Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION
   Product Name: Nisseiken Swine AP Vaccine 125RX
   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 adjuvant)

Ingredients and Contents: Per 100mL (for 100 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>1×10^{11} - 5×10^{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>1×10^{11} - 5×10^{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>1×10^{11} - 5×10^{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>8 - 12 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>8 - 12 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>8 - 12 mg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(7) Formalin</td>
<td>Not more than 0.25%</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 0.36%</td>
<td>21645-51-2</td>
</tr>
<tr>
<td>(10) Phosphate-buffered saline</td>
<td>Residual quantity</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Chemical Properties (chemical formula):
(1) - (6), (10); Not applicable
(7); HCHO, (8); C_{9}H_{9}HgNaO_{2}S, (9); Al(OH)_{3}

Official Gazette Notification Reference Number (Chemical Substances Control Law):
(1) - (6), (8), (10); 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 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 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 homogeneous opaque suspension
  Odor: Odorless
  pH: 7.2-7.8
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
- Biototoxicity: 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) Insert used needles into container specific for recovery of used needles.
Consign the container for used needles to traders with permission of industrial waste collection
and transport and industrial waste disposal operation.

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.