GENERAL SECTION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers

Product name: Borrelia IgM ELISA ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IgM-ANTIBODIES TO BORRELIA IN PLASMA, SERUM OR CEREBROSPINAL FLUID

Product Number: CAT. NO. BI-21042, 12 X 8 TESTS

Brand: Biomedica Medizinprodukte GmbH

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

Identified uses: IN-VITRO DIAGNOSTICS IN EU (CE marked)

1.3. Details of the supplier of the data sheet

Company: Biomedica Medizinprodukte GmbH, A-1210 Wien, Divischgasse 4

Telephone: +43/1/291 07 45

Fax: +43/1/291 07 85

E-mail: info@bmgrp.com

Prepared by Biomedica Slovakia s.r.o., 84101 Bratislava, Drobneho 27

1.4. Emergency telephone number

Phone: +43-1-4064343

1.5. Further information

All reagents sold by BIOMEDICA must be handled only by qualified laboratory personal. All preservative substances used in our products are there in too low concentrations to constitute any danger and standard laboratory precautions should suffice for effective protection.

Nonetheless, in the case of unusual exposure, the form(s), furnished in the appendix, provoke(s) all the necessary information.

1.6. Partition of section 2-16 of the data safety sheet in specific forms

The following are hazardous substances present in this product:

<table>
<thead>
<tr>
<th>Hazardous substance</th>
<th>Substance part of the following ELISA kit component, [Identification name of vial]</th>
<th>Quantity/concentration of (hazardous) substance</th>
<th>Material Safety data sheet [no.]</th>
<th>Page of this MSDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substrate (TMB solution)</td>
<td>SUB</td>
<td>0.1%</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>STOP</td>
<td>2.95%</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Standard</td>
<td>STD</td>
<td>100%</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Sample diluent</td>
<td>DIL</td>
<td>0.05%</td>
<td>4</td>
<td>19</td>
</tr>
</tbody>
</table>
SPECIFIC SECTION

Material safety data sheet no.1

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers
   Kit component name: TMB substrate
   component ID: Sol C
   Brand: Biomedica Medizinprodukte GmbH

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses: AS A SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet
   Company: Biomedica Medizinprodukte GmbH,
   A-1210 Wien, Divischgasse 4
   Telephone: +43/1/291 07 45
   Fax: +43/1/291 07 85
   E-mail: info@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
   Although it is not classified as hazardous according to the European Regulation (EC) No. 1272/2008 the product should be handled with the usual care for all chemicals, in order to avoid synergistic effects.

2.2. Labeling elements
   Labeling according Regulation (EC) No 1272/2008 [CLP]
   Pictogram none
   Signal word none
   Supplemental hazard statements none

2.3. Other hazards
   None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
   See section 3.2

3.2. Mixtures
   Dangerous components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification R-phrases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,3’,5,5’-Tetramethylbenzidine</td>
<td>H315, H319, H335</td>
<td>&lt;0.06%</td>
</tr>
<tr>
<td>EINECS: 259-364-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-NR: 54827-17-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triethylenetetramine</td>
<td>H312, H314, H317, H412</td>
<td>&lt;0.06%</td>
</tr>
<tr>
<td>EINECS: 203-950-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-NR: 112-24-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

4.1. Description of the first aid measures

General advice
Contaminated clothing should be washed prior to next use. Consult a physician, show this safety data sheet to the doctor in attendance.

In case of skin contact
After contact with skin carefully wash with water.

In case of eye contact
After contact with the eyes carefully rinse the opened eye with running water for several minutes and consult a physician.

If swallowed
After swallowing, rinse mouth and drink water. Consult a physician.

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
No data available.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture
No data available.

5.3. Advice for firefighters
In case of fire toxic vapours can be released.
Wear breath protective mask and protective clothes if necessary during fire fighting.

5.4. Further information
The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid contact with skin and eyes.

6.2. Environmental precautions
Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up
Dilute with plenty of water. Ventilate and clean affected area very carefully after having completely disposed off the material.
6.4. Reference to other sections
No data available.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

7.2. Conditions for safe storage, including any incompatibilities
At 2-8°C in closed HDPE or PP bottles. Protect from light.

7.3. Specific end uses
No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
Components with workplace parameters
By using the product according to the requirements, no air pollution is to be expected.

