



Safety Data Sheet

Revision date: 21st July 2014

Version: 1.0

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Section 1: Identification of the Substance or Mixture and of the Supplier

Product Name: AviPro 108 FC4 Vaccine
Synonyms: Fowl Cholera Vaccine
Chemical Family: Mixture

Intended Use: Poultry Vaccine
Restrictions of Use: Not for human use

New Zealand Supplier: Pacifivet Limited

Address: 3 Hickory Place, Hornby, Christchurch, New Zealand

Telephone Number: +64 3 349 8438

Emergency Telephone: Toll Free NZ 0508 388 388

Details of Supplier: Lohmann Animal Health International
375 China Road
Winslow
Maine 04901 United States

Date of Preparation: 21st July 2014

Section 2: Hazards Identification

Hazard Classification: HSNO: Not Listed
MPI: Permit to Import Restricted Biological Products of Animal Origin
ERMA: Import into Containment – Vaccine for re-export
ACVM Group Number: N/A **IMPORTANT: Vaccine not for use in New Zealand**
Dangerous Goods: Not Listed

Details: Not classified as Hazardous according to the New Zealand Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. Not scheduled according to the New Zealand Toxic Substances Regulations 1983.
Adverse health effects are considered unlikely when vaccine is used according to instructions.

Section 3: Composition and Information on Ingredients

<u>Ingredient</u>	<u>CAS No.</u>	<u>Proportion</u>
Infectious Bronchitis antigen solution	Not applicable	<1%
Mineral Oil	8042-47-5	70%
Sterile Saline	Not applicable	26%
Merthiolate 10%	54-64-8	2%
Aqueous emulsifier	Not applicable	<2%

All ingredients are classified as not hazardous

Threshold Limit Value:	No limit
ACGIH Threshold Limit Value:	Not applicable
OSHA Threshold Limit Value:	Not applicable

Section 4: First Aid Measures

Ingestion: Ingestion is relatively non-toxic, product has laxative properties and may result in abdominal cramps and diarrhoea. Drink one – two glasses of water. Seek medical assistance.

Eye Contact: Flush with water for 15 minutes

Skin Contact: Wash with soap and water.

Inhalation: Not considered a normal route of potential exposure.

Self-injection: **In the case of accidental self-injection please seek immediate medical attention.** Take the last page of this SDS with you entitled "Accidental Self-Injection of Oil Emulsion Vaccines". **Time is extremely important, DO NOT DELAY SEEKING TREATMENT.**

Notes for medical

Personnel: Oil-adjuvant containing products may cause severe vasospasm following accidental injection. There is also potential for an allergic reaction to occur. After entry into the hand the product may remain in a small area, or can distribute along the tendon sheath and neurovascular bundles far from the injection site. There will be direct injury to the tissue at time of injection, however within 24 hours there will usually be an inflammatory response causing significant swelling and increasing pain. **Recommended that the patient be immediately referred to a specialist experienced in the care of hand injuries.**

Section 5: Fire Fighting Measures

Fire hazard properties: Flammable, dense smoke generated while burning. Carbon Monoxide, Carbon Dioxide and other Oxides may be generated as products of combustion.

Extinguishing media: Use dry agent (CO₂), sand, dolomite, or foam.

Section 6: Accidental Release Measures

Action to take for Spills: Absorb with an inert material such as paper, rags or saw dust and place in a sealed container for disposal in an appropriate garbage system. Clean the spill area to lessen the risk of slippery surfaces due to oil emulsion. Product will float on water, use absorbent pads or similar material to trap product. Comply with all laws and regulations.

Environmental Precautions: Keep out of waterways. Prevent discharge to drains.

Section 7: Handling and Storage

Technical Precautions: No Special Precautions required.

Precautions of Safe

Handling: Avoid accidental injection. Proper instruction in the administration of this vaccine and the serious nature of the injury from accidental injection should be stressed.

Handling: Keep out of the reach of Children.

Storage: Keep only in original container. Keep chilled at a temperature between 2-7°C. Do not Freeze. Do not store with Food items.

Section 8: Exposure Controls/Personal Protection

Exposure Standards:	Threshold Limit Value:	No Limit
	ACGIH Threshold Limit Value:	Not applicable
	OSHA Threshold Limit Value:	Not applicable

Engineering Controls: No special measures required.

Personal Protective Equipment:	Eye Protection:	Not required for normal use
	Respiratory Protection:	Not required for normal use
	Skin Protection:	Not required for normal use

Section 9: Physical and Chemical Properties

Colour:	White oily liquid.
Odour:	No Odour
Solubility:	Negligible, Miscible
Specific Gravity:	approximately 0.88 to 0.96
Boiling Point:	100°C
Vapour Pressure:	<1
Flash Point:	Above 150°C
% Volatility by Volume:	Negligible
pH Value:	6.6 – 7.0
Evaporation Rate:	Not data

Section 10: Stability and Reactivity

Stability of Substance: Stable

Conditions to avoid: Not applicable as product is stable

Material to avoid: As a precautionary measure keep away from strong oxidizers.

