

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Enterisol Ileitis
Product code:	A009569
Recommended use:	Oral vaccine for active immunisation of pigs from three weeks of age and older as an aid in the prevention and control of porcine proliferative enteropathy (Ileitis) caused by <i>Lawsonia intracellularis</i> infection.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	4 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Powder for reconstitution

Product components:
 USDA Veterinary biologic.
Lawsonia intracellularis

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Ingredients determined to be non-hazardous	N/A	100%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	Not classified as Hazardous according to the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, New Zealand. Not classified as Dangerous Goods for transport according to the New Zealand Standard NZS 5433:2012 Transport of Dangerous Goods on Land.
Priority and secondary identifiers:	N/A
Risk and safety phrases:	N/A

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	<p>For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.</p> <p><u>General:</u> Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.</p> <p><u>Ingestion:</u> If swallowed, seek medical attention. Do NOT induce vomiting. Wash mouth out thoroughly with water.</p> <p><u>Eyes:</u> If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical</p>
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SAFETY DATA SHEET

Product Name: Enterisol Ileitis

Page 2 of 6
Reviewed on: 4 February 2020

	attention.
	<p><u>Skin</u>: If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with soap and water. In case of self-injection, seek immediate medical attention.</p> <p><u>Inhalation</u>: Not a likely source of exposure. However if inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms develop, seek medical attention.</p>
Workplace facilities:	No special facilities required.
Required instructions:	Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse.
Notes for medical personnel:	Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Non flammable
Fire hazard properties:	Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases.
Extinguishing media and methods:	Use appropriate fire extinguisher for the surrounding environment.
Hazchem code:	NA
Recommended protective clothing:	Fire fighters should wear full protective clothing including self-contained breathing apparatus operated in positive pressure mode. Fight fire from safe location.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	<p>Wear appropriate personal protective equipment and clothing. Avoid inhalation of dusts, and skin or eye contact.</p> <p>For a small spill: Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, and then transfer material to a suitable labelled container for subsequent recycling or disposal. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.</p> <p>For a large spill: Increase ventilation. Evacuate all unprotected personnel. If possible, contain the spill. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, then transfer material to a suitable container. Wash surfaces well with soap and water. Seal all wastes in labelled plastic containers for subsequent recycling or disposal.</p> <p>Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.</p>
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Use as directed on label or package insert. Avoid generating dust. Use in a well ventilated area. Exposure without protection should be prevented in order to lessen the possibility of disorders. Maintain high standards of personal hygiene i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities.
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SAFETY DATA SHEET

Product Name: Enterisol Ileitis

Page 3 of 6
Reviewed on: 4 February 2020

Approved handlers:	Not required
Conditions for safe storage:	Store in a cool, dry, well-ventilated area, out of direct sunlight. Protect from light and moisture. Store in suitable, labelled containers. Keep containers closed when not in use. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.
Store site requirements:	Store between 2 °C and 8 °C. Do not freeze.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	No exposure standards have been established for the mixture. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.
Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.
Engineering controls:	None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If dusts are produced, local exhaust ventilation should be used.
Personal protection:	<p>Respiratory Protection Industrial application: Use with good general ventilation. If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable dust/particulate/ mist filter should be used. Refer to relevant regulations for further information concerning respiratory protective requirements.¹</p> <p>Eye Protection Safety glasses with side shields, chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/ face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²</p> <p>Hand Protection None required, when used as intended. However, where exposure to the contents is likely wear gloves of impervious material. Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.³</p> <p>Body Protection Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.</p> <p>Other Information No exposure standards have been established for this material. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels. The exposure limits for particulates not otherwise classified are as follows: Particulates TWA 10 mg/m³ (inhalable) TWA 3 mg/m³ (respirable) TWA (Time Weighted Average): The average airborne concentration of a particular substance when calculated over a normal eight-hour working day, for a five-day week.</p>
References:	<ol style="list-style-type: none">1. Reference should be made to Australian Standards AS/ NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory

SAFETY DATA SHEET

Product Name: Enterisol Ileitis

Page 4 of 6
Reviewed on: 4 February 2020

Protective Devices, in order to make any necessary changes for individual circumstances.

2. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data: Formulation type: Powder for reconstitution
Appearance: Not available
Specific gravity: Not available
Boiling Point: Not available
Vapour Pressure: Not available
Solubility in Water: Not available
Flammability: Non flammable

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance: Stable under normal conditions of use and storage. Reacts with incompatible materials.

Conditions to avoid: Extreme temperatures and direct sunlight.

Material to avoid: Not available.

Hazardous decomposition products: Under fire conditions this product may emit toxic and/or irritating fumes and gases.

Hazardous polymerization: Will not occur.

Specific data: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data: No toxicity data available for this material.

Ingestion
Ingestion of this product may irritate the gastric tract causing nausea and vomiting.

Inhalation
Inhalation of product dusts may cause irritation of the nose, throat and respiratory system.

Skin
May be irritating to skin. The symptoms may include redness, itching and swelling.

Eye
May cause eye irritation with tearing, stinging, blurred vision and redness.

Respiratory sensitisation
Not expected to be a respiratory sensitiser.

Skin Sensitisation
Not expected to be a skin sensitiser.

Germ cell mutagenicity
Not considered to be a mutagenic hazard.

Carcinogenicity
Not considered to be a carcinogenic hazard.

Reproductive Toxicity
Not considered to be toxic to reproduction.

STOT-single exposure
Not expected to cause toxicity to a specific target organ.

STOT-repeated exposure
Not expected to cause toxicity to a specific target organ.

Aspiration Hazard

SAFETY DATA SHEET

Product Name: Enterisol Ileitis

Page 5 of 6
Reviewed on: 4 February 2020

Not expected to be an aspiration hazard.
Other Information
Possible hypersensitization (development of abnormal sensitivity).

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	N/A
Data organisation :	N/A
Environmental risk and safety phrases:	Prevent this material from entering waterways, drains and sewers

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	<p>The disposal of the spilled or waste material must be done in accordance with applicable local and national regulations. Used needles should be placed in a designated sharps container.</p> <p><u>Product Disposal:</u> This product can be disposed through a licensed commercial waste collection service. This product is non-hazardous and therefore the New Zealand HSNO regulations regarding disposal do not apply, however other regulations may apply.</p> <p>This product is a non-hazardous, combustible substance; It should be recycled whenever possible or sent to an approved high temperature incineration plant for disposal.</p> <p><u>Container Disposal:</u> The product is non-hazardous, therefore, the packaging may be re-used or recycled if it has been treated to remove any residual contents of the substance. Any wash-off water from the container cleaning process should be sent to a suitable waste water treatment plant before discharge into the environment.</p> <p>In New Zealand, the packaging (that may or may not contain any residual substance) may be lawfully disposed of by consumers through a public or commercial waste collection service.</p>
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as dangerous for rail, road, air or sea transport.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	<p>Registered pursuant to the ACVM Act 1997, No. A009569. See www.foodsafety.govt.nz for registration conditions</p> <p>Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian.</p> <p>Not classified as Hazardous according to the New Zealand Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.</p>
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

SAFETY DATA SHEET

Product Name: Enterisol Ileitis

Page 6 of 6
Reviewed on: 4 February 2020

Additional information:

For product information visit the Boehringer Ingelheim website
www.boehringer-ingelheim.co.nz

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