



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Enterisol® Ileitis FF
Product No.: Not applicable
MSDS ID#: N10L1.01
GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Vaccine

Manufacturer:
Boehringer Ingelheim Vetmedica, Inc.
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 Telephone: (800) 821-7467

Intended 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*.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Avirulent live bacteria supplied in a frozen liquid solution in 100mL plastic bottles.

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

Odor: No data available



WARNING!**Allergic reactions can occur.****For use in pigs only.****Not for human use.****Precautionary Statements**

Keep only in original container.

Keep at temperature -70°C

Keep frozen until ready to use.

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and incinerate.

If swallowed, seek medical advice immediately and show this container or label.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Potential Health Effects**Inhalation:** Not expected to be an inhalation hazard with prescribed use.**Eye Contact:** Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.**Skin Contact:** Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.**Ingestion:** Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.**Chronic Health Effects:** Possible hypersensitization (development of abnormal sensitivity).**Target Organ(s):** Intestines**OSHA Regulatory Status:** Non-hazardous (Exempt)**Environment:** No data available**3 COMPOSITION / INFORMATION ON INGREDIENTS**

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
<i>Lawsonia intracellularis</i> – Attenuated live bacteria	----	----	proprietary	----	---

Glycerol	200-289-5	56-81-5	1%	----	---
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The full texts for all R-Phrases are displayed in Section 16, if applicable.

4 FIRST AID MEASURES

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

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Note to Physician: For animal use only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7	HANDLING AND STORAGE
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Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Do not swallow. Wash hand thoroughly after handling.

Storage: Store frozen at -70°C (-94°F). Do not store thawed vaccine. Do not thaw until ready to vaccinate. Shake well before use.

8	EXPOSURE CONTROLS / PERSONAL PROTECTION
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Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Glycerin, mist	ACGIH	TWA	10 mg/m ³	URT irritation
Glycerin mist, respirable fraction	OSHA Z-1	PEL	5 mg/m ³	----
Glycerin mist, total dust	OSHA Z-1	PEL	15 mg/m ³	----

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

Engineering Controls: Not generally required when handling vials or containers. Good 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.

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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

9	PHYSICAL AND CHEMICAL PROPERTIES
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Color: Yellow to orange-red; Translucent to opaque.

Odor: No data available

Odor Threshold: No data available

Physical State: Avirulent live bacteria supplied in a frozen liquid solution in 100mL plastic bottles.

pH: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: No data available

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: No data available

Partition Coefficient (n-Octanol/water): No data available

Autoignition Temperature: Not applicable

Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11 TOXICOLOGICAL INFORMATION

Enterisol® Ileitis FF is considered non-toxic.

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Glycerol	Administration into the eye (rabbit): 500 mg/24 h, Mild Irritant Administration onto the skin (rabbit): 500 mg/24 h, Mild Irritant Oral LD50 (rat): 12600 mg/kg Dermal LD50 (rabbit): >10000 mg/kg

Chronic Toxicity – Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: None listed.

12	ECOLOGICAL INFORMATION
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Ecotoxicity:

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Glycerin	LC50 (rainbow trout): 51,000 – 57,000 mg/l (96 hours)

Persistence and degradability: Expected to be readily biodegradable.

Mobility in soil: No data available.

Other adverse effects: Not expected to be harmful to the environment. An environmental hazard cannot be excluded when large quantities are spilled.

Germany WGK: Glycerin: ID No: 116: WGK 1 (slightly water-endangering).

13	DISPOSAL CONSIDERATIONS
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General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: Dispose of this material by burning container in procedures allowed by local, state, and Federal regulations. Do not empty into drains. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

14	TRANSPORT INFORMATION
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15	REGULATORY INFORMATION
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Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Non-controlled, Exempt

Inventory Status

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – None listed

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

CERCLA Hazardous Substance List (40 CFR 302.4): None listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed.

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A): None listed.

Section 311/312 (40 CFR 370): Not Regulated.

Section 313 Toxic Release Inventory (40 CFR 372): None listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: Glycerin mist

Minnesota Hazardous Substances List: Glycerin mist

New Jersey Right-To-Know List: Glycerin

Pennsylvania Right-To-Know List: Glycerin mist

Rhode Island Right-To-Know List: Glycerin mist

European Regulations

Austria MAK List (Annex I): None listed.

Denmark (Annex 3.6): None listed.

Germany (Dangerous Substances Ordinance 2004, Annex III): None listed.

Norway (List of Dangerous Substance): None listed.

Sweden (Annex 3): None listed.

Switzerland (Toxins List 1): Glycerin

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	0	N/A

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

EU Symbol and R Phrase Definitions: None listed

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

References:

1. Enterisol® Ileitis FF MSDS and Label
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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