Izovac FC ®

Section 1: Identification of the Substance and Supplier	
Product name:	**Izovac FC**
Other name:	Fowl Cholera Vaccine
ACVM Registration:	A011231
Recommended use:	For the immunisation of chickens against Fowl Cholera
Company details:	Pacificvet Limited
Address:	3 Hickory Place Hornby 8042 Christchurch New Zealand
Telephone number:	+64 3 349 8438 (business hours 8:30 am to 5:00 pm)
Emergency telephone:	Pacificvet Limited: 0508 388 388 National Poisons Centre: 0800 764 766 (0800 POISON)
Date of Preparation:	20th September 2022
Section 2: Hazard Identification	
Hazard classifications:	HSNO classification Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2022 HSNO Approval: HSR100757 Aspiration Hazard Category 1 Skin Sensitizer Category 1 Not a Dangerous Good according to IATA of NZTA. Hazchem code: 2Y (recommended)
Pictograms:	
Signal words:	Danger
Hazard statements:	H304 May be fatal if swallowed and enters airways H317 May cause an allergic skin irritation
Precautionary statements:	P102 Keep out of the reach of children P103 Read label before use P280 Wear protective gloves and protective clothing

Section 2: Hazard Identification (continued)	
Prevention statements:	For Animal Treatment P102 Keep out of the reach of children P103 Read label before use P272 Contaminated work clothing should not be allowed out of the workplace P280 Wear protective gloves and protective clothing
Response statements:	P101 If medical advice is needed, have product container or label at hand P301 + P310 IF SWALLOWED: Immediately call a POISION CENTER or doctor/ physician P331 Do NOT induce vomiting P302 + P352 IF ON SKIN: Wash immediately with plenty of soap and water. P321 Thimerosal is a recorded contact sensitiser. There is potential for an immunological reaction following skin exposure to the substance. Future exposure to smaller amounts of the substance can trigger an allergic skin reaction of a rash or contact dermatitis. Wear gloves to avoid accidental contact with the product. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P363 Wash contaminated clothing before re-use.
Storage statements:	P405 Store locked up. Store in unopened bottle in a refrigerator at 2°C to 8°C. Do not freeze.
Disposal statements:	Product must be disposed of through an appropriate hazardous waste company.
Other hazards:	Accidental injection or self-injection may result in severe pain and swelling, particularly if injected into a joint or finger. Seek prompt medical advice even if only a very small amount is injected. If pain persists for more than 12 hours after medical examination, seek medical advice again. The product contains mineral oil which acts as an irritant when accidentally injected, causing a severe inflammatory response.

Section 3: Composition			
Substance characterisation:	White oil emulsion		
Product components:	**Name**	**CAS**	**Proportion**
	Inactivated *Pasteurella multocida* bacteria in media		30 - 50%
	Phosphate Buffered Saline		<5%
	Mineral Oil	8042-47-5	>50%
	Sorbitan oleate	13338-43-8	5 - 10%
	Polysorbate 80	9005-65-8	<1%
	Thimerosal	54-64-8	<0.01%
	Other components are below reportable levels.		