8.2. Expose controls
Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3. Personal protective equipment
Respiratory protection: not required
Hand protection: protective gloves of nitril-rubber or natural latex
Eye protection: protective glasses. Tightly fitting safety goggles. Face-shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties
a) Appearance form: liquid product, slightly foaming when shaken
b) Colour: clear
c) Odour: characteristic
d) pH: 3.1 ± 0.5
e) Melting point/freezing point: no data available.
f) Initial boiling point and boiling range: 100°C
g) Flash point: not applicable
h) Evaporation rate: no data available.
i) Flammability (solid, gas): no data available.
j) Upper/lower flammability or explosive limits: no data available.
k) Vapour pressure: no data available.
l) Vapour density: no data available.
m) Relative density: 1.003 g/ml
n) Water solubility: complete soluble/miscible
9.2. Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity
No data available.

10.2. Chemical stability
Chemically stable under recommended conditions of use and storage.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Strong heat, light, especially sunlight will not cause a dangerous reaction, but destroys the quality as substrate solution.

10.5. Incompatible materials
Heavy metal salts, peroxidases and catalases will not cause a dangerous reaction, but destroys the quality as substrate solution.

10.6. Hazardous decomposition products
High temperature or fire conditions may cause toxic vapor formation, including oxides of carbon, nitrogen, and formation of hydrogen chloride gas.

11. TOXICOLOGICAL INFORMATION
Not classified as acutely toxic by oral, dermal, or inhalation routes.

11.1. Information on toxicological effects

Further toxicological information:
Quantitative data concerning toxicity of the product do not exist.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
No data available.

12.2. Persistence and degradability
No data available.

12.3. Bio-accumulative potential
No data available.

12.4. Mobility in soil
12.5. Results of PBT and vPvB assessment
No data available.

12.6. Other adverse effects
If used properly, no ecological problems are to be expected.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods
Product
May not be discarded together with the normal waste. Chemicals or remaining residues have to be treated as special waste and should be discarded according to the appropriate legislation. Information can be collected from the responsible public authorities.

Contaminated packaging
Disposal according to the instructions of the public authorities. Contaminated packages have to be treated like the substance itself. Packaging, that is not contaminated, can be recycled or treated like normal house garbage.

14. TRANSPORT INFORMATION

14.1. UN number
Non-regulated, non-hazardous for transport.

14.2. UN proper shipping name
Non-regulated, non-hazardous for transport.

14.3. Transport hazard class(es)
Non-regulated, non-hazardous for transport.

14.4. Packaging group
Non-regulated, non-hazardous for transport.

14.5. Environmental hazards
No data available.

14.6. Reportable Quantity (RQ)
No data available.

14.7. Emergency Telephone Number (during transport)
CHEMTREC: 1-800-424-9300 (US and Canada)
1-703-527-3887 (International shipments)

14.8. Special precautions for user
No data available.

15. REGULATORY INFORMATION
This safety datasheet complies with the requirements of Regulation (EC) No.1272/2008.

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Symbol: not applicable.
Designation: not applicable.

15.2. Chemical Safety assessment

16. OTHER INFORMATION
Text of H-code(s) mentioned in Section 3

<table>
<thead>
<tr>
<th>classification</th>
<th>Number</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>302</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td></td>
<td>314</td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td></td>
<td>312</td>
<td>Harmful in contact with skin.</td>
</tr>
<tr>
<td></td>
<td>317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td></td>
<td>318</td>
<td>Causes serious eye damage.</td>
</tr>
<tr>
<td></td>
<td>315</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td></td>
<td>319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td></td>
<td>335</td>
<td>May cause respiratory irritation.</td>
</tr>
<tr>
<td></td>
<td>412</td>
<td>Harmful to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

Further information
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.
SPECIFIC SECTION

Material safety data sheet no.2

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers
- Kit component name: Sulfuric acid (H₂SO₄)
- Component ID: STOP
- Brand: Biomedica Medizinprodukte GmbH

1.2. Relevant identified uses of the substance or mixture and uses advised against
- Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet
- Company: Biomedica Medizinprodukte GmbH, A-1210 Wien, Divischgasse 4
- Telephone: +43/1/291 07 45
- Fax: +43/1/291 07 85
- E-mail: info@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
- Not classified as hazardous according to Regulation (EC) No. 1272/2008.

