



Safety Data Sheet

Borrelia burgdorferi IgM

According to EEC Directive 91/155/EEC
Date of issue: 28.11.2006

I. Identification of the preparation and the company

Identification of the product

Product name: Borrelia burgdorferi IgM
Product classification: in-vitro-diagnostics
Product number: BORM0040

Manufacturer identification

Company: NovaTec Immundiagnostica GmbH
Waldstr. 23 A6
D-63128 Dietzenbach (Germany)
Tel.: 06074/48760

Emergency Telephone number: Please contact the local hospitals.

II. Composition/ Ingredients Information

1. Coated Wells (IgM):

Chemical Characterisation: 96 wells-microtiter plastic plate coated with inactivated antigen
Dangerous ingredients: -

2. IgM Sample Diluent:

Chemical Characterisation: aqueous buffer solution for sample dilution
Dangerous ingredients: Name according to EEC directive:

Kathon CG

Hazard symbols: C
CAS No.: 26172-55-4, 2682-20-4
7786-30-3, 10377-60-3
R-sentences: 23/24/25-34-43-50/53
Content: 0.1% (w/v)

Sodium azide

Hazard symbols: T+
EINECS No.: 011-004-00-7
CAS No.: 26628-22-8
R-sentences: 28-32
Content: 0.09% (w/v)

3. Stop Solution:

Chemical Characterisation: aqueous solution for stopping the reaction
Dangerous ingredients: Name according to EEC directive:

Sulphuric Acid

Hazard symbols: C
EINECS No.: 231-639-5
CAS No.: 7664-93-9
R-sentences: 35
Content: ≥ 1 - $< 5\%$ (w/v)

4. Washing Solution:

Chemical characterisation: 20-fold concentrated buffer solution for washing the wells

Product name: Borrelia burgdorferi IgM
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Dangerous ingredients: Name according to EEC directive:

Kathon CG

Hazard symbols: C
CAS No.: 26172-55-4, 2682-20-4 R-sentences: 23/24/25-34-43-50/53
7786-30-3, 10377-60-3 Content: 0.01% (w/v)

5. Anti-IgM Conjugate:

Chemical characterisation: conjugate solution of peroxidase labelled rabbit antibody to human IgM

Dangerous ingredients: Name according to EEC directive:

5-bromo-5-nitro-1,3dioxane dissolved in 1,2propylene glycol

Hazard symbols: C, N
EINECS No.: 2003380
2500017
CAS No.: 57-55-6 R-sentences: 22/34/50/53
30007-47-7 Content: 0.2% (w/v) in the conjugate buffer

6. TMB Substrate Solution:

Chemical characterisation: aqueous solution for giving a blue reaction product

Dangerous ingredients: Name according to EEC directive:

3,3', 5,5' Tetramethylbenzidin

Hazard symbols: Xn
CAS No.: 54827-17-7 R-sentences: 20/21/22-36/37/38-40
Content: 0.036% (w/v)

Ethylendiaminetetracetate

Hazard symbols: Xn
CAS No.: 6381-92-6 R-sentences: 22-36/37/38
Content: 0.093% (w/v)

Kathon CG

Hazard symbols: C
CAS No.: 26172-55-4, 2682-20-4 R-sentences: 23/24/25-34-43-50/53
7786-30-3, 10377-60-3 Content: < 0.0015% (w/v)

7. IgM Negative/Positive/Cut-off Control:

Chemical characterisation: aqueous control sera (human sera/plasma)

Dangerous ingredients: Name according to EEC directive:

Sodium azide

Hazard symbols: T+
EINECS No.: 011-004-00-7 R-sentences: 28-32
CAS No.: 26628-22-8 Content: 0.09% (w/v)

Kathon CG

Hazard symbols: C
CAS No.: 26172-55-4, 2682-20-4 R-sentences: 23/24/25-34-43-50/53
7786-30-3, 10377-60-3 Content: 0.1% (w/v)

The classification and the risk warnings given in point II, refer to the substances! The same information referring to the preparation is given in point XV.

III. Hazards identification

The preparation is not classified as dangerous according to Directive 67/548/EWG, Directive 1999/45/EG and its amendments.

