

1. Identification

Product identifier	Enterisol® Ileitis FF
Other means of identification	
Product code	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

Chemical name	CAS number	%
Glycerol	56-81-5	1.0
Lawsonia intracellularis - Attenuated live bacteria		Proprietary

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.
General information	In case of accidental injection, wash the site thoroughly. Contact a physician immediately. 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 (CO ₂).
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.
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. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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.
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	
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 (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 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.

Components	Species	Test Results
Glycerol (CAS 56-81-5)		
Acute		
Dermal		
LD50	Rabbit	> 18700 mg/kg
Oral		
LD50	Rat	27200 mg/kg

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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.

Components	Species	Test Results
Glycerol (CAS 56-81-5)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50 Daphnia magna	> 10000 mg/l, 24 Hours

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.

Safe Drinking Water Act (SDWA) Not regulated.

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

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

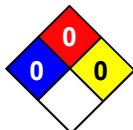
*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

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 27-April-2017
Revision date -
Version # 01
HMIS® ratings Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings



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