Label elements
- Labeling according Regulation (EC) No 1272/2008 [CLP]
  - Pictogram: none
  - Signal word: none
  - Supplemental hazard statements: none

2.2. Other hazards
- No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances
- See section 3.2

3.2. Mixtures

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>Skin Corr. Category 1A; Corrosive to metals (Cat 1); H 315, H319, H335</td>
<td>2.95%</td>
</tr>
<tr>
<td>CAS-No. 7664-93-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-Nr. 231-639-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INDEX-Nr. 016-020-00-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>-</td>
<td>97.05%</td>
</tr>
<tr>
<td>CAS-No. 7732-18-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No. 231-791-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the H-statements mentioned in this section, see section 16.

4. FIRST AID MEASURES

4.1. Description of the first aid measures

General advice
- Consult a physician, show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact**
Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact**
Rinse thoroughly with plenty of water for at least 15 min and consult a physician.

**If swallowed**
Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### 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
No data available.

### 5. FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing media
**Suitable extinguishing media**
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### 5.2. Special hazards arising from the substance or mixture
No data available.

#### 5.3. Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

#### 5.4. Further information
No data available.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

#### 6.2. Environmental precautions
Do not let product enter drains.

#### 6.3. Methods and materials for containment and cleaning up
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

#### 6.4. Reference to other sections
No data available.

### 7. HANDLING AND STORAGE

#### 7.1. Precautions for safe handling
- **P280** Wear protective gloves/protective clothing/eye protection/face protection.
- **P301+P330+P331** If swallowed: Rinse mouth out, do not induce vomiting.
- **P305+P351** IN CASE OF CONTACT WITH THE EYES: Rinse carefully with water for a few minutes. Remove any contact lenses if possible. Continue rinsing.
7.2. Conditions for safe storage, including any incompatibilities
   Store in a 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 uses
   No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1. Control parameters
   Components with workplace parameters
   No data available.

8.2. Expose controls
   Appropriate engineering controls
   Handle in accordance with good industrial hygiene and safety practice. Wash hands
   before breaks and at the end of workday.

8.3. Personal protective equipment
   Eye/face protection
   Tightly fitting safety goggles. Face-shield (8-inch minimum). Use equipment for eye
   protection tested and approved under appropriate government standards such as NIOSH
   (US) or EN 166 (EU).
   Skin protection
   Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal
   technique (without touching glove's outer surface) to avoid skin contact with this product.
   Dispose of contaminated gloves after use in accordance with applicable laws and good
   laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy
   the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
   Body protection
   Lab coat protecting against chemicals, the type of protective equipment must be selected
   according to the concentration and amount of the dangerous substance at the specific
   workplace.
   Respiratory protection
   Where risk assessment shows air-purifying respirators are appropriate use a full-face
   respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator
   cartridges as a backup to engineering controls. If the respirator is the sole means of
   protection, use a full-face supplied air respirator. Use respirators and components tested
   and approved under appropriate government standards such as NIOSH (US) or CEN
   (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on basic physical and chemical properties
   a) Appearance form: liquid
   b) Odour: no data available.
   c) Odour Threshold: no data available.
   d) pH: no data available.
   e) Melting point/freezing point: no data available.
   f) Initial boiling point and boiling range: no data available.
   g) Flash point: no data available.
   h) Evaporation rate: no data available.
   i) Flammability (solid, gas): no data available.
   j) Upper/lower flammability or explosive limits: no data available.
k) Vapour pressure: no data available.
l) Vapour density: no data available.
m) Relative density: no data available.
n) Water solubility: no data available.
o) Partition coefficient: n-octanol/water: no data available.
p) Auto-ignition temperature: no data available.
q) Decomposition temperature: no data available.
r) Viscosity: no data available.
s) Explosive properties: no data available.
t) Oxidizing properties: no data available.

9.2. Other safety information
No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity
No data available.

10.2. Chemical stability
Chemically stable under recommended conditions of use and storage.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
No data available.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No data available.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity
No data available.
Sk

Skin corrosion/irritation
No data available.
Serious eye damage/eye irritation
No data available.
Respiratory or skin sensitization
No data available.
Germ cell mutagenicity
No data available.
Carcinogenicity
IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (Sulfuric acid)
Reproductive toxicity
No data available.
Specific target organ toxicity - single exposure
No data available.
Specific target organ toxicity - repeated exposure
No data available.
Aspiration hazard
No data available.
Potential health effects
Inhalation  May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.

Ingestion  May be harmful if swallowed. Causes burns.

Skin  May be harmful if absorbed through skin. Causes skin burns.

Eyes  May be harmful in contact with eyes. Causes eye burns.

Additional information  
No data available.

