Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION
   Product Name: Nisseiken Japanese Encephalitis Vaccine (Inactivated TC Origin)
   Company Name: Nisseiken Co., Ltd.
   Address: 9-2221-1 Shin-machi, Ome, Tokyo 198-0024, Japan
   Tel.: +81-428-33-1001
   Responsible Dept.: Business department
   Tel.: +81-428-33-1003
   Fax.: +81-428-33-1130
   Recommended Use/Restriction of Use: Veterinary medicinal products

2. HAZARDS IDENTIFICATION
   Most Important Hazard: None
   Hazards: None
   Environmental Impact: No data available
   Physical and Chemical Hazards: None
   Specific Hazards: None
   Main Symptoms: None
   Classification Name: None
   Summary of Expected Emergency: None
3. **COMPOSITION/INFORMATION ON INGREDIENTS**  
Single Component or Mixture: Mixture  
Generic name: Japanese encephalitis virus inactivated vaccine  

Ingredients and Contents: Per 1 mL of the vaccine

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Contents</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Inactivated Japanese encephalitis virus BMIII strain grown in MPK-III aC1 cells (before inactivation)</td>
<td>$10^{7.5}$ TCID$_{50}$ or more</td>
<td>Not applicable</td>
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<tr>
<td>(2) Formalin</td>
<td>Not more than 0.10%</td>
<td>50-00-0</td>
</tr>
<tr>
<td>(3) Thimerosal</td>
<td>Not more than 0.010%</td>
<td>54-64-8</td>
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<tr>
<td>(4) Gelatin</td>
<td>0.2 mg</td>
<td>Not applicable</td>
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</tbody>
</table>

Chemical Properties (chemical formula):  
(1), (4); Not applicable  
(2); HCHO, (3); C$_9$H$_9$HgNaO$_7$S  

Official Gazette Notification Reference Number (Chemical Substances Control Law):  
(1), (3), (4); Not applicable  
(2); 2-482

Components Contributing to the Hazard: Not applicable  
Impurities Contributing to the Hazard: Not applicable
4. FIRST AID MEASURES

In Case of Inhalation: Expose the users to fresh air and, if necessary, seek medical treatment with a description attached to the product.
In Case of Contact with Skin: Wash out with soap and water as necessary, and disinfect with 70% alcohol.
In Case of Contact with Eye: Flush with water or warm water and, if necessary, seek medical treatment with a description attached to the product.
In Case of Ingestion: Wash the mouth well with water and, if necessary, seek medical treatment with a description attached to the product.

Brief Information Concerning the Most Important Signs and Symptoms: Not applicable
Protection for Persons who Practice First Aid Measures: Not applicable
Special Precautions for Doctor: Not applicable

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Water, sand, carbon dioxide, and dry chemical powder or foam
Extinguishing Media to Avoid: Not specified
Specific Hazards Arising from the Product: Not applicable
Specific Fire-Fighting: Spread extinguishing media to the fire sources.
Protection for Persons Who Extinguish a Fire: Not specified

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: No data available
Environmental Precautions: No data available
Methods for Cleaning Up: Collect in a vessel as much as possible, and disinfect with 70% alcohol.
Prevention of Second Accident: No data available

7. HANDLING AND STRAGE

Handling:
Technical Measures: Not applicable
Precautions:
(1) Do not use the product with any abnormal appearance and content.
(2) Do not use the vaccine after expiry.
(3) Do not add other medicinal products (vaccines) to the product.
(4) Use sterilized injection devices. Do not use ones disinfected with chemical agent (except for gas sterilization) or contaminated by other medicine. When sterilize injection devices by dry heat, steam or boiling, use them after they return to ambient temperature.
(5) Shake well to homogenize the vaccine before and when using it.
(6) Sterilize rubber caps of the vaccine with 70% alcohol, and insert sterilized needle into rubber cap and absorb the vaccine and use it. The rubber cap should not be off when you use this vaccine, because the vaccine should be contaminated.
(7) Do not give hard shock as the bottles are fragile.
(8) Caution should be taken not to cut your fingers with the cut section of the aluminum cap when opening the bottle.

Safely Handling Precautions:
Precautions:
Wash hands well with soap after handling.

Storage:
Appropriate Storage Conditions:
(1) Store in light-resistant containers at 2-10°C.
(2) Keep the product out of children’s reach.
(3) Avoid direct sunlight and freeze because it influences the product quality.

Safe Packing Materials: No data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
   Appropriate Engineering Controls: No data available
   Occupational Exposure Limit: No data available
   Administrative Exposure Limit: No data available
   Protective Equipment
      Respiratory Protective Equipment: Not applicable
      Hand Protection: Not applicable
      Eye Protection: Not applicable
      Skin and Body Protection: Not applicable
   Appropriate Hygiene Measures: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES
   Physical State
      Shape: Liquid
      Color: Pale yellow opacity homogeneous suspension
      Odor: Odorless
      pH: 6.8-7.6
   Physical State Changing Specific Temperature/Temperature Range
      Boiling Point: No data available
      Boiling Range: No data available
      Melting Point: No data available
      Decomposition Temperature: No data available
      Flash Point: No data available
      Ignition Point: No data available
      Explosive Properties: Not applicable

10. STABILITY AND REACTIVITY
    Stability: No data available
    Reactivity: No data available
    Conditions to Avoid: No data available
    Materials to Avoid: No data available
    Hazardous Decomposition Products: No data available
    Others: No data available

11. TOXICOLOGICAL INFORMATION
    Acute Toxicity: No data available
    Local Effect: No data available
    Sensitization: No data available
    Chronic/Long-Term toxicity: No data available
    Carcinogenicity: No data available
    Mutagenicity: No data available
    Teratogenicity: No data available
    Reproductive Toxicity: No data available
    Others: Not applicable
12. ECOLOGICAL INFORMATION
   Mobility: No data available
   Persistence/Degradability: No data available
   Bioaccumulative Potential: No data available
   Biotoxicity: No data available
   Fish Toxicity: No data available
   Others: No data available

13. DISPOSAL CONSIDERATIONS
   (1) Dispose used bottles in accordance with laws enacted by a local public entity.
   (2) The used needle should be placed in a designated container for collection of needles.
       Disposition of the container for needle collection should be disposed in accordance with a
       guideline from your local waste regulation authority.

14. TRANSPORT INFORMATION
   International Regulations: No data available
   UN Class: No data available
   UN No.: No data available
   Domestic Regulations: No data available
   Additional Regulations: No data available
   Specific Safety Measures and Conditions for Transport: No data available

15. REGULATORY INFORMATION
   The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and
   Medical Devices
   Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the
   Environment and Promotion of Improvements to the Management Thereof: Class I specified
   chemical substance, class I designated chemical substance

16. Other Information
   (1) This drug is specified as powerful drug in The Law on Securing Quality, Efficacy and Safety
       of Products Including Pharmaceuticals and Medical Devices.
   (2) This product should be used only pursuant to the prescription or direction of a veterinarians,
       because it is a prescription drug.
   (3) Confirm precautions mentioned in a description attached to the product before use.
   (4) In case of accidental injection to human, take appropriate actions such as disinfection of the
       lesion. Consult a doctor and show a description attached if necessary.

The information above is believed to be accurate and represents the best information currently
available to us for safe handling, use, treatment, store, transport, disposal, and accidental release
measures of this product. However, it is not to guarantee anything and not to specify the quality.