



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Enterisol® Ileitis
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: Lyophilized avirulent live bacteria supplied as a solid cake with a solution of liquid diluent.

Color: Tan

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 a temperature between 2 - 7°C.

Do not freeze.

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 | ---- | --- |

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

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

Storage: Store at 2°-7° C (35°-45° F). Do not freeze. Store out of direct sunlight to protect product integrity. Shake well before using.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: None Established

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

Color: Tan

Odor: No data available

Odor Threshold: No data available

Physical State: Lyophilized avirulent live bacteria supplied as a solid cake with a solution of liquid diluent.

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

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| 10 | STABILITY AND REACTIVITY |
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Stability: Stable

Conditions to Avoid: Temperatures below 2° C (35° F)

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

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| 11 | TOXICOLOGICAL INFORMATION |
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Enterisol® Ileitis is considered non-toxic.

Specified Substances

Acute Toxicity: No data available

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

Listed Carcinogens: None listed.

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| 12 | ECOLOGICAL INFORMATION |
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Ecotoxicity: No data available
Persistence and degradability: No data available
Mobility in soil: No data available
Other adverse effects: No data available

Germany WGK: Not applicable.

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

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

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| 14 | TRANSPORT INFORMATION |
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

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| 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: None listed.

Minnesota Hazardous Substances List: None listed.

New Jersey Right-To-Know List: None listed.

Pennsylvania Right-To-Know List: None listed.

Rhode Island Right-To-Know List: None listed.

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): None listed.

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| 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 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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