Material Safety Data Sheet

Japanese Encephalitis IgM ELISA

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

Product Name: Japanese Encephalitis IgM Antibody Capture ELISA
Catalog No: 8403-25
Synonyms: N/A
Product Description: Diagnostic Kit for Japanese Encephalitis Infection
Intended Use: Laboratory Use
Kit Storage: 2-8°C

SECTION 1. HAZARD IDENTIFICATION

· Classification of the substance or mixture:
  Classification according to Regulation (EC) No 1272/2008
  The product is not classified according to the CLP regulation.

· Label elements:
  · Labelling according to Regulation (EC) No 1272/2008 Non-Regulated Material
  · Hazard pictograms Non-Regulated Material
  · Signal word: Non-Regulated Material
  · Hazard statements: Non-Regulated Material
  · Additional information:
    0% of the mixture consists of component(s) of unknown toxicity. Contains 0% of components with unknown hazards to the aquatic environment: Coated Microtiter Strips, Sample Dilution Buffer, Negative Control, Ready to Use JE Antigen (JERA), Ready to Use Enzyme Conjugate-HRP, EnWash, Liquid TMB Substrate, Stop Solution.
    1% of the mixture consists of component(s) of unknown toxicity. Contains 1% of components with unknown hazards to the aquatic environment: Positive Control, Ready-to-Use Normal Cell Antigen (NCA).
    Contains 2.4% of components with unknown hazards to the aquatic environment. Safety data sheet available on request: 10X Wash Buffer

· Other hazards: None known
· Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.

SECTION 2. Composition/Information on Ingredients

Coated Microtiter Strips:
· Description: Mixture: consisting of non-regulated material.
· Dangerous Components: Non-Regulated Material
· Additional information: For the wording of the listed hazard phrases refer to section 15.

Sample Dilution Buffer:
· Description: Mixture: consisting of non-regulated material.
· Dangerous Components: Non-Regulated Material
· Additional information: For the wording of the listed hazard phrases refer to section 15.

Positive Control:
· Description: Mixture: consisting of non-regulated material.
· Dangerous Components: Non-Regulated Material
· Additional information: For the wording of the listed hazard phrases refer to section 15.
Negative Control:
- Chemical characterization: Substance
- CAS No. Description
  Human Serum (normal)

Ready to Use JE Antigen (JERA):
- Description: Mixture: consisting of non-regulated material.
- Dangerous Components: Non-Regulated Material
- Additional information: For the wording of the listed hazard phrases refer to section 15.

Ready to Use Normal Cell Antigen (NCA):
- Description: Mixture: consisting of non-regulated material.
- Dangerous Components: Non-Regulated Material
- Additional information: For the wording of the listed hazard phrases refer to section 15.

Ready to Use Enzyme Conjugate-HRP:
- Description: Mixture: consisting of non-regulated material.
- Dangerous Components: Non-Regulated Material
- Additional information: For the wording of the listed hazard phrases refer to section 15.

EnWash:
- Description: Mixture: consisting of non-regulated material.
- Dangerous Components: Non-Regulated Material
- Additional information: For the wording of the listed hazard phrases refer to section 15.

10x Wash Buffer:
- Description: Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Substance</th>
<th>％</th>
</tr>
</thead>
<tbody>
<tr>
<td>7647-14-5</td>
<td>Sodium Chloride</td>
<td>5-10%</td>
</tr>
<tr>
<td>231-598-3</td>
<td>EINECS: 231-598-3, RTECS: VZ4725000</td>
<td></td>
</tr>
<tr>
<td>7558-79-4</td>
<td>Sodium Phosphate</td>
<td>≤2.5%</td>
</tr>
<tr>
<td>231-448-7</td>
<td>EINECS: 231-448-7, RTECS: WC 4500000</td>
<td></td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed hazard phrases refer to section 15.

Liquid TMB Substrate:
- Description: Mixture: consisting of non-regulated material.
- Dangerous Components: Non-Regulated Material
- Additional information: For the wording of the listed hazard phrases refer to section 15.

Stop Solution:
- Description: Mixture of substances listed below with non-hazardous additions.