Section 4: First Aid Measures	
General:	For advice contact the National Poisons Centre on 0800 POISON (08000 764 766) or a doctor if you feel that you may have been harmed by this product.
Personal precautions protective equipment:	Wear suitable protective clothing such as overalls and gloves to avoid contact with skin.
Inhalation:	Significant inhalation exposure is considered unlikely. Aspiration of the product liquid into lungs is a potential hazard with the associated risks of exogenous lipoid pneumonia caused by the mineral oil component acting as an irritant.
Ingestion:	May be fatal if swallowed and enters airways. Immediately seek medical advice if aspiration is suspected. If product is swallowed do NOT induce vomiting. Product is mildly irritating to the mucous membranes of the gastrointestinal tract but is unlikely to cause anything more than mild transient discomfort and have a laxative effect.
Self-Injection:	Accidental injection or self-injection may result in severe pain and swelling, particularly if injected into a joint or finger. **Seek prompt medical advice even if only a very small amount is injected**. If pain persists for more than 12 hours after medical examination, seek medical advice again.
Skin Contact:	Flush with lukewarm gently flowing water for 5 minutes or until product is removed. Then wash with soap and water to remove final traces. Seek medical attention if skin reaction occurs.
Eye Contact:	If product gets into the eye, keep the eye lid open and rinse immediately with large quantities of lukewarm gently flowing water for at least 15 minutes or until product is removed. Remove contact lenses, if present and easy to do. If eye irritation develops seek medical advice/ attention.
Most important symptoms and effects, acute and delayed from exposure and medical attention required	
Inhalation:	Aspiration of product liquid into lungs is a risk and could lead to exogenous lipoid pneumonia. Urgent Medical advice is required in suspected cases.
Ingestion:	Product is an Aspiration hazard and may be fatal if swallowed and enters airways. **Any breathing issue following ingestion requires urgent medical investigation.** Product may cause a mild transient laxative effect and discomfort. Seek medical advice if digestive upset continues.
Self-injection:	Product is an irritant in puncture wounds. Potential of severe inflammatory response. **Seek urgent medical attention.** If pain and inflammatory response continues after the initial medical examination, seek medical attention again, as surgical debridement of the wound site may be required to remove product from the tissue.
Skin Contact:	Product contains Thimerosal a component that may cause skin sensitisation. Seek medical advice should a skin rash or contact dermatitis develop and advise the practitioner that the product contains Thiomersal a known skin sensitiser. Take this SDS with you.
Eye Contact:	Should discomfort and irritation of eye persist after flushing with water to clear the product seek urgent medical attention.

Section 4: Medical Advice	
Advice to Doctor:	The product contains mineral oil known to cause a persistent inflammatory response when injected into tissue. Even if only small amounts have been accidentally injected, this product can cause intense swelling and lipogranuloma formation, which may result in necrosis and even loss of a digit. Prompt surgical attention is required and may necessitate early incision and irrigation of the injected area, especially when there is involvement of the finger tissue or tendons. In very rare cases of ingesting the product there is the potential for exogenous lipoid pneumonia due to the possibility of aspiration of the oil component of the product into the lungs. Ciliary clearance of product from the tracheobronchial tree is also disrupted by the mineral oil component. The product contains Thiomersal a recorded skin sensitiser. Vaccines containing between 0.005 – 0.1% Thiomersal content are considered hazardous under the HSNO Act.

Section 5: Fire Fighting Measures	
Type of hazard:	Product and packaging not readily combustible. In case of fire: Toxic or flammable decomposition vapours are expected. Incomplete combustion is likely to give rise to carbon monoxide and unidentified organic and inorganic compounds.
Extinguishing media and methods:	Use extinguishing media suitable to burning materials such as water fog, foam, dry agent (CO_2), sand or dolomite. Avoid water jet as this will spread the fire.
HAZCHEM code	2Y (recommended)
Special protective equipment and Precautions	Wear self-contained breathing apparatus.

Section 6: Spillage and Accidental Release Measures	
Personal precautions, protective equipment:	Wear personal protection equipment such as gloves and overalls to prevent skin contact.
Environmental Precautions:	Treat the recovered material as toxic and dispose through an appropriate hazardous waste company. Do not allow product to enter into the surface waterways, surface drainage systems or sewers.
Containment and Clean up	Use absorbent material such as paper or cloth to collect product and place in appropriate containers for disposal. Clear contaminated area thoroughly of product residue by wet mopping using Detergent in warm water, the cleaning residue should be diluted prior to disposal in sewage system. Product residue is a slippery hazard if left on floor surfaces.
Emergency Response:	Does not normally trigger thresholds as spillage will generally be single bottles.

Section 7: Handling and Storage	
Precautions for safe handling:	Read product label instructions prior to use. **Wear protective clothing such as overalls and gloves to prevent contact on the skin by the product.**
Regulatory requirements:	Keep out of the reach of children. For animal treatment only. Read label before use. If medical advice is needed: Have product container or label at hand.
Handling practices:	No special control measures for handling this product. **Wear protective clothing such as overalls and gloves to prevent contact on the skin by the product.**
Certified handlers:	Not applicable.
Conditions for safe storage:	Keep out of the reach of children. Store in closed original container in a locked /secured refrigerator at 2° to 8°C. Do not freeze. Use within 10 hours of opening bottle.
Store site requirements:	Maybe subject to a **Hazardous Substances Emergency Response Plan** when quantities greater than 1000 litres (2000 x 500mL bottles) are held in store.
Packaging:	Store only in original packaging. Once seal is broken use all of the product.
Specific end use:	Only to be used according to the directions on the label.

