1. Identification

Product identifier Enterisol® Ileitis
Other means of identification None.
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 None known.
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 a temperature between 2 - 7°C Do not freeze.
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>Lawsonia intracellularis - Attenuated live bacteria</td>
<td>Proprietary</td>
<td></td>
</tr>
</tbody>
</table>

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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
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.

General information
Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

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. 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.

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. Keep at a temperature between 2 - 7°C (33 - 45° F). Store away from foodstuffs. Protect from direct sunlight. Protect from freezing.

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
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
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.
Wear appropriate thermal protective clothing, when necessary.

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
- Physical state: Liquid.
- Form: Lyophilized avirulent live bacteria supplied as a solid cake with a solution of liquid diluent.
- Color: Tan.
- Odor: Not 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): Not available.

Upper/lower flammability or explosive limits
- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.
- Explosive limit - lower (%): Not available.
- Explosive limit - upper (%): Not available.
- Vapor pressure: Not available.
- Vapor density: Not available.
- Relative density: Not available.
- Solubility(ies)
  - 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.

Hazardous decomposition products
- No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure
- Inhalation: No adverse effects due to inhalation are expected.
- Skin contact: No adverse effects due to skin contact are expected. May cause an allergic skin reaction.
- 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

In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Information on toxicological effects

Acute toxicity
This product is considered nontoxic.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
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
No ecotoxicity data noted for the ingredient(s).

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

Bioaccumulative potential
No data available.

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

15. Regulatory information

US federal regulations

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 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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>
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<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>
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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>
<td>No</td>
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<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>
</tbody>
</table>
Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | Yes

*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

Issue date | 22-July-2015
Revision date | 16-January-2018
Version # | 03
HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings

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