime transport in bulk according to IMO instruments

Not regulated

Section 15. Regulatory information

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

Relevant information regarding authorization: Not applicable.

Relevant information regarding restriction: Not applicable.

Other EU regulations: Employment restrictions concerning young person must be observed.

For use only by technically qualified individuals.

National regulations:

Not applicable

15.2. Chemical safety assessment

No

Section 16. Other information

Reason of Change:

Version 05 Amended by (EU) 2020/878

Hazard statements mentioned in Sections 2 and 3:

Directive (EC) 127/2008:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulation for rail International transportation of Dangerous goods

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: Code international maritime dangerous goods code

ICAO: International Civil Aviation Organization

IATA: International Air Transport Association

UFI: Unique Formula Identifier

LC50: median lethal concentration

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EC50: The effective concentration of substance that causes 50% of the maximum response.

NOEC: No Observed Effect Concentration

DNEL: derived no-effect level

PNEC: predicted no-effect concentration

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