

SAFETY DATA SHEET



Ingelvac Mycoflex Mycoplasma Hyopneumoniae Inactivated Vaccine for Pigs

Version 2

Issue Date: 22 April 2020

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Section 1 - Identification of the Material and Supplier

Product name: Ingelvac Mycoflex Mycoplasma Hyopneumoniae Inactivated Vaccine for Pigs

APVMA Code: 69810

Recommended Use: Animal vaccine for use as described on the product label.

Supplier name: Boehringer Ingelheim Animal Health Australia Pty Limited

Address: Level 1, 78 Waterloo Road
North Ryde NSW 2113 AUSTRALIA

Telephone number (toll-free): 1800 808 691

All hours emergency phone number - Poisons Information Centre 131126 anywhere in Australia

Chemical nature: Vaccine containing inactivated Mycoplasma hyopneumoniae

This version issued: April, 2020 and is valid for 5 years from this date.

Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Not classified as hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

SUSMP Classification: None allocated.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

UN Number: None allocated

GHS Signal word: NONE. Not hazardous.

PREVENTION

P262: Do not get in eyes, on skin, or on clothing.

P264: Wash contacted areas thoroughly after handling.

P281: Use personal protective equipment as required.

RESPONSE

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P410: Protect from sunlight.

P411+P235: Store at temperatures not exceeding 8°C. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency Overview

Physical Description & Colour: Clear to slightly turbid rose to brown liquid.

Odour: No data.

Major Health Hazards: no significant risk factors have been found for this product.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc, /mL	TWA (mg/m ³)	STEL (mg/m ³)
Inactivated Mycoplasma hyopneumoniae	-	>1.0 RP	not set	not set
Carbomer	-	1 mg	not set	not set
Other non hazardous ingredients	secret	to 1 mL	not set	not set

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This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed liquid. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Wash gently and thoroughly with water (use non-abrasive soap if necessary) for 5 minutes or until chemical is removed.

Eye Contact: No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: Not combustible. Use extinguishing media suited to burning materials.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Not flammable.

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

Flammability Class: No data.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed.

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The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Refrigerate, preferably between 2 and 8°C, but do not freeze. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: **AS/NZS 4501** set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits	TWA (mg/m³)	STEL (mg/m³)
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Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: This product should only be used where there is ventilation that is adequate to keep exposure below the TWA levels. If necessary, use a fan.

Eye Protection: Eye protection such as protective glasses or goggles is recommended when this product is being used.

Skin Protection: You should avoid contact even with mild skin irritants. Therefore you should wear suitable impervious elbow-length gloves and facial protection when handling this product for lengthy periods. See below for suitable material types.

Protective Material Types: There is no specific recommendation for any particular protective material type.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: Clear to slightly turbid rose to brown liquid.

Odour: No data.

Boiling Point: Not available.

Freezing/Melting Point: No specific data. Liquid at normal temperatures.

Volatiles: No data.

Vapour Pressure: No data.

Vapour Density: No data.

Specific Gravity: No data.

Water Solubility: No data.

pH: 6-8

Volatility: No data.

Odour Threshold: No data.

Evaporation Rate: No data.

Coeff Oil/water Distribution: No data

Autoignition temp: No data.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Refrigerate, preferably between 2 and 8°C, but do not freeze. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

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Incompatibilities: strong oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient

Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be irritating, but is unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. Available data shows that this product is not harmful. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

Section 12 - Ecological Information

Insufficient data to be sure of status.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage.

Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

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Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association the trade association for the world's airlines.
IMSBC	Formerly IMDG, the code for carriage of Dangerous Goods by sea freight.
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

SUPPLIER STATEMENT: *The product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information in this SDS is based on the level of knowledge at the time of preparation and relates to the product in the state in which it is supplied. The information describes the product from the safety point of view and is not intended to guarantee any particular properties and shall not establish a legally valid contractual relationship*

Please read SDS and all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (Feb 2016)

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