



Creation Date: 21 February, 2019  
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Reference Number: 95

## Safety Data Sheet

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Nisseiken PED 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

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### 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

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Single Component or Mixture: Mixture

Generic name: Porcine epidemic diarrhea virus modified live vaccine

#### Ingredients and Contents:

	Component Name	Contents	CAS No.
1 bottle of lyophilized vaccine (for 10 pigs)	(1) Attenuated porcine epidemic diarrhea virus strain P-5V grown in Vero cells	10 <sup>5.5</sup> TCID <sub>50</sub> or more	Not applicable
	(2) Lactose	15%	5989-81-1
1 bottle of diluent (20 mL)	(3) Sodium chloride	0.80%	7647-14-5
	(4) Sodium dihydrogen phosphate dihydrate	0.043%	13472-35-0
	(5) Disodium hydrogen phosphate 12-water	0.26%	10039-32-4
	(6) Purified water	residual quantity	Not applicable

Chemical Properties (chemical formula):

(1), (6); Not applicable

(2); C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · H<sub>2</sub>O, (3); NaCl

(4); NaH<sub>2</sub>PO<sub>4</sub> · 2H<sub>2</sub>O, (5); Na<sub>2</sub>HPO<sub>4</sub> · 12H<sub>2</sub>O

Official Gazette Notification Reference Number (Chemical Substances Control Law):

(1), (2), (6); Not applicable

(3); 1-236, (4); 1-497, (5); 1-497

Components Contributing to the Hazard: Not applicable

Impurities Contributing to the Hazard: Not applicable

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#### **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

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#### **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

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#### **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

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#### **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

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## **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

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## **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

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## **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

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## **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

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## **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

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## **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 waster regulation authority.

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## **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

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## **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

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## **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.

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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.