12. ECOLOGICAL INFORMATION

12.1. Toxicity  
No data available.

12.2. Persistence and degradability  
No data available.

12.3. Bio-accumulative 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  
No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods  
Product  
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging  
Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1. UN number  
Non-regulated, non-hazardous for transport.

14.2. UN proper shipping name  
Non-regulated, non-hazardous for transport.

14.3. Transport hazard class(es)  
Non-regulated, non-hazardous for transport.

14.4. Packaging group  
Non-regulated, non-hazardous for transport.

14.5. Environmental hazards  
No data available.

14.6. Reportable Quantity (RQ)  
No data available.

14.7. Emergency Telephone Number (during transport)  
CHEMTREC: 1-800-424-9300 (US and Canada)  
1-703-527-3887 (International shipments)

14.8. Special precautions for user  
No data available.

15. REGULATORY INFORMATION
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

15.2. Chemical safety assessment
No data available.

16. OTHER INFORMATION
Text of H-code(s) mentioned in Section 3

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>315</td>
<td>Causes severe skin burns</td>
</tr>
<tr>
<td></td>
<td>319</td>
<td>Causes severe eyes irritation</td>
</tr>
</tbody>
</table>

Further information
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.
SPECIFIC SECTION

Material safety data sheet no.3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers
   Kit component name: Control
   Component ID: CTRL 1+2
   Kit component name: Calibrator
   Component ID: CAL
   Brand: Biomedica Medizinprodukte GmbH

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet
   Company: Biomedica Medizinprodukte GmbH, A-1210 Wien, Divischgasse 4
   Telephone: +43/1/291 07 45
   Fax: +43/1/291 07 85
   E-mail: info@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
   Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements
   Labeling according Regulation (EC) No 1272/2008 [CLP]
   The product does not need to be labeled in accordance with EC directives or respective national laws.

2.3. Other hazards
   No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
   See section 3.2

3.2. Mixtures

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>human serum</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

4.1. Description of the first aid measures
   General advice
   Consult a physician, show this safety data sheet to the doctor in attendance.

   If inhaled
   Move to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

   In case of skin contact
In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.

**In case of eye contact**
In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

**If swallowed**
If swallowed, wash out mouth with water provided person is conscious. Call a physician immediately.

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
No data available.

5. FIRE-FIGHTING MEASURES
5.1. Extinguishing media
**Suitable extinguishing media**
Suitable: Use extinguishing media appropriate to surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture
Nature of decomposition products not known.

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

5.4. Further information
No data available.

6. ACCIDENTAL RELEASE MEASURES
6.1. Personal precautions, protective equipment and emergency procedures
Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves.

6.2. Methods and materials for containment and cleaning up
Sweep up, place in a bag and store for waste disposal. Avoid raising dust. Wash spill site with 10% bleach and ventilate area after material pickup is complete.

6.3. Reference to other sections
No data available.

7. HANDLING AND STORAGE
7.1. Precautions for safe handling
Avoid inhalation. Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.

7.2. Conditions for safe storage, including any incompatibilities
Conditions of storage: Keep tightly closed. Store at < -25°C after reconstitution.

7.3. Specific end uses
No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1. Control parameters
Components with workplace parameters
No data available.

8.2. Expose controls
ENGINEERING CONTROLS:
Safety shower and eye bath. Mechanical exhaust required.
GENERAL HYGIENE MEASURES:
Wash thoroughly after handling.

8.3. Personal protective equipment:
Respiratory protection: Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator.
Hand protection: Compatible chemical-resistant gloves.
Eye protection: Chemical safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on basic physical and chemical properties
a) Appearance form: lyophilised
b) Colour: clear - yellowish
c) Odour: characteristic
d) pH: no data available.
e) Melting point/freezing point: no data available.
f) Initial boiling point and boiling range: no data available.
g) Flash point: no data available.
h) Evaporation rate: no data available.
i) Flammability (solid, gas): no data available.
j) Upper/lower flammability or explosive limits: no data available.
k) Vapour pressure: no data available.
l) Vapour density: no data available.
m) Relative density: no data available.
n) Water solubility: no data available.
o) Partition coefficient: n-octanol/water: no data available.
p) Auto-ignition temperature: no data available.
q) Decomposition temperature: no data available.
r) Viscosity: no data available.
s) Explosive properties: no data available.
t) Oxidizing properties: no data available.

9.2. Other safety information
No data available.

10. STABILITY AND REACTIVITY
10.1. Reactivity
Hazardous polymerization: will not occur.

10.2. Chemical stability
Chemically stable under recommended conditions of use and storage.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Strong oxidizing agents.
10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
Nature of decomposition products not known.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity
No data available.

Skin corrosion/irritation
Skin contact: May cause skin irritation.
Skin absorption: May be harmful if absorbed through the skin.

Serious eye damage/eye irritation
May cause eye irritation.

Respiratory or skin sensitization
Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.

Germ cell mutagenicity
No data available.

Carcinogenicity
No data available.

Reproductive toxicity
No data available.

Specific target organ toxicity - single exposure
No data available.

Specific target organ toxicity - repeated exposure
No data available.

Aspiration hazard
No data available.

Additional information
May be harmful if swallowed.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
No harmful effect at used concentration.

12.2. Persistence and degradability
No data available.

12.3. Bio-accumulative 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
No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product
Contact a licensed professional waste disposal service to dispose of this material. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal, state, and local environmental regulations.
14. TRANSPORT INFORMATION
14.1. UN number
Non-regulated, non-hazardous for transport.
14.2. UN proper shipping name
Non-regulated, non-hazardous for transport.
14.3. Transport hazard class(es)
Non-regulated, non-hazardous for transport.
14.4. Packaging group
Non-regulated, non-hazardous for transport.
14.5. Environmental hazards
No data available.
14.6. Reportable Quantity (RQ)
No data available.
14.7. Emergency Telephone Number (during transport)
CHEMTREC: 1-800-424-9300 (US and Canada)
1-703-527-3887 (International shipments)
14.8. Special precautions for user
No data available.

15. REGULATORY INFORMATION
CLASSIFICATION AND LABELING ACCORDING TO EU DIRECTIVES
INDICATION OF DANGER: B Biohazard.
Not hazardous according to Directive 67/548/EEC.
Caution: Substance not yet fully tested (EU).
COUNTRY SPECIFIC INFORMATION
Germany
WGK: 3
Self-Classification

15.1. Safety, health and environmental regulations/legislation specific for the
substance or mixture
No data available.

15.2. Chemical safety assessment
No data available.

16. OTHER INFORMATION
No data available.

Further information
The above information is believed to be correct but does not purport to be all inclusive
and shall be used only as a guide. The information in this document is based on the
present state of our knowledge and is applicable to the product with regard to
appropriate safety precautions. It does not represent any guarantee of the properties
of the product. Biomedica Medizinprodukte GmbH shall not be held liable for any
damage resulting from handling or from contact with the above product. See reverse
side of invoice or packing slip for additional terms and conditions of sale.
SPECIFIC SECTION

Material safety data sheet no.4

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE
   COMPANY/UNDERTAKING

1.1. Product identifiers
   Kit component name: Sample diluent
   component ID: DIL
   Brand: Biomedica Medizinprodukte GmbH

1.2. Relevant identified uses of the substance or mixture and uses advised against
   Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet
   Company: Biomedica Medizinprodukte GmbH,
   A-1210 Wien, Divischgasse 4
   Telephone: +43/1/291 07 45
   Fax: +43/1/291 07 85
   E-mail: info@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
   Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements
   Labeling according Regulation (EC) No 1272/2008 [CLP]
   Pictogram none
   Signal word none
   Hazard statement none
   Precautionary statement none
   Supplemental hazard statements none

2.3. Other hazards
   None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
   See section 3.2

3.2. Mixtures
   Dangerous components:
<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration/percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary formulation; no hazardous components above 1% or carcinogens above 0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No. None</td>
<td>Not classified</td>
<td>100%</td>
</tr>
<tr>
<td>EINECS-No. None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumine, from bovine serum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No. 9048-46-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No. 232-936-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   | -                                |                 | 0.05%                    |
4. FIRST AID MEASURES
4.1. Description of the first aid measures
   General advice
   Consult a physician, Show this safety data sheet to the doctor in attendance.
   
   If inhaled
   If breathed in, move person into fresh air. If not breathing, give artificial respiration.
   
   In case of skin contact
   Wash off immediately with soap and plenty of water.
   
   In case of eye contact
   Rinse thoroughly with plenty of water, also under the eyelids.
   
   If swallowed
   Never give anything by mouth to an unconscious person. Call a physician.

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
   No data available.

5. FIRE-FIGHTING MEASURES
5.1. Extinguishing media
   Suitable extinguishing media
   No restriction; Use appropriate agent for surrounding fire.

5.2. Special hazards arising from the substance or mixture
   Hazardous decomposition products formed under fire conditions. - Nature of decomposition products not known.

