

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Ingelvac MycoFLEX
Product code:	A010147
Recommended use:	For active immunisation of healthy pigs from 3 weeks of age or older as an aid in the reduction of lung lesions following infection with <i>Mycoplasma hyopneumoniae</i> .
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:	Liquid	
	Formaldehyde is used to inactivate the virus and is then subsequently removed from the solution. The maximum concentration remaining will be no more than 0.74 g/L.	
Product components:		
<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Inactivated bacterin - <i>Mycoplasma hyopneumoniae</i>	N/A	0-100%

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: 2007 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:	For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately. Animals or persons developing anaphylactic (life- threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. <u>Ingestion:</u> If swallowed, seek immediate medical attention. Do NOT induce vomiting. Wash out mouth thoroughly with water. <u>Eyes:</u> If in eyes, hold eyelids apart and flush the eyes continuously with running water. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical attention. <u>Skin:</u> Wash affected area thoroughly with soap and water. If
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Workplace facilities:	symptoms develop, seek medical attention.
Required instructions:	Animals developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. In case of self-injection, seek immediate medical attention. <u>Inhalation:</u> Not a likely source of exposure. However if inhaled, remove affected person to fresh air. If symptoms develop, seek medical attention.
Notes for medical personnel:	No special facilities required. 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. Treat symptomatically. For animal injection only. Not for human use. Antidote: Epinephrine is indicated for anaphylactoid reactions.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Non combustible
Fire hazard properties:	Under fire conditions this product may emit toxic and/ or irritating fumes and gases including carbon monoxide and carbon dioxide.
Extinguishing media and methods:	Use foam, carbon dioxide, dry powder or water fog.
Hazchem code:	N/A
Recommended protective clothing:	Fire fighters should wear Self-Contained Breathing Apparatus operated in positive pressure mode and full protective clothing to prevent exposure to vapours or fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Wear appropriate personal protective equipment and clothing. For a small liquid spill: Wipe up or soak up using an inert non-combustible absorbent material. Collect the material and place into a suitable labelled container for disposal. Dispose of waste according to relevant government regulations. For a large liquid spill: Place inert absorbent material onto spillage. Collect the material and place into a suitable labelled container for disposal. Dispose of waste according to relevant government regulations.
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Use only in a well ventilated area. Avoid contact with clothing, skin or eyes and accidental injection. Use entire contents when first opened. Sterilise all injection apparatus before use. Shake well before opening. Use entire contents when first opened. Inject a single 1mL dose intramuscularly. If possible, avoid injection during wet weather or dusty conditions. Maintain high standards of personal hygiene i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities.
Approved handlers:	Not required
Conditions for safe storage:	Store in at temperatures between 2 °C and 8 °C (do not freeze), in a dry, well-ventilated area, out of direct sunlight. Store in suitable, labelled containers. Keep containers closed when not in use. Ensure that storage conditions comply with applicable local and national regulations.
Store site requirements:	Store in at temperatures between 2 °C and 8 °C (do not freeze), in a dry, well-ventilated area, out of direct sunlight.

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SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:

No exposure standards have been established for the mixture by the Occupational Safety and Health Service (OSH) of the New Zealand Department of Labour.

Application in the workplace:

Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.

Engineering controls:

Additional ventilation requirements are not expected under normal conditions of use. However if there is risk of airborne exposure, provide sufficient ventilation to keep airborne levels as low as possible.

Personal protection:

Respiratory Protection

Not required under normal conditions of use. However where applicable, if engineering controls are not effective in controlling airborne exposure then an approved respirator should be used.¹

Eye Protection

Safety glasses with side shields or chemical goggles are recommended. Final choice of appropriate eye/face protection will vary according to individual circumstances.²

Hand Protection

Not required under normal conditions of use. 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.³

Body Protection

Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended.

References:

1. Reference should be made to Australian/New Zealand Standards AS/NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/ NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances
2. Eye protection devices 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: Liquid

Appearance: Clear to slightly turbid rose to brown liquid in multi-dose vials: 10, 50, 100, 250 and 500 mL high density plastic bottles.

Boiling Point: Not available

Vapour Pressure: Not available

Solubility in Water: Not available

pH value: 6.0 to 8.0

Flammability: Non-combustible material

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:

Stable under normal conditions of use and storage.

Conditions to avoid:

Temperatures below 2 °C.

Material to avoid:

Strong oxidizing agents.

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Hazardous decomposition products:	Under fire conditions this product may emit toxic and/ or irritating fumes and gases including carbon monoxide and carbon dioxide.
Hazardous polymerization:	Will not occur.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data:	No toxicity data available for this product.
Inhalation	Not a likely source of exposure under normal conditions of use.
Ingestion	Not considered a likely source of exposure. Ingestion may cause vomiting, nausea or other systemic effects.
Skin	May cause mild transient skin irritation. After injection, animals developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. May cause skin sensitisation through contact.
Eye	Not considered a likely source of exposure. May cause mild transient eye irritation.
Chronic Effects	Possible hypersensitization (development of abnormal sensitivity).

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	N/A
Data organisation :	Ecotoxicity Not available Persistence / Degradability Not available Mobility Not available
Environmental risk and safety phrases:	Do not discharge this material into waterways, drains and sewers.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	The disposal of the spilled or waste material and container must be done in accordance with applicable local and national regulations. Used needles should be placed in a designated sharps container.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as Dangerous Goods for transport according to the NZS 5433:2007 Transport of Dangerous Goods on Land.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

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Regulatory status:

Registered pursuant to the ACVM Act 1997, No. A010147
See www.foodsafety.govt.nz for registration conditions

Restricted Veterinary Medicine.
For use only under the authority or prescription of a veterinarian.

Not classified as Hazardous according to the New Zealand
Hazardous Substances (Minimum Degrees of Hazard) Regulations
2001.

HSNO and ACVM controls:

Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:

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

While the information set forth is believed to be accurate as of the
date hereof, BOEHRINGER INGELHEIM makes no warranty with
respect hereto and disclaims all liability from reliance thereon.