Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION
   Product Name: Nisseiken TGE • PED combined live vaccine
   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:** Transmissible gastroenteritis virus and porcine epidemic diarrhea virus combination modified live vaccine

**Ingredients and Contents:**

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Contents</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 bottle of lyophilized vaccine (for 10 pigs)</td>
<td>(1) Attenuated transmissible gastroenteritis virus strain h-5 grown in MPK-III a cells</td>
<td>$10^{6.5} \text{TCID}_{50}$ or more</td>
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<tr>
<td></td>
<td>(2) Attenuated porcine epidemic diarrhea virus strain P-5V grown in Vero cells</td>
<td>$10^{5.5} \text{TCID}_{50}$ or more</td>
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<tr>
<td></td>
<td>(3) Lactose</td>
<td>15%</td>
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<tr>
<td>1 bottle of diluent (20 mL)</td>
<td>(4) Sodium chloride</td>
<td>0.80%</td>
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<tr>
<td></td>
<td>(5) Sodium dihydrogen phosphate dihydrate</td>
<td>0.043%</td>
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<tr>
<td></td>
<td>(6) Disodium hydrogen phosphate 12-water</td>
<td>0.26%</td>
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<tr>
<td></td>
<td>(7) Purified water</td>
<td>residual quantity</td>
</tr>
</tbody>
</table>

**Chemical Properties (chemical formula):**
(1), (2), (7); Not applicable  
(3); C₁₂H₂₂O₁₁ ⋅ H₂O, (4); NaCl  
(5); NaH₂PO₄ ⋅ 2H₂O, (6); Na₂HPO₄ ⋅ 12H₂O

**Official Gazette Notification Reference Number (Chemical Substances Control Law):**
(1) - (3), (7); Not applicable  
(4); 1-236, (5); 1-497, (6); 1-497

**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 STORAGE**
   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) Disinfect the rubber stopper for the vaccine and diluent with 70% alcohol, and inject the diluent into the vaccine vial using sterilized injectors, etc., and mix it well to dissolve the solution uniformly.
   (6) Use the dissolved vaccine after aspirating into syringe by inserting the sterilized needle through rubber stopper. Do not remove the rubber stopper because of risk of contamination.
   (7) Avoid physical damage to the vaccine vial, because it may break due to vacuum.
   (8) Cautions should be taken not to cut your fingers with the cut section of the aluminum cap when opening the vial.
   Safe 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.
(4) Avoid freezing the diluent because the container may break.

Safe Packaging Materials: No data available

8. EXPOSURE CONTROLS/PERSOHAL 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: Lyophilized vaccine; Solid
  Diluent; Liquid
Color:
  Lyophilized vaccine; pale pinkish white colored dried material. When it is reconstituted with the accompanying diluent and shaken, it turns to be homogeneous liquid colored with slightly orangehued light pink.
  Diluent; colorless and transparent liquid
Odor: Odorless
pH:
  Lyophilized vaccine; No data available
  Diluent; 7.0-7.4
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 the left over vaccine and used bottles in accordance with laws enacted by a local public entity, or process them as infectious waste after disinfection or sterilization.
(2) The used needle should be placed in a designated container for collection of needles. Disposition of the container for needle collection, unused portion of the vaccine and used containers 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: Not applicable

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, storage, transport, disposal, and accidental release measures of this product. However, it is not to guarantee anything and not to specify the quality.