1. Identification
Product identifier Ingelvac Provenza
Other means of identification
   Product code APHIS Code-19A5.R2, Family Code -772
   Recommended use Veterinary vaccine
   Recommended restrictions For use in pigs only. Not for human use.
Manufacturer/Importer/Supplier/Distributor information
Manufacturer Boehringer Ingelheim Animal Health USA Inc.
Address 2621 North Belt Hwy
          St. Joseph, MO 64506-2002
Transportation emergency For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night
   Within USA and Canada: 1-800-424-9300
   Outside USA and Canada: +1 703-527-3887 (collect calls accepted)
Medical Emergency (24HR): (888) 637-4251
Non-Emergency calls: (888) 637-4251

2. Hazard(s) identification
Physical hazards Not classified.
Health hazards Not classified.
OSHA defined hazards Not classified.
Label elements
   Hazard symbol None.
   Signal word None.
   Hazard statement The mixture does not meet the criteria for classification.
Precautionary statement
   Prevention Avoid contact with eyes, skin and clothing. Wear protective gloves/eye protection. Wash hands thoroughly after handling.
   Response Take off contaminated clothing and wash before reuse. Wash hands after handling. If skin irritation or rash occurs, seek medical attention. If on skin: Wash with plenty of water. If swallowed: Immediately call a poison center/doctor. Get medical attention/advice if you feel unwell.
   Storage Store in original container. Store locked up. Do not freeze. Store at Cold Temperature—Refrigerate 2°- 8°C (36°- 46°F).
   Disposal Dispose of contents/container in accordance with local/regional/national/international regulations. None known.
Hazard(s) not otherwise classified (HNOC) None known.
Supplemental information
Wear appropriate personal protective equipment to avoid inhalation and contact with eyes and skin. For more information on personal protective equipment, consult current OSHA guidance for Commercial Swine Farmers and Pork Producers. Wash hands thoroughly after handling.
It is recommended that immunocompromised individuals not handle or otherwise be exposed to this product. Pregnant women should consult their medical practitioner before working with this product.
Supplemental information

For further information regarding influenza and recommended practices at swine facilities, please consult the following publications:

- CDC Interim Guidance for Workers who are Employed at Commercial Swine Farms: Preventing the Spread of Influenza A Viruses (https://www.cdc.gov/flu/swineflu/guidance-commercial-pigs.htm)

- People at High Risk of Developing Flu-Related Complications: (https://www.cdc.gov/flu/about/disease/high_risk.htm)


3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1N1 Modified Live Virus</td>
<td>Proprietary</td>
<td></td>
</tr>
<tr>
<td>H3N2 Modified Live Virus</td>
<td>Proprietary</td>
<td></td>
</tr>
</tbody>
</table>

Composition comments

Components not listed are either non-hazardous or are below reportable limits.

4. First-aid measures

Inhalation
Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact
Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed
Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. If anaphylactoid reactions occur, epinephrine may be used as an antidote.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid inhalation of vapors or mists.

Conditions for safe storage, including any incompatibilities

Protect from direct sunlight. Store at 2-8°C (35-46°F). Do not freeze.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Not generally required when handling vials or containers. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear suitable gloves.

Other

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Respiratory protection

Wear appropriate personal protective equipment to avoid inhalation. For more information on personal protective equipment, consult current OSHA guidance for Commercial Swine Farmers and Pork Producers.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Solid with a solution of liquid diluent

Form

Lyophilized cake supplied with a solution of colored diluent

Color

Lyophilized cake is cream to tan. After rehydration: slight pink to red color

Odor

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) 

Not available.

Flammability limit - upper (%) 

Not available.
Vapor pressure  Not available.
Vapor density  Not available.
Relative density  Not available.
Solubility(ies)
   Solubility (water)  Not available.
Partition coefficient  Not available.
(n-octanol/water)
Auto-ignition temperature  Not available.
Decomposition temperature  Not available.
Viscosity  Not available.

10. Stability and reactivity
Reactivity Chemical  The product is stable and non-reactive under normal conditions of use, storage and transport.
stability Possibility of Material is stable under normal conditions.
hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid  Temperatures below 2°C.
Incompatible materials  None known.
Hazardous decomposition products  No hazardous decomposition products are known.

11. Toxicological information
Information on likely routes of exposure
Inhalation  Avoid inhalation. For more information on personal protective equipment, consult current OSHA guidance for Commercial Swine Farmers and Pork Producers.
Skin contact  Prolonged skin contact may cause temporary irritation.
Eye contact  Direct contact with eyes may cause temporary irritation.
Ingestion  Not expected to be a significant route of exposure. Ingestion may cause vomiting, nausea or other systemic effects.

Information on toxicological effects
Acute toxicity  Not expected to be acutely toxic.
Skin corrosion/irritation  Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation  Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization
   Respiratory sensitization  Not available.
   Skin sensitization  This product is not expected to cause skin sensitization.
Germ cell mutagenicity  No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity  This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
   IARC Monographs. Overall Evaluation of Carcinogenicity  Not listed.
   NTP Report on Carcinogens  Not listed.
Reproductive toxicity  Not available.
Specific target organ toxicity - single exposure  Not classified.
Specific target organ toxicity - repeated exposure  Not classified.
12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
This material and its container must be disposed of in a safe way. Do not discharge into drains, water courses or onto the ground. Do not contaminate water, food, or feed by disposal.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

15. Regulatory information

US federal regulations
One or more components are not listed on TSCA. This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.
Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
  Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
  Not regulated.
Safe Drinking Water Act (SDWA)
  Not regulated.

US state regulations
US. Massachusetts RTK - Substance List
  Not regulated.
US. New Jersey Worker and Community Right-to-Know Act
  Not listed.
US. Pennsylvania Worker and Community Right-to-Know Law
  Not listed.
US. Rhode Island RTK
  Not regulated.
California Proposition 65
  California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material
  is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*"Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
*A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision
Issue date 22-March-2017
Revision date 04-June-2019
Version # 06
HMIS® ratings
  Health: 0
  Flammability: 1
  Physical hazard: 0
NFPA ratings

1 0 0
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