SAFETY DATA SHEET

1. Identification

Product identifier
Enterisol® Ileitis FF

Other means of identification
APHIS Code - 10L1.00, Family Code - 296

Recommended use
For the vaccination of healthy, susceptible swine 3 weeks of age or older as an aid in the prevention and control of porcine proliferative enteropathy (ileitis) caused by Lawsonia intracellularis.

Recommended restrictions
Not for human use.

Manufacturer/Importer/Supplier/Distributor information
Manufacturer
Boehringer Ingelheim Vetmedica, 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):
(866)638-2226
Non-Emergency calls:
(800) 821-7467

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
Observe good industrial hygiene practices.

Response
Wash hands after handling.

Storage
Store away from incompatible materials. Keep at temperature -70°C. Keep frozen until ready to use.

Disposal
Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC)
None known.

Supplemental information
Not applicable.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>1.0</td>
</tr>
<tr>
<td>Lawsonia intracellularis - Attenuated live bacteria</td>
<td>Proprietary</td>
<td></td>
</tr>
</tbody>
</table>

Composition comments
All concentrations are in percent by weight. 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: Direct contact with eyes may cause temporary irritation.

Indication of immediate medical attention and special treatment needed: For use in pigs only. Not for human use.

5. Fire-fighting measures


Unsuitable extinguishing media: None known.

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.

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. 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.

Environmental precautions: Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling: Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities: Store in original tightly closed container. Store away from foodstuffs. Keep at temperature -70°C. Keep frozen until ready to use. Do not thaw until ready to vaccinate.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol (CAS 56-81-5)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

Biological limit values: No biological exposure limits noted for the ingredient(s).

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

**Hand protection**
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**
Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Respirator type: NIOSH approved organic vapor respirator.

**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**
Avirulent live bacteria supplied in a frozen liquid solution in plastic bottles.

**Physical state**
Liquid.

**Form**
Liquid.

**Color**
Yellow to orange-red; Translucent to opaque.

**Odor**
No data available.

**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)**
Will burn if involved in a fire.

**Upper/lower flammability or explosive limits**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Vapor pressure**
Not available.

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility (water)**
Not available.

**Partition coefficient (n-octanol/water)**
Not available.

**Auto-ignition temperature**
Not available.

**Decomposition temperature**
Not available.

**Viscosity**
Not available.

### 10. Stability and reactivity

**Reactivity**
The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**
Material is stable under normal conditions.

**Possibility of hazardous reactions**
No dangerous reaction known under conditions of normal use.

**Conditions to avoid**
Contact with incompatible materials.

**Incompatible materials**
Strong oxidizing agents.
11. Toxicological information

Information on likely routes of exposure

**Inhalation**
No adverse effects due to inhalation are expected.

**Skin contact**
May cause skin sensitization in hypersensitive individuals.

**Eye contact**
Direct contact with eyes may cause temporary irritation.

**Ingestion**
Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

**Acute toxicity**
This product is considered nontoxic.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol (CAS 56-81-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt; 18700 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>27200 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**
May cause skin sensitization in hypersensitive individuals.

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.

Not regulated.

Reproductive toxicity
This product is not expected to cause reproductive or developmental effects.

**Specific target organ toxicity - single exposure**
Not classified.

**Specific target organ toxicity - repeated exposure**
Not classified.

Aspiration hazard
Due to partial or complete lack of data the classification is not possible.

Chronic effects
Possible hypersensitization (development of abnormal sensitivity).

12. Ecological information

Ecotoxicity
Not expected to be harmful to aquatic organisms.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol (CAS 56-81-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 10000 mg/l, 24 Hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
Expected to be readily biodegradable.

Bioaccumulative potential
No data available.
Partition coefficient n-octanol / water (log Kow)
Glycerol (CAS 56-81-5) -1.76

Mobility in soil
This product has not been tested.

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
Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA. 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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

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

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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.
Not regulated.

Safe Drinking Water Act (SDWA)
US state regulations
- This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.
  - **US. Massachusetts RTK - Substance List**
    - Glycerol (CAS 56-81-5)
  - **US. New Jersey Worker and Community Right-to-Know Act**
    - Glycerol (CAS 56-81-5)
  - **US. Pennsylvania Worker and Community Right-to-Know Law**
    - Glycerol (CAS 56-81-5)
  - **US. Rhode Island RTK**
    - Glycerol (CAS 56-81-5)

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>Yes</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>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>27-April-2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>-</td>
</tr>
<tr>
<td>Version #</td>
<td>01</td>
</tr>
<tr>
<td>HMIS® ratings</td>
<td>Health: 0</td>
</tr>
<tr>
<td></td>
<td>Flammability: 0</td>
</tr>
<tr>
<td></td>
<td>Physical hazard: 0</td>
</tr>
<tr>
<td>NFPA ratings</td>
<td>0 0 0</td>
</tr>
</tbody>
</table>
The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIVI, and which BIVI has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIVI neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.