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Substance</th>
<th>％</th>
</tr>
</thead>
<tbody>
<tr>
<td>7664-93-9</td>
<td>Sulfuric Acid</td>
<td>2-12%</td>
</tr>
<tr>
<td>231-639-5</td>
<td>EINECS: 231-639-5</td>
<td></td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed hazard phrases refer to section 15.

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**SECTION 3. FIRST AID MEASURES**

- General information: No special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** If swallowed and symptoms occur, consult a doctor.
· **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed:** No further relevant information available.

### SECTION 4.  
**FIRE-FIGHTING MEASURES**

· **Suitable extinguishing agents:**
  - CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture:** No further relevant information available.
· **Advice for firefighters:**
  - **Protective equipment:**
    - As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

### SECTION 5.  
**ACCIDENTAL RELEASE MEASURES**

· **Personal precautions, protective equipment and emergency procedures:** Not required.
· **Environmental precautions:** Dilute with plenty of water. Do not allow to enter sewers/surface or ground water.
· **Methods and material for containment and cleaning up:**
  - Dispose of the collected material according to regulations.
  - Absorb with liquid-binding material (i.e sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections:**
  - See Section 6 for information on safe handling.
  - See Section 7 for information on personal protection equipment.
  - See Section 12 for disposal information.

### SECTION 6.  
**HANDLING AND STORAGE**

· **Precautions for safe handling:** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Specific end use(s):** No further relevant information available.

### SECTION 7.  
**EXPOSURE CONTROL / PERSONAL PROTECTION**

· **Additional information about design of technical systems:** No further data; see section 6.
· **Control parameters:**
  - **Stop Solution:**
    - **Components with occupational exposure limits:**
      - 7664-93-9 Sulfuric Acid
      - WEL: Long-term value: 0.05* mg/m³
      - *mist: defined as thoracic fraction

**Other Components:**

· **Components with occupational exposure limits:** The rest of the product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
· **Exposure controls:**
  - **General protective and hygienic measures:**
    - The usual precautionary measures for handling chemicals should be followed.
  - **Breathing equipment:** Not required.
  - **Protection of hands:**
Protective gloves.

- **Material of gloves:** Nitrile rubber, NBR.
- **Penetration time of glove material:** The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
- **Eye protection:**

Goggles recommended during refilling.

### SECTION 8. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th></th>
<th>Coated microtiter strips</th>
<th>Sample Diluent Buffer</th>
<th>Positive Control</th>
<th>Negative Control</th>
<th>Ready to Use JE Antigen</th>
<th>Ready to Use Normal Cell Antigen</th>
<th>Ready to Use Conjugate-HRP</th>
<th>EnWash</th>
<th>10X Wash Buffer</th>
<th>Liquid TMB substrate</th>
<th>Stop Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form</strong></td>
<td>Strip</td>
<td>Liquid</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Colorless</td>
<td>Clear</td>
<td>yellow</td>
<td>Pink to yellow</td>
<td>Clear</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless</td>
<td>slight</td>
<td></td>
<td></td>
<td>Odorless</td>
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</tr>
<tr>
<td><strong>pH</strong></td>
<td>N/A</td>
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<td></td>
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</tr>
<tr>
<td><strong>Melting point/range</strong></td>
<td>Not determined</td>
<td></td>
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<tr>
<td><strong>Boiling point/range</strong></td>
<td>Not determined</td>
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<tr>
<td><strong>Flash point</strong></td>
<td>NA / Not determined</td>
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<tr>
<td><strong>Flammability</strong> (solid, gas)</td>
<td>NA / Not determined</td>
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<tr>
<td><strong>Ignition Temperature</strong></td>
<td>Not determined</td>
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<tr>
<td><strong>Decomposition temperature</strong></td>
<td>Not determined</td>
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</tr>
<tr>
<td><strong>Self-igniting</strong></td>
<td>Product is not self-igniting</td>
<td>Not determined</td>
<td></td>
<td></td>
<td>Product is not self-igniting</td>
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<tr>
<td><strong>Danger of explosion</strong></td>
<td>Product does not present an explosion hazrd</td>
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<tr>
<td><strong>Lower Explosion limits</strong></td>
<td>Not determined</td>
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<tr>
<td><strong>Upper Explosion limits</strong></td>
<td>Not determined</td>
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<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not determined / NA</td>
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<td><strong>Relative density</strong></td>
<td>Not determined</td>
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<tr>
<td><strong>Vapor density</strong></td>
<td>Not determined / NA</td>
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<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not determined / NA</td>
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</tr>
<tr>
<td><strong>Solubility in water</strong></td>
<td>Insoluble</td>
<td>Fully miscible</td>
<td>Soluble</td>
<td>Fully miscible</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Partition coefficient</strong></td>
<td>Not determined</td>
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</tr>
<tr>
<td><strong>Dynamic Viscosity</strong></td>
<td>N/A</td>
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</tr>
</tbody>
</table>
Kinematic Viscosity | N/A |
---|---|
Other Information | Not determined |
Organic solvents | 0.0% |
Other Information | No further relevant information available |