Section 8: Exposure Controls/Personal Protection	
	
Workplace Exposure Standards:	A workplace exposure standard (WES) has not been established by WorkSafe New Zealand for this product.
Engineering Controls:	Exposure can be reduced by use of personal protective equipment.
Personal Protective Equipment:	Guidance from AS/NZS 4501 Occupational Protective Clothing, AS/NZS 2161 Occupational Protective Gloves and AS/NZS 2210 Occupational Protective Footwear is recommended.
Eye/Face Protection:	Eye and Face Protection is not generally required.
Skin Protection:	Suitable overalls and gloves are to be worn. Single-use gloves of natural rubber or natural latex may be used. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with product. Dispose of contaminated gloves in appropriate disposal system. Overalls must be washed prior to reuse.
Respiratory Protection:	Respiratory Protection not generally required.
General Hygiene:	Always observe good personal hygiene measures, such as washing hands after handling the product and before eating, drinking and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and Chemical Properties	
Appearance:	White liquid
Odour:	Odourless
Odour threshold:	Does not apply
pH:	No data, expected to be slightly alkaline
Freezing/ Melting Point:	No data, likely to be in the range from 0°C to -4°C due to mineral oil content
Boiling Point:	No data, likely be above 220°C
Flash Point:	No data, expected to be >160°C
Flammability:	Not flammable
Explosive limits:	Does not apply
Fire Hazard Properties:	Combustible
Vapour pressure:	No data available
Vapour density:	No data available
Specific gravity or density:	No data available
Solubility:	Miscible emulsion
Partition coefficient:	No data available
Auto-ignition temperature:	No data available, likely >260°C
Decomposition temperature:	No data available
Viscosity:	20 - 60 mPa-s
Particle characteristics:	No data available

Section 10: Stability and Reactivity	
Reactivity:	Unlikely to react or decompose under normal storage.
Stability:	Stable stored under recommended conditions. Do not freeze – dispose of product if frozen.
Conditions to avoid:	None for handling of product.
Incompatible materials:	Strong oxidizing agents.
Hazardous Decomposition Materials:	No data available.
Hazard Reactions:	Product will not auto-polymerize.

Section 11: Toxicological Information	
Toxicological Information:	**No data available for product. Component ingredients have recorded:** **Light White Mineral Oil:** Acute toxicity Dermal: >2,000 mg, Source: ECHA **Thiomersal:** Skin Sensitisation 0.005 – 0.1% concentration, Source: New Zealand EPA Determination HAZ01001 **Polysorbate 80:** Acute toxicity LD_{50} Oral Rat >63.840 mg/kg Source: NCBI USA
Acute toxicity via Oral:	Based on available date, the classification criteria are not met when considering the component ingredients of the product as there is no actual data for the product.
Acute toxicity via Dermal:	Mineral Oil component may be harmful in contact with skin for individuals with sensitive skin.
Acute toxicity via Inhalation:	No data available. Considered that the classification criteria are not met.
Skin Corrosivity / Skin Irritation	No data available. Considered that the classification criteria are not met.
Eye Corrosivity / Eye Irritation	No data available. Considered that the classification criteria are not met.
Respiratory or Skin Sensitisation:	Classified as **Skin Sensitizer Category 1**, the product is classified as a sensitizer due to Thiomersal component present at above the 0.005% level.
Germ Cell Mutagenicity:	Not classified as a mutagen.
Carcinogenicity:	Not classified as a carcinogen.
Reproductive toxicity:	Not classified as a reproductive toxin.
Specific Target Organ Toxicity – single exposure:	Not classified as causing specific organ damage.
Specific Target Organ Toxicity – repeated exposure:	Not classified as causing organ damage from repeated exposure.
Aspiration Hazard:	Classified **Aspiration Hazard Category 1** as kinematic viscosity of refined pharmaceutical mineral oils (hydrocarbon derivative) sits in the range of ≤20.5 mm^2/s measured at 40°C and there is medical evidence of aspiration of mineral oil into the lungs following ingestion of mineral oil when used as a laxative.
Acute and chronic health effects:	None recorded
Skin Contact short term exposure:	Available data indicates product could be irritating to skin. Symptoms in include redness and a rash.
Skin Contact long term exposure:	Thimerosal has been linked with skin sensitization following repeat exposure. Resulting in a contact dermatitis.
Eye Contact short term exposure:	Product may cause mild eye irritation when in contact with the eye and symptoms include discomfort. This will resolve once the product is removed.
Eye Contact long term exposure:	No data recorded for health effects from multiple accidental contact events in the eye.

