

SAFETY DATA SHEET

Zoetis New Zealand Limited
Level 3, 14 Normanby Road, Mt Eden, Auckland



Section 1: Identification of the Substance and Supplier

Trade Name:	EWEGUARD[®] Plus Se B12
ACVM Registration No.:	A009659
Classification:	Unrestricted
Recommended Use:	Injectable vaccine for prevention of enterotoxaemia (pulpy kidney), blackleg, malignant oedema, black disease, tetanus and caseous lymphadenitis ("lympho" or cheesy gland) in ewes, rams and wethers. For treatment and control of internal parasites and nasal bot of adult sheep, and a supplementary source of selenium and vitamin B12.
Company Details:	Zoetis New Zealand Limited
Address:	Level 3,14 Normanby Road Mt Eden Auckland 1024 New Zealand
Telephone No.:	0800 650 277 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	13 February 2013

Section 2: Hazards Identification

Hazard Classification:	6.1E, 6.5B, 6.8B, 6.8C, 9.1A, 9.2C, 9.4B
Priority Identifier(s):	WARNING – KEEP OUT OF REACH OF CHILDREN ECOTOXIC
Secondary Identifier(s):	6.1E May be harmful if swallowed, inhaled or absorbed through the skin. 6.5B May cause an allergic skin reaction. Avoid skin contact. 6.8B Suspected of damaging fertility or the unborn child from repeated oral exposure. 6.8C May cause harm to breast-fed children from repeated oral exposure. 9.1A Very toxic to aquatic organisms. Avoid contamination of any water supply with product or empty container. 9.2C Harmful to the soil environment. 9.4B Toxic to terrestrial invertebrates.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Moxidectin	113507-06-5	0.5%
Selenium (as Sodium selenate)	13410-01-0	0.1%
<i>Clostridium chauvoei</i> toxoid	Not applicable	Variable
<i>Clostridium novyi</i> type b toxoid	Not applicable	Variable
<i>Clostridium perfringens</i> type d toxoid	Not applicable	Variable
<i>Clostridium septicum</i> toxoid	Not applicable	Variable
<i>Clostridium tetani</i> toxoid	Not applicable	Variable
<i>Corynebacterium pseudotuberculosis</i> exotoxin	Not applicable	Variable
Vitamin B12 (as Hydroxocoalbumin acetate)	22465-48-1	0.1%
Thiomersal	54-64-8	< 0.1%
Other ingredients determined not to be hazardous.	-	To 100%

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:

For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.

Self-Injection: Immediate medical advice should be sought on the management of **all** instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely; avoid squeezing the injection site to avoid spread of the product. Clean wound thoroughly with soap and water, and then keep it clean and dry.

Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.

Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.

Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.

Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.

Poisoning Symptoms: No specific information available.

Workplace Facilities: No specific facilities required. Standard emergency equipment must be available.

Hygiene Practices: Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Notes for Medical Personnel:

Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising should be treated medically or surgically.

Section 5: Fire-Fighting Measures

Type of hazard:	This product is non-flammable, non-combustible and non-explosive.
Fire Hazard Properties:	There is no risk of an explosion from this product under normal circumstances if it is involved in a fire. It will produce only minor quantities of decomposition products at temperatures normally achieved in a fire. Likely to decompose only after heating to dryness followed by further strong heating. Do not allow fire water to enter waterways.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use dry chemical, foam, carbon dioxide or water to extinguish fires involving this product.
Hazchem Code:	3Z
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	No special technical protective measures required. No special handling advice required.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store between 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	A requirement for an emergency management plan, secondary containment and signage is applicable when quantities of 100 L are stored.
Packaging:	Packaging Schedule 3 (UN Packing Group III) for quantities > 5 L (Hazardous Substances Packaging Regulations 2001).

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:	A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m ³ for dusts or mists when limits have not otherwise been established.
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	<p>Moxidectin:</p> <ul style="list-style-type: none"> ▪ ADE: 0.002 mg/kg bw/day ▪ PDE_{food}: 0.0014 mg/kg bw/day ▪ PDE_{drinking water}: 0.0004 mg/kg bw per day ▪ PDE_{dermal}: 0.0002 mg/kg bw per day ▪ TEL_{skin surface deposition}: 0.03 mg/m² ▪ EEL_{water}: 0.0000003 mg/L
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	Cloudy suspension.
Odour:	No data available. Expected to be odourless.
Specific Gravity / Density:	No data available. Expected to be approximately 1.0.
Freezing / Melting Point:	Approximately 0°C
Boiling Point:	Approximately 100°C at 100 kPa
pH:	No data available. Expected to be near neutral.
Solubility in Water:	Completely soluble in water.
Flashpoint:	Not applicable. This product is not flammable.
Oxidising Properties:	Not applicable. This product is not an oxidiser.
Corrosive Properties:	Not applicable. This product is not corrosive.
Vapour Pressure:	2.37 kPa at 20°C (water vapour pressure).