### SECTION 9. STABILITY AND REACTIVITY

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 10. TOXICOLOGICAL INFORMATION

- **Information on toxicological effects:**
- **Acute toxicity:**

#### 7647-14-5 Sodium Chloride

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>4000 mg/kg (mouse)</td>
</tr>
<tr>
<td>Dermal</td>
<td>3000 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;10000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

#### 7558-79-4 Sodium Phosphate

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>17000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

#### 7664-93-9 Sulfuric Acid

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>2140 ml/kg (rat)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>375 mg/l (rat)</td>
</tr>
</tbody>
</table>

- **Primary irritant effect:**
- **Skin corrosion/irritation:** For Stop Solution, it may be irritated. For the others, based on available data, the classification criteria are not met.
- **Serious eye damage/irritation:** For Stop Solution, it may be irritated. For the others, based on available data, the classification criteria are not met.
- **Sensitisation:** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

### SECTION 11. ECOLOGICAL INFORMATION

- **Aquatic toxicity:**

#### 7664-93-9 Sulfuric Acid

<table>
<thead>
<tr>
<th>Route</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>22 mg/l (daphnia)</td>
</tr>
</tbody>
</table>

#### 7647-14-5 Sodium Chloride

<table>
<thead>
<tr>
<th>Route</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>340.7-469.2 mg/l (Water flea)</td>
</tr>
</tbody>
</table>

- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
  - **Bioaccumulative potential:** No further relevant information available.
  - **Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
  - **General notes:**
    Do not allow undiluted product or product that has not been neutralized to reach ground water, water course...
or sewage system.

- **Results of PBT and vPvB assessment:**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

### SECTION 12. DISPOSAL CONSIDERATIONS

- **Waste treatment methods:**
  - **Recommendation:** Smaller quantities can be disposed of with household waste. Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### SECTION 13. TRANSPORT INFORMATION

- **UN-Number:**
  - DOT, ADR, ADN, IMDG, IATA: Non-Regulated Material
- **UN proper shipping name:**
  - DOT, ADR, ADN, IMDG, IATA: Non-Regulated Material
- **Transport hazard class(es):**
  - DOT, ADR, ADN, IMDG, IATA: Non-Regulated Material
- **Class:**
  - DOT, ADR, ADN, IMDG, IATA: Non-Regulated Material
- **Packing group:**
  - DOT, ADR, ADN, IMDG, IATA: Non-Regulated Material
- **Environmental hazards:**
  - Not applicable.
- **Special precautions for user:**
  - Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:**
  - Not applicable.
- **UN "Model Regulation":**
  - Non-Regulated Material

### SECTION 14. REGULATORY INFORMATION

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients are listed.
- **National regulations:**
  - For Negative Control, Substance is not listed.
  - For the others, the product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 15. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Abbreviations and acronyms:**
  - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
- **Data compared to the previous version altered.**
<table>
<thead>
<tr>
<th>Date Adopted</th>
<th>2017-Feb-01</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REF</strong> 8403-25</td>
<td>AccuDiag™- Japanese Encephalitis IgM Antibody Capture ELISA Test Kit</td>
</tr>
<tr>
<td>Revision Date</td>
<td>2016-07-08</td>
</tr>
</tbody>
</table>