

SAFETY DATA SHEET

Product Name: ESTROMIL INJECTION

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This revision issued: April, 2015

Section 1 - Identification of The Material and Supplier

Troy Laboratories Australia Pty. Ltd ABN: 21 000 283 769 Tel: (02) 8808 3600 (office hours) 31-35 Glendenning Road Fax: (02) 9677 9300

Glendenning NSW 2761

Chemical nature: Water solution of ingredients (see below). Active ingredient is cloprostenol, a

prostaglandin.

Trade Name: ESTROMIL INJECTION

APVMA Code: 51716

Product Use: Synthetic prostaglandin for cattle and horses.

Creation Date: July, 2005

This version issued: April, 2015 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: Hazardous according to the criteria of SWA Australia.

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

Risk Phrases: R61, R21/22. May cause harm to the unborn child. Harmful in contact with skin and if swallowed. **Safety Phrases:** S20, S45, S53, S24/25, S36/37. When using, do not eat or drink. In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre immediately (show the label where possible). Avoid exposure obtain special instructions before use. Avoid contact with skin and eyes. Wear suitable protective clothing and gloves.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated





GHS Signal word: WARNING.

HAZARD STATEMENT:

H302: Harmful if swallowed.

H312: Harmful in contact with skin.

H360: May damage fertility or the unborn child.

PREVENTION

P102: Keep out of reach of children.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

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

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P281: Use personal protective equipment as required.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P363: Wash contaminated clothing before reuse.

P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

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

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P308+P313: If exposed or concerned: Get medical advice.

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

STORAGE

P405: Store locked up.

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Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)

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P402+P404: Store in a dry place. Store in a closed container. P403+P235: Store in a well-ventilated place. Keep cool.

DISPOSAL

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

Emergency Overview

Physical Description & Colour: Clear, colourless liquid.

Odour: No odour.

Major Health Hazards: may cause harm to unborn children, harmful in contact with skin, and if swallowed.

Cloprostenol can be absorbed through the skin and therefore care should be taken when handling the product especially by women of child-bearing age and by asthmatics. Cloprostenol may cause broncho-spasm in man. Accidental inhalation or injection may cause a rapid acting broncho-dilation - Cloprostenol may cause peritonitis in the cases that they are in pyometral condition with a stenosed cervix.

Potential Health Effects

Cloprostenol can be absorbed through the skin and therefore care should be taken when handling the product especially by women of child-bearing age and by asthmatics.

Inhalation

Short Term Exposure: Significant inhalation exposure is considered to be unlikely. 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 shows that this product will cause abortion in pregnant women.

However product is unlikely to cause any health problems in normal use.

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

Eye Contact:

Short Term Exposure: Exposure via eyes is considered to be unlikely. This product is believed to be not irritating to eyes

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 will cause abortion in pregnant women.** This product is unlikely to cause any irritation problems in the short or long term.

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 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m³)
Cloprostenol (sodium salt)	55028-72-3	0.025	not set	not set
Other non hazardous ingredients	secret	<2	not set	not set
Water	7732-18-5	to 100	not set	not set

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

The 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 should not be exceeded for more than 15 minutes and should not be repeated for 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.

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Any pregnant woman who comes into contact with this product, or who suspects she has come into contact with this product, even by skin contact, should seek immediate medical attention.

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 vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

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 warm water (use non-abrasive soap if necessary) for 10-20 minutes or until product is removed. Under running water, remove contaminated clothing, shoes and leather goods (e.g. watchbands and belts) and completely decontaminate them before reuse or discard.

Eye Contact: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. **Ingestion:** If swallowed, do NOT induce vomiting. Wash mouth with water and contact a Poisons Information Centre, or call a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness.

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: Does not burn.

Upper Flammability Limit: Does not burn.

Lower Flammability Limit: Does not burn.

Autoignition temperature: Not applicable - does not burn.

Flammability Class: Does not burn.

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. 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: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. 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)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

The ADI for Cloprostenol (sodium salt) is set at 0.0005mg/kg/day. The corresponding NOEL is set at 0.05mg/kg/day. ADI means Acceptable Daily Intake and NOEL means No-observable-effect-level. Values taken from Australian ADI List, June 2013.

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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: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: Prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber, PVC.

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

Safety deluge showers should, if practical, be provided near to where this product is being used.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: Clear, colourless liquid.

Odour: No odour.

Boiling Point: Approximately 100°C at 100kPa.

Freezing/Melting Point: Approximately 0°C. Volatiles: Water component.

Vapour Pressure: 2.37 kPa at 20°C (water vapour pressure).

Vapour Density: No data. Specific Gravity: No data.

Water Solubility: Completely soluble in water.

pH: No data.
 Volatility: No data.
 Odour Threshold: No data.
 Evaporation Rate: No data.
 Coeff Oil/water Distribution: No data

Autoignition temp: Not applicable - does not burn.

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: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: No particular Incompatibilities.

Fire Decomposition: Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness. Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water, sodium compounds. 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: none known

Classification of Hazardous Ingredients

Ingredient Risk Phrases

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

Section 12 - Ecological Information

Insufficient data to be sure of status.

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Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

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.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this product are compliant with NICNAS regulations. The following ingredient: Cloprostenol, is mentioned in the SUSMP.

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, 7th Edition

AICS Australian Inventory of Chemical Substances
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
SWA Safe Work Australia, formerly ASCC and NOHSC

NOS Not otherwise specified

NTP National Toxicology Program (USA)

R-Phrase Risk Phrase

SUSMP Standard for the Uniform Scheduling of Medicines & Poisons

UN Number United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous

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