

EU Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 453/2010

DIAQUICK Mononucleosis Cassette

1. Identification of the substance/preparation and of the company/undertaking

1.1 Identification of the substance or preparation

DIAQUICK Mononucleosis Cassette

The product is part of the following catalogue numbers:

Z06620CE Z05620B

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

General use: Reagent for in-vitro diagnostics in human samples

1.3 Details of the supplier of the safety data sheet

<u>Company name:</u>	Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
<u>Street:</u>	IZ NÖ-Süd, Hondastrasse, Objekt M55
<u>Postal code, city, state:</u>	A-2351 Wr. Neudorf, Austria
<u>World Wide Web:</u>	www.dialab.at
<u>E-mail:</u>	office@dialab.at
<u>Telephone:</u>	+43 (0)2236 660910-0
<u>Telefax:</u>	+43 (0)2236 660910-30
<u>Dept. Responsible for information:</u>	+43 (0)2236 660910-0

1.4. Emergency telephone number

Vienna General Hospital, Toxication Centre, phone: +43-(0)1-4064343

2. Hazards identification

2.1 Classification of the substance or mixture:

Classification according to EC regulation 1272/2008 (CLP):
This mixture is classified as not hazardous.

2.2 Label elements:

None.

2.3 Other hazards:

No risks worthy of mention.

3. Composition / information on ingredients

3.1 Substances not applicable

3.2 Mixtures

Chemical characterization (preparation):

In vitro diagnostics reagent test device. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

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Hazardous ingredients:

<u>Ingredient</u>	<u>Chemical name</u>	<u>Content</u>	<u>Classification</u>
CAS: 26628-22-8	Sodium azide	< 0.1 %	Acute Tox Oral CAT 4; H302
EC: 247-852-1			Acute Aquatic Tox CAT 3; H412
Index No.: 011-004-00-7			

Additional information:

Each device is packaged in a foil pouch.

For the wording of the listed risk phrases refer to section 16.

Contains sodium azide (< 0.1 %) as preservative.

4. First aid measures

4.1 Description of first aid measures

<u>After inhalation:</u>	Move victim to fresh air. In case of respirator difficulties seek medical attention.
<u>In case of skin contact:</u>	After contact with skin, wash immediately with soap and plenty of water. Change contaminated clothing. In case of skin reactions, consult a physician.
<u>After eye contact:</u>	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.
<u>After swallowing:</u>	Rinse mouth thoroughly with water. Induce vomiting. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), extinguishing powder or water spray/fog.
Fight larger fires with water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None.

5.2 Special hazards arising from the substance or mixture

Nitrogen oxides (NO_x), Oxides of phosphorus (P_xO_y), Carbon monoxide (CO) and Carbon dioxide (CO₂)

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus. Wear suitable protective clothing.

Additional information:

Hazchem-Code: -

Collect contaminated firefighting water separately. Do not allow fire water to penetrate into surface or ground water.

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6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with the substance. Wear personal protection equipment. Do not breathe vapour/aerosol. Provide adequate ventilation.

6.2 Environmental precautions:

Do not allow to enter into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent, liquid-binding materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Clean the contaminated area with: bleaching agent 10%-solution.

6.3 Reference to other sections

Refer additionally to chapter 13.

7. Handling and storage

7.1 Precautions for safe handling:

Information on safe handling:

For use only by qualified technical staff. Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. This product contains a substance with human origin. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial. Refer additionally to chapter 11. Make sure that all applicable workplace limits are observed.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Observe all local and national regulations for storage of water polluting products. Keep containers tightly closed and at a temperature between 2°C and 30°C. Protect from heat and light.

Hints on joint storage:

Keep away from food, drink and animal feeding stuffs.

Storage class:

12 non-combustible liquids

7.3 Specific end use(s)

Reagent for in-vitro diagnostics in human samples.

8. Exposure controls/personal protection

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

Sodium azide	WEL (Great Britain):	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³
	TLV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³
		Skin

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Additional information: The lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures:

Change contaminated clothing. When using do not eat, drink or smoke. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

Respiratory protection:

Provide adequate ventilation.

Hand protection:

Protective gloves according to EN 374.

Glove material: Nitrile rubber-Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

Tightly sealed safety glasses according to EN 166.

Body protection:

Lab coat.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state:

Laminated test strip, housed in a plastic holder

Colour:

off white plastic holder with blue font

Odour:

odourless

Melting point/-range:

not determined

Boiling point/-range:

not determined

Flash point:

not applicable

Self-inflammability:

product is not self-igniting.

Danger of explosion:

product is not explosive.

Density:

not determined

Water solubility:

soluble

9.2 Other information

No data available

10. Stability and reactivity

10.1 Reactivity

Refer to 10.3

10.2 Chemical stability

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat /sunlight.

10.5 Incompatible materials

Strong acids, strong oxidizing agents, heavy metals

10.6 Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds.

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Dangerous products of decomposition:

Nitrogen oxides (NO_x), Oxides of phosphorus (P_xO_y), Carbon monoxide (CO) and Carbon dioxide (CO₂)

11. Toxicological information

11.1 Information on toxicological effects

General remarks:

Sodium azide	Oral	LD50	27 mg/kg (rat)
	Dermal	LD50	20 mg/kg (rabbit)

Primary irritant effect on the skin: No irritant effect.

Primary irritant effect on the eye: No irritant effect.

Sensitization: No sensitizing effect known.

Additional toxicological information: The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. Ecological information

12.1 Toxicity

Aquatic toxicity:

Sodium azide	LC50/96 h	0.7 mg/L (bluegill (Iepomis macrochirus))
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Water hazard class 1 (Self-assessment): Slightly hazardous for water.

12.2 Persistence and degradability

Further details: 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

No data available

12.6 Other adverse effects

General information:

Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

13.1 Waste treatment methods

Product:

Waste key number:

160506 = Laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals.

Recommendation:

Clean with water, if necessary with cleaning agent. Dispose of waste according to applicable legislation.

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Contaminated packaging:

Waste key number: 150102 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.

14. Transport information

14.1 UN number

ARD/RID, IMDG, IATA-DGR: not applicable

14.2 UN proper shipping name

ARD/RID, IMDG, IATA-DGR: not restricted

14.3 Transport hazard class(es)

not applicable

14.4 Packing group

not applicable

14.5 Environmental hazards

Marine Pollutant - IMDG: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

15. Regulatory information

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

National regulations – Great Britain: Hazchem-Code: -

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Hazard statements:

H302 Harmful if swallowed

H412 Harmful to aquatic life with long lasting effects

Precautionary statements:

P301+312 IF SWALLOWED: Call a POISON CENTER/doctor/.../if you feel unwell

P330 Rinse mouth

P264 Wash hands thoroughly after handling

P270 Do not eat, drink or smoke when using this product

P273 Avoid release to the environment

P501 Dispose of content/container to ... in accordance with local/regional/national/international regulations

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In vitro diagnostics use only.

Sodium azide is been used as preservative. Products containing Sodium azide must be handled with due caution: Do not ingest or allow to contact skin or mucous membranes!

Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

Reason of change: EC regulation 1272/2008 (CLP)

Group that issues data sheet

Contact person: see chapter 1, department responsible for information.

The information in this data sheet has been established to our best knowledge and was up-to-date of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

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