Hazardous decomposition

Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapours

Specific Data: None

Section 11: Toxicological Information

General:	No adverse health effects expected when vaccine is used according to label directions and this Safety Data Sheet.
Inhalation LC50 (rat):	Not determined
Principle Routes of Exposure:	None
Eye Contact:	Mild irritation, Corneal injury unlikely.
Skin:	Frequent repeated skin exposure may cause allergic reaction in sensitive individuals.
Inhalation:	Not considered a risk
Self-Injection:	Oil-adjuvant containing products may cause severe vasospasm following accidental injection. There is also potential for an allergic reaction to occur. There will be direct injury to the tissue at time of injection, however within 24 hours there will usually be an inflammatory response causing significant swelling and increasing pain.
Systemic (Other Target Organ) Effects:	None recorded
Carcinogenic Effects:	No evidence of human carcinogenic effects.

Section 12: Ecological Information

Environmental Precautions:	Keep out of waterways.
Environmental Fate:	No known significant effects or critical hazards
Environmental Hazards:	Avoid releases of product as likely to affect adversely the functioning of water treatment plants.
Ecotoxicity Effects:	Analysis for effects has not been conducted on this product, however if spilled the product's contamination of soil or water may be harmful to human, animal and aquatic life.

Aquatic Toxicity: Could be fatal to aquatic life and waterfowl. Mineral oils will normally float on water and may limit the natural atmospheric oxygen transport into water.

Bioaccumulation: Not determined.

Section 13: Disposal Considerations

Disposal method : Incinerate container and all unused contents. Alternatively wrap product with an inert material such as paper or rags and place in a sealed container for disposal in an appropriate garbage system according to waste by-laws applicable at the time.

Section 14: Transport Information

Dangerous Goods Classification: Not Listed

Section 15: Regulatory Information

HSNO Classification: Not controlled
Other Regulation: ACVM Group Number A8021

Section 16: Other Information

Additional Advice: Use this product only in accordance with the directions provided on the product label.

Warning: The information provided in this Safety Data Sheet is based on current knowledge. However this does not constitute a warranty by the Company for that information. The product user is responsible for the appropriate and intended handling, use and disposal of this product in accordance with the label or package insert precautions and this information. All materials may present unknown hazards and should be used with caution.

Accidental Self-Injection of Oil Emulsion Vaccines

Lohmann Animal Health International cannot legally recommend medical treatment of humans. This document serves only as an informational aid to physicians.

Injection Injuries to the Hand

The injection of foreign material into the fingers or palm is a potentially serious injury. Vaccine, utilized to immunize poultry, consists of inactivated virus and/or bacteria in an oil emulsion carrier. This can be accidentally injected into the fingers if proper care is not taken while performing the injection.

Pathology

After entry of the vaccine into the hand, it can remain in a small area or distribute itself along the tendon sheath and neurovascular bundles far from the injection site. There is some direct injury to tissue at the time of injection but within 24 hours, there is usually an inflammatory response resulting in significant swelling and increasing pain. Subsequent problems occur with the possible onset of bacterial infection and late formation of oleogranulomas (swelling resulting from chronic inflammation because of the body's response to the oil emulsion). If the blood supply of the finger remains intact, the late problems consist of continuing pain and stiffness of the involved part. One would not expect the inactivated viruses or bacteria involved to be a problem by themselves as they do not produce disease in man, and further there are no living organisms present.

Suggested Possible Treatment

The best treatment is prevention! These injuries occur more often in persons less experienced in the use of injection equipment. Proper instruction in their use and the serious nature of the injury should be stressed.

If an accident does occur, it is recommended that the victim be immediately referred to a surgeon experienced in the care of hand injuries. They should not be handled in an office setting by someone unfamiliar with the problem. **TIME IS EXTREMELY IMPORTANT. DO NOT DELAY TREATMENT.**

Although there is some disagreement among hand surgeons about treatment, the following is an outline of the usual course taken.

1. Zeroradiograms (special soft tissue x-rays) can help to ascertain the extent of distribution of the oil material in the finger or hand. If little or no oil was actually injected, the inflammation may subside spontaneously over several weeks or with the use of Cortisone, even if the needle penetrated deeply into the hand. If history and radiograms indicate a conservative approach, a period of close careful observation and functional evaluation (flexion studies) should be carried out.
2. If oil emulsion vaccine was actually injected, an extensive debridement (opening the affected part and removing as much of the foreign material as possible) should be carried out. The wound is generally left open and closed later.
3. Broad spectrum antibiotics are given in high doses for as long as two weeks depending on the clinical picture.
4. The use of an anti-inflammatory drug, such as Cortisone, should be considered.

Prevention first.