Section 11: Toxicological Information (continued)	
Ingestion effects:	**Swallowing the product has the risk of Aspiration into the lungs (see below).** Generally small amounts of the product being swallowed should not be harmful. Product is mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort and have a laxative effect.
Aspiration hazard exposure effect:	Droplets of product aspirated into the lungs through an accidental ingestion event may cause exogenous lipoid pneumonia caused by the mineral oil component acting as an irritant.
Specific Target Organ Toxicity effect:	No data linking product as a specific toxicant to any organs of the body.

Section 12: Ecological Information	
Toxicity to aquatic and terrestrial plants and animals:	**No data available for product's Aquatic toxicity:** **Light Mineral Oil CAS No. 8042-47-5** Acute fish toxicity LC_{50} ≥ 100 mg/L 96 hours species *Oncorhynchus mykiss* (rainbow trout) static test LC_{50} (OECD Test Guideline 203) Acute crustacea toxicity LC_{50} ≥ 100 mg/L 48 hours *Daphnia magna* (water flea) static test (OECD Test Guideline 202)
Persistence and degradability:	Components are considered to be non-persistent in an aquatic environment.
Bioaccumulation potential:	No indication of bio-accumulation potential.
Mobility in soil:	No data available.
Ecotoxicity Hazard Statements:	Slightly harmful in the Aquatic Environment. Does not trigger the hazard threshold for Ecotoxicity in the Soil environment and is not a hazard for Terrestrial Vertebrates or Terrestrial Invertebrates.

Section 13: Disposal Considerations	
Disposal method:	Avoid disposal of unused vaccine it is best to use the product. Product must be disposed of through an appropriate hazardous waste company. This product is NOT suitable for disposal by either landfill or via sewers, drains, natural streams or rivers. This product should be incinerated directly in appropriate equipment.

Section 14: Transport Information	
UN Number:	This product is not classified as a Dangerous Good by the NZTA or IATA.
HAZCHEM Code:	2Y (recommended)
Special Precautions for transport:	Transport in original packaging with lid sealed.
Health and Safety at Work (Hazardous Substances) Regulations 2017	May be subject to a **Hazardous Substances Emergency Response Plan**. The threshold quantity for secondary containment applies for a Skin Sensitization Category 1 classified product **when the quantity held is greater than 1000 litres** (2000 x 500mL bottles).

Section 15: Regulatory Information	
ERMA Register Approval Number:	Not applicable
HSNO Controls:	Approval HSR100757 Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2022
Approved Handlers Certificate:	Not required
Workplace Exposure Standards (WES):	Not applicable
ACVM controls:	Registered pursuant to the ACVM Act 1997, No. A11231. See www.foodsafety.govt.nz for registration conditions.
Health and Safety at Work (Hazardous Substances) Regulations 2017	May be subject to a **Hazardous Substances Emergency Response Plan**. The threshold quantity for secondary containment applies for a Skin Sensitization Category 1 classified product **when the quantity held is greater than 1000 litres** (2000 x 500mL bottles).

Section 16: Other Information		
Additional Information:	This product is to be used only in accordance with the directions provided on the product label and instruction sheet.	
Warning:	The information provided in this Safety Data Sheet is based on current knowledge of the Health and Safety Hazard of the product detailed in this SDS. While all information supplied in this SDS is believed to be accurate this does not constitute a warranty by Pacificvet Limited for the information. The company disclaims any liability resulting from the use of this information. The product user is responsible for the appropriate and intended handling, use and disposal of the product. If clarification or further information is need to ensure that an appropriate risk assessment can be made prior to use of the product in the workplace, the user should contact Pacificvet Limited. The information contained in this SDS is only safety related information, for all other product information please refer to the product label and instruction sheet.	
Version issued:	20th September 2022 and is valid for 5 years from this date.	
Revision history:	Date of Revision	Reason
	20th September 2022	Transfer to GHS classification

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