IV. First aid measures

Product name: Borrelia burgdorferi IgM
Company: NovaTec Immundiagnostica GmbH

1. Coated Wells (IgM):

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2. IgM Sample Diluent:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician.

3. Stop Solution:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician.
Inhalation: Remove victim from the origin of exposure to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Contact a physician. Wash contaminated dress before using it again.

4. Washing Solution:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician.

5. Anti-IgM Conjugate:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician.
Inhalation: Remove victim from the origin of exposure to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Contact a physician.

6. TMB Substrate Solution:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician.
Inhalation: Remove victim from the origin of exposure to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Contact a physician. Wash contaminated dress before using it again.

7. IgM Negative/Positive/Cut-off Control:

Contact with skin: Avoid contact with skin. Remove contaminated Cloths, wash immediately with plenty of water.
Contact with eyes: Avoid contact with eyes. Flush eyes immediately with plenty of water for 15 minutes.
Ingestion: After ingestion rinse mouth several times with plenty of water, give extensive water for drinking, contact a physician. Don't initiate sickness!
Inhalation: Remove victim from the origin of exposure to fresh air. Contact a physician.

V. Fire fighting measures

Usable extinguishing media:

In case of fire use water spray (fog), foam or dry powder. Use in accordance to the surroundings.

For safety reason unusable extinguishing media:

Not specified

Product name: Borrelia burgdorferi IgM
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Special risks caused by the ingredients, the preparation itself, combustion products and gases:

1. Coated wells (IgM):

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2. IgM Sample diluent:

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3. Stop Solution:

In case of fire hazardous combustion gases or vapours can be released. Combustion product: Sulphur oxides (SO₂, SO₃ etc.)

4. Washing Solution:

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5. Anti-IgM Conjugate:

The substance may be combustible at high temperature. Combustion products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂ ...), halogenated compounds, hydrogen bromide gas.

6. TMB Substrate Solution:

In case of fire toxic vapours can be released.

7. IgM Negative/Positive/Cut-off Control:

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Special protective equipment for fire fighting:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

VI. Accidental release measures

Personal precautions:

Avoid contact with the preparation. Don't inhale vapours or atomised spray. Be assured of adequate air ventilation.

Environmental precautions:

Use appropriate tools to put the spilled substances in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Procedure for cleaning/absorption:

Absorb with liquid absorbing material (sand, diatomine, universal binders). Forward to disposal. Clean affected area with plenty of water.

VII. Handling and storage

Handling:

Handle according to good industrial hygiene and safety practices for diagnostic products.

Keep container tightly closed after use. Protect from physical damage.

Do not swallow.

Avoid contact with eyes.

Avoid a prolonged and excessive contact with skin.

Handle all materials as potentially infectious.

Wear rubber gloves and protective clothes. After handling, always wash hands with soap and water.

Storage:

Store kit at 2-8°C in its original container. Keep protected from light.

VIII. Exposure controls/personal protection

1. Personal protective equipment:

Respiratory protection: Avoid inhaling vapour and spray fog. Breathing protection not necessary.

Hand protection: wear safety gloves

Eye protection: wear safety glasses

Body protection: wear a lab coat. Change contaminated cloths immediately. Wash hands after handling with soap and water.

2. Limitation and control of the environmental exposure:

Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposures limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Product name: Borrelia burgdorferi IgM
Company: NovaTec Immundiagnostica GmbH

IX. Physical and chemical properties of the preparation

1. Coated Wells (IgM):

Look: 12 clear breakapart 8-well plastic snap-off strips
Odour: none

2. IgM Sample diluent:

Look: a clear, green liquid
Odour: none
pH-Value: 7.2 ± 0.2
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: data not available
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

3. Stop Solution:

Look: a clear liquid
Odour: none
pH-Value: pH 1 - 2
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: soluble in water
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

4. Washing Solution:

Look: a clear liquid
Odour: none
pH-Value: 7.2 ± 0.2
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: data not available
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

5. Anti-IgM Conjugate:

Look: a clear, red liquid
Odour: none
pH-Value: 7.2 ± 0.2
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: soluble
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

