

estroPLAN Safety Data Sheet

Revision 4, Date 26 September 2018

1. IDENTIFICATION OF PRODUCT AND COMPANY

MANUFACTURER COMPANY DETAILS:

Parnell Technologies Pty. Ltd.

Address

Unit 4, Century Estate
476 Gardeners Road
Alexandria, NSW 2015
Australia

Telephone Number

+61 2 9667 4411

Emergency Telephone Number

+61 2 9667 4411 (Business Hours)

Facsimile Number

+61 2 9667 4139

Trade names:

estroPLAN injection

Product name :

Cloprostenol sodium injection

Description:

Clear, colorless solution with a mild amine odor.

Recommended use:

FOR ANIMAL TREATMENT ONLY. An analogue of prostaglandin F_{2α} for intramuscular injection in beef and dairy cattle.

DISTRIBUTOR DETAILS:

Parnell U.S. 1, Inc

Address

7015 College Blvd.
Level 6
Overland Park, KS 66211
United States of America

Telephone Number

1-800-88PARNELL
(1-800-887276355)

Emergency Telephone Number

1-800-88PARNELL (Business Hours)

2. COMPOSITION

Chemical Entity

Citric Acid/Sodium Citrate (Buffering Agents)
Cloprostenol (as sodium)*
Chlorocresol
Sodium Chloride
Water

CAS Number

77-92-9/6132-04-3
55028-72-3
59-50-7
7647-14-5
7732-18-5

Proportion

<1% w/v
0.025% w/v
0.1% w/v
<1% w/v
to 100%

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Signal word:

CAUTION!

Statements of hazard:

MAY CAUSE HARM TO THE UNBORN CHILD

Eye effects:

None known; however, direct contact with any foreign material may cause eye irritation.

Skin effects:

May be absorbed through the skin and cause systemic effects. Mild diarrhea has been reported following absorption of cloprostenol through skin.

Inhalation effects:

May be absorbed through mucous membranes and cause systemic effects. See 'Statements of hazard' and/or 'Other potential health effects' in this section.

Ingestion effects: Ingestion should be avoided. See 'Statements of hazard' and 'Other potential health effects' in this section.

Other potential health effects: Women of child bearing age, asthmatics or other people with bronchial disease should use extreme caution when handling this product as cloprostenol has the potential to induce abortion or acute bronchostriction.

NOTE: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Wash off any *Estroplan* contacting skin immediately using soap and water. Seek medical assistance if required.

Swallowed: Seek medical assistance if required.

Eye: