Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION
   Product Name: Nisseiken Swine AP Vaccine ME
   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: Swine *Actinobacillus pleuropneumoniae* (serotypes 1, 2 and 5, and non-toxic recombinant toxins) inactivated vaccine (with oil adjuvant)

Ingredients and Contents: Per 50 mL (for 50 pigs) of the vaccine

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Contents</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Inactivated <em>Actinobacillus pleuropneumoniae</em> strain 41-1 (serotype 1) (total bacterial count)</td>
<td>(2.5 \times 10^{10} - 1.25 \times 10^{11})</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(2) Inactivated <em>Actinobacillus pleuropneumoniae</em> strain SHP-1 (serotype 2) (total bacterial count)</td>
<td>(2.5 \times 10^{10} - 1.25 \times 10^{11})</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(3) Inactivated <em>Actinobacillus pleuropneumoniae</em> strain Ng-2 (serotype 5) (total bacterial count)</td>
<td>(2.5 \times 10^{10} - 1.25 \times 10^{11})</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(4) Non-toxigenic cytotoxins of <em>A. pleuropneumoniae</em> (derived from <em>Escherichia Coli</em>) rApx I protein (protein content)</td>
<td>2 - 3 mg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(5) Non-toxigenic cytotoxins of <em>A. pleuropneumoniae</em> (derived from <em>Escherichia Coli</em>) rApx II protein (protein content)</td>
<td>2 - 3 mg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(6) Non-toxigenic cytotoxins of <em>A. pleuropneumoniae</em> (derived from <em>Escherichia Coli</em>) rApx III protein (protein content)</td>
<td>2 - 3 mg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(7) Formalin</td>
<td>Not more than 0.13%</td>
<td>50-00-0</td>
</tr>
<tr>
<td>(8) Thimerosal</td>
<td>Not more than 0.010%</td>
<td>54-64-8</td>
</tr>
<tr>
<td>(9) Aluminum hydroxide gel (as aluminum content)</td>
<td>Not more than 0.18%</td>
<td>21645-51-2</td>
</tr>
<tr>
<td>(10) Micro-emulsion</td>
<td>25 mL</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(11) Phosphate-buffered saline</td>
<td>Residual quantity</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Chemical Properties (chemical formula):
(1) - (6), (10), (11); Not applicable
(7); HCHO, (8); C₉H₉HgNaO₂S, (9); Al(OH)₃

Official Gazette Notification Reference Number (Chemical Substances Control Law):
(1) - (6), (8), (10), (11); Not applicable
(7); 2-482, (9); 1-17

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 devises. 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 Packaging 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: Grayish white to brownish grayish white homogeneous opaque suspension
     Odor: Odorless
     pH: No data available
   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**
   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: 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, tell that a vaccine with oil adjuvant for animals is injected accidentally, 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.