6. TMB Substrate Solution:

Look: a clear light-yellow up to light-blue liquid
Odour: none

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pH-Value: 3,6 ± 3,8
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: completely soluble
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

7. IgM Negative/Positive/Cut-Off Controls:

Look: a clear, light yellow liquid
Odour: none
pH-Value: 7.2 ± 0.2
Boiling temperature: data not available
Ignitibility: data not available
Explosive properties: data not available
Density: data not available
Solubility in water: data not available
Viscosity: data not available
Vapour density: data not available
Evaporation rate: data not available

X. Stability and reactivity

1. Coated Wells (IgM):

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2. IgM Sample diluent:

Conditions to be avoided: excess heat
Substances to be avoided: incompatible materials
Hazardous decomposition products: data not available

3. Stop Solution:

Conditions to be avoided: excess heat and incompatible materials.
Substances to be avoided: reactive with organic materials, alkalis acids, combustible materials.
Hazardous decomposition products: sulphur oxides (SO₂, SO₃, ..)

4. Washing Solution:

Conditions to be avoided: excess heat
Substances to be avoided: incompatible materials
Hazardous decomposition products: --

5. Anti-IgM Conjugate:

Conditions to be avoided: excess heat and incompatible materials. The substance is sensitive to light
Substances to be avoided: reactive with oxidizing agents
Hazardous decomposition products: --

6. TMB Substrate Solution:

Conditions to be avoided: excess heat. The substance is sensitive to light.
Substances to be avoided: reactive with heavy metal salts, peroxidase, catalase
Hazardous decomposition products: data not available

7. IgM Negative/Positive/Cut-Off Controls:

Conditions to be avoided: excess heat.
Substances to be avoided: incompatible materials.
Hazardous decomposition products: --

the test procedure, the information, the precautions and warnings in the instruction for use have to be strictly followed.

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XI. Toxicological information

Expected properties due to the contact with components of the preparation:

5-Bromo-5-nitro-1,3-dioxane:	Skin irritation, eye irritation, respiratory tract and mucous membrane irritation. May affect behaviour/central nervous system (tremor, convulsions, excitement).
Sodium azide:	systemic effects like Tachycardia, decrease of blood pressure, shortness of breath.
Kathon:	Skin irritation, allergic contact dermatitis observed.
Tetramethylbenzidin:	data not available

Further dangerous properties cannot be ruled out.

The preparation must be handled with the usual care for chemicals.

XII. Ecological information

Quantitative data about the ecological effect of the preparation are not available.

Use the preparation according to GLP and avoid dispersion in the environment. An environmental risk cannot be excluded if handling and/or disposal is inadequate.

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

XIII. Disposal considerations

The waste produced from utilizing the preparation and the unused preparation should be disposed of according to the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each Country.

The disposal of liquid effluents should be carried out according to the existing local laws and to the existing local regulation governing water pollution.

XIV. Transport information

No subject to transport regulations

XV. Regulatory information

The preparation is classified and labelled according to EEC directives:

Symbol:	none
R-sentences:	none
S-sentences:	none

Use the preparation according to the national regulations (Chemikaliengesetz, Mutterschutzgesetz, Jugendarbeitsschutzgesetz, Heimarbeitsgesetz).

XVI. Other information

Full text of R-Phrases appearing in point II:

- R 20: harmful to health in case of inhalation
- R 21: harmful to health during contact with skin
- R 22: harmful to health when swallowing
- R 23: poisonous with the inhalation
- R 24: poisonous during contact with the skin
- R 25: poisonous when swallowing
- R 34: causes burns
- R 35: causes heavy burns
- R 36: provokes the eyes
- R 37: provokes the respiratory organs
- R 38: provokes the skin

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R 50: toxic to aquatic organisms

R 53: may cause long-term adverse effects in the aquatic environment

History:

Date of issue: 28.11.2006

This safety sheet has been drafted according to the directives issued by the council and the commission of the European communities.

The purpose of the safety sheet is to ensure correct and safe use, storage, shipment and disposal of the preparation. All included information is based on our knowledge of the preparation at the date of issue of this sheet. It does not represent a guarantee of the properties of the product.

For further information about the preparation please contact NovaTec: info@novatec-id.com;
www.novatec-id.com.