

Material and Safety Data Sheets

Phadebact® Monoclonal GC Test

1. Identification of company and product(s)

Trade name: Phadebact® Monoclonal GC Test 10-6419-12

Synonyms: not applicable

CAS-no: not applicable

Formula: not applicable

EC-no: not applicable

Manufacturer:

MKL Diagnostics AB, Kung Hans Väg 3, 192 68 Sollentuna, Sweden. info@mkldiagnostics.com

2. Composition and Information on ingredients

Component/Substance	CAS-no	Content %	Hazard information	R-phrases
WI Reagent/ <u>Sodium azide</u>	26628-22-8	<0.1%	T+, N	R28, R32, R50-53
WII/WIII Reagent/ <u>Sodium azide</u>	26628-22-8	<0.1%	T+, N	R28, R32, R50-53

Other constituents in the reagents are phosphate buffer with sodium chloride, specific antibodies raised in rabbits, murine monoclonal antibodies or gammaglobulin coupled to non-viable *Staphylococcus aureus* cells (2% w/w) coloured with methylene blue. These mixtures have not been tested, but at the concentrations used in the Phadebact® reagents, none of the constituents should present a risk to the user if used in accordance with the product insert, instructions and precautions.

Key: T+=Highly toxic, T=Toxic, C=Corrosive, Xn=Harmful, Xi=Irritating, E=Explosive, O=Oxidizing, F+=Extremely flammable, F=Highly flammable, B=Biohazardous, N=Dangerous for the environment

3. Hazard identification

Sodium azide is not classified as hazardous in this preparation, however, the solution may be sensitizing. Sodium azide in a more concentrated solution than 0.1% is considered harmful to highly toxic by inhalation, skin contact or ingestion.

T, Toxic substances (in some countries also an extra class, highly toxic, **T+**) are hazardous when inhaled, swallowed or in contact with the skin and eye and may even lead to death. Avoid contact or breathing of vapours. Immediately contact a doctor when contact is known or suspected.

C, Corrosive substances can cause severe burns (destructive to all tissue, e.g. mucous membranes, eye and skin) and are harmful if swallowed, inhaled or absorbed through skin. Do not breathe vapours and avoid contact with skin, eyes and clothing.

Xn, Harmful substances can cause adverse symptoms (short term headache, irritability, gastric disturbance or long term sensitizing or mutagenic effects) when inhaled, swallowed or in contact with eye and skin. Avoid contact or breathing of vapours.

Xi, Irritating substances may have an irritant effect on skin, eyes and respiratory organs. Avoid contact or breathing of vapours.

E, Explosive substances may explode under definite conditions. Avoid shock, friction, sparks and heat.

O, Oxidizing substances can ignite combustible material or worsen existing fires. Keep away from combustible material.

F, Highly flammable substances (in some countries also an extra class, extremely flammable, **F+**) are 1) Spontaneously flammable substances. Avoid contact with air; 2) Highly flammable gases. Avoid mixture with air and keep away from sources of ignition; 3) Substances sensitive to moisture forming flammable gases in contact with water. Avoid contact with moisture or water; 4) Flammable liquids with a flash point below 21 °C. Avoid open fire, sparks or heat.

B, Biohazardous i.e. potentially infectious and may contain material transmitting human disease. Avoid contact, handle and dispose of contaminated material not to cause aerosols or cuts.

N, Dangerous for the environment, substances may cause acute toxic effects or long-term adverse effects on living organisms or the aquatic, terrestrial or atmospheric environment.

4. First aid measures

Ingestion

If swallowed, wash out mouth with water.

Inhalation

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Contact with skin

Flush skin with water, clean with soap and water.

Contact with eyes

Flush eyes with a large volume of water. Ensure flushing by separating the eyelid with fingers if necessary.

5. Fire-fighting measures

General information

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Recommended fire extinguishing material

Water, dry powder or vapourizing liquids (e.g. CO₂) may be used.

6. Accidental release measures

Personal protective measure

Wear chemical resistant gloves, safety goggles and protective clothing (laboratory coat).

Environmental protective measure

Flush with water upon disposal.

Spillage measures

Spillage should be mopped with damp paper towels and the waste disposed of according to local recommendations. It is recommended that the assays are performed on a suitable containment tray or absorbent sheeting.

7. Handling and storage

Handling

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Storage

Store at 2-8 °C, use within expiry date.

8. Exposure control/personal protection

Limitation of exposure

Use only in designated laboratory area following established methods for good laboratory practice in clinical microbiology laboratories.

Protective measures

Do not pipette by mouth. Wear laboratory coat and use other safety measures for handling of biohazardous specimen. Do not eat, drink or smoke in the laboratory or before washing hands after handling. Dispose of used material safely.

9. Physical and chemical properties

The material is in aqueous solution consisting of inactivated cells (particles) coated with rabbit or mouse antibodies specifically directed against surface antigens of the microorganism to be identified (see reagent designation). When that microorganism is present in the (culture) specimen at a detectable level, the surface antigen will interact with the particles to produce a visible agglutination. The particles are coloured blue to facilitate reading of the agglutination.

10. Stability and reactivity

Stability

All reagents are stable under the recommended storage conditions.

Reactivity

Sodium azide may react with e.g. metals to form highly explosive metal azides.

Hazardous products upon decomposition

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11. Toxicological information

Acute toxicity

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Health effects

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Antidotes

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12. Ecological information

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13. Disposal considerations

The reagents contain sodium azide as preservative (NaN_3). Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Specimen (samples) and used material should be handled as clinical waste and incinerated.

14. Transport information

<u>Transport</u>	<u>UN-nr.</u>	<u>Class</u>
Road (ADR)		Not classified
Railway (RID)	-"-	
Sea (IMDG)	-"-	
Airway (DGR-IATA)	-"-	

15. Regulatory information

Classification/labelling

Hazard classification:	Sodium azide is not classified as hazardous at the concentration used
Risk phrases:	None
Safety phrases:	None

Europe: The material and safety data sheet has been designed according to the directions given by the Swedish National Chemicals Inspectorate (KIFS 2005:7) following the directives 67/548/EEG with amendment 98/98/EG and 1999/45/EC.

US: These products are subject to regulation under the US Federal Food, Drug and Cosmetic Act.

This information does not constitute an assessment of risk of use in the workplace, but may be used in such an assessment. Risk assessment is the responsibility of the user and depend on local conditions of use.

Bactus AB believes that the information given in this document is reliable as of the date of release, but no representation guarantee or warranty, expressed or implied, is made as to the accuracy, reliability or completeness of information. Any person receiving this document should make their own assessment as to the suitability and completeness of the information for their specific application.

16. Other information

Further information can be supplied on request. The information given above relates only to the products specified. Upon any incident with suspected contact with hazardous substances or symptoms (malaise) following exposure to chemical substances it is recommended to take contact with a doctor.

It is recommended that each distributor of these products shall design country-specific material and safety data sheets.