5.3. Advice for firefighters
   Wear self-contained breathing apparatus and protective suit.

5.4. Further information
   No data available.

6. ACCIDENTAL RELEASE MEASURES
6.1. Personal precautions, protective equipment and emergency procedures
   Use personal protective equipment.

6.2. Methods and materials for containment and cleaning up
   Soak up with inert absorbent material. Do not let product enter drains.

6.3. Reference to other sections
   No data available.

7. HANDLING AND STORAGE
7.1. Precautions for safe handling
   No special handling advice required.

7.2. Conditions for safe storage, including any incompatibilities
   Keep in properly labeled containers; Store at 2-8°C.
7.3. Specific end uses
No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
Components with workplace parameters
No data available.

8.2. Expose controls
Appropriate engineering controls
Ensure adequate ventilation, especially in confined areas.
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Tightly fitting safety goggles.

Skin protection
Handle with chemical-resistance gloves.

Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance form: liquid
b) Colour: clear - yellowish
c) Odour: none
d) pH: No data available.
e) Melting point/freezing point: No data available.
f) Initial boiling point and boiling range: 100°C
g) Flash point: No data available.
h) Evaporation rate: No data available.
i) Flammability (solid, gas): no applicable
j) Upper/lower flammability or explosive limits: no applicable
k) Vapour pressure: No data available.
l) Vapour density: No data available.
m) Relative density: No data available.
n) Water solubility: completely
o) Partition coefficient: n-octanol/water: No data available.
p) Auto-ignition temperature: no applicable
q) Decomposition temperature: No data available.
r) Viscosity: No data available.
s) Explosive properties: not explosive
t) Oxidizing properties: No data available.

9.2. Other safety information
No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity
Hazardous polymerization: will not occur
10.2. **Chemical stability**

Chemically stable under recommended conditions of use and storage.

10.3. **Possibility of hazardous reactions**

No data available.

10.4. **Conditions to avoid**

No data available.

10.5. **Incompatible materials**

No data available.

10.6. **Hazardous decomposition products**

No data available.

11. **TOXICOLOGICAL INFORMATION**

11.1. **Information on toxicological effects**

   **Acute toxicity**
   No data available.

   **Skin corrosion/irritation**
   No data available.

   **Serious eye damage/eye irritation**
   No data available.

   **Respiratory or skin sensitzation**
   No data available.

   **Germ cell mutagenicity**
   No data available.

   **Carcinogenicity**
   No data available.

   **Reproductive toxicity**
   No data available.

   **Specific target organ toxicity - single exposure**
   No data available.

   **Specific target organ toxicity - repeated exposure**
   No data available.

   **Aspiration hazard**
   No data available.

   **Additional information**
   Not available

12. **ECOLOGICAL INFORMATION**

12.1. **Toxicity**

No data available.

12.2. **Persistence and degradability**

No data available.

12.3. **Bio-accumulative 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**

No data available.
13. DISPOSAL CONSIDERATIONS
13.1. Waste treatment methods
Product
Prevent product from entering drains. Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

14.1. UN number
Non-regulated, non-hazardous for transport

14.2. UN proper shipping name
Non-regulated, non-hazardous for transport

14.3. Transport hazard class(es)
Non-regulated, non-hazardous for transport

14.4. Packaging group
Non-regulated, non-hazardous for transport

14.5. Environmental hazards
No data available

14.6. Reportable Quantity (RQ)
No data available.

14.7. Emergency Telephone Number (during transport)
CHEMTREC: 1-800-424-9300 (US and Canada)
1-703-527-3887 (international shipments)

14.8. Special precautions for user
Not known

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS
CERCLA (COMPREHENSIVE ENVIRONMENTAL RESPONSE COMPENSATION, AND LIABILITY ACT): Not applicable
SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT): Not listed

INTERNATIONAL REGULATIONS
There are no hazardous ingredients in an amount that requires identification and labeling according to European Community Directives.
EUROPEAN UNION’S REACH (REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS):
This product meets the definition of a preparation. The aggregate volume of each non-exempt substance in this product does not exceed the 1 metric ton per year threshold. Therefore, registration is not required.
This safety data sheet has been prepared to comply with the requirements of Annex II, European Community Regulation No. 1907/2006 (REACH) and ANSI Z400.1-2004 guidelines.

15.4. Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

15.5. Chemical safety assessment
No data available.
16. OTHER INFORMATION

No data available.

Further information
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.