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions of use.
Conditions to Avoid:	Store as recommended. No special conditions to avoid.
Material to Avoid:	No particular materials to avoid.
Hazardous Decomposition Products:	This product is unlikely to spontaneously decompose. Based on composition of proteins, the following might be expected: Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Oxides of sulphur (sulphur dioxide is a respiratory hazard) and other sulphur compounds. Water. Will be released only in small quantities.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

- 6.1E** May be harmful if swallowed, inhaled or absorbed through the skin.
- 6.5B** May cause an allergic skin reaction. Avoid skin contact.
- 6.8B** Suspected of damaging fertility or the unborn child from repeated oral exposure.
- 6.8C** May cause harm to breast-fed children from repeated oral exposure.

Acute Effects

Moxidectin:	Moxidectin is a macrocyclic lactone, structurally similar to ivermectin, abamectin and milbemycin. Moxidectin is an acute oral toxin with nervous system effects [LD ₅₀ (oral, mice) 42 mg/kg, LD ₅₀ (dermal) is >2000 mg/kg]. Only mild signs of skin irritation were seen (rabbit, exposure for up to 72 hrs). Moderate eye irritation was noted (rabbit), but signs resolved 48-72 hrs after treatment.
Thiomersal:	Thiomersal is acutely toxic [LD ₅₀ (oral, rat) 40 mg/kg], a skin and eye irritant and an allergic contact sensitiser.

Chronic / Long Term Effects

- Moxidectin:** Laboratory rodent reproductive studies reported foetal malformations, decreased number of live births, reduced pup weights and neonatal & lactational deaths [lowest NOEL 0.4 mg/kg/day]. A chronic feeding study (90 days; 0 to 1.6 mg/kg/d) induced toxicity in dogs. At the highest dose lacrimation, tremors, salivation, slight ataxia and a languid appearance were reported. Dose dependant reductions in absolute body weight and food consumption were noted [NOEL 0.3 mg/kg]. In a second study (52 weeks; 0-1.15 mg/kg/d), no signs of toxicity occurred and body weights remained comparable to controls throughout the study [NOEL 1.15 mg/kg]. Moxidectin is not mutagenic or carcinogenic.
- Thiomersal:** Studies of mutagenicity were inconclusive. Methylmercury compounds are possibly carcinogenic to humans (Group 2B). Metallic mercury and inorganic mercury compounds are not classifiable as to their carcinogenicity to humans (Group 3). Mercury and mercury compounds are listed by CalEPA as developmental toxicants. Chronic exposure to high doses may cause neurotoxicity and nephrotoxicity.

Section 12: Ecotoxicity Information

HSNO Classifications

- 9.1A** Very toxic to aquatic organisms. Avoid contamination of any water supply with product.
- 9.2C** Harmful to the soil environment.
- 9.4B** Toxic to terrestrial invertebrates.

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

- Moxidectin:** Moxidectin is very toxic to aquatic life [Bluegill sunfish LC₅₀ (96 hrs) 0.62 ppb; Rainbow trout LC₅₀ (96 hrs) 0.16 ppb; Daphnia magna EC₅₀ (48 hrs) 30 ppt; bioaccumulative] and soil life [Dung beetle EC₅₀s are 2.5677 mg/kg; 0.4693 mg/kg & 0.134 mg/kg. Soil DT₅₀ > 30 days]. Moxidectin is also very toxic to terrestrial vertebrates [LD₅₀ (mice) = 42 mg/kg] and bees [LD₅₀ (oral) = 0.46 ug/bee; LD₅₀ (contact) 0.02 5 ug/bee]
- Selenium:** Selenium is an essential mineral, but is toxic to aquatic life at high concentrations. It can persist in soils until diluted or washed away by rain.
- Thiomersal:** Thiomersal (contains mercury) is a bioaccumulative environmental toxin (water, soil). The level of thiomersal in EWEGUARD Plus Se B12 is very low and it is not a significant environmental toxin for this mixture.

Environmental Fate

No further information available.

Section 13: Disposal Considerations

- Product Disposal:** Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.
- Container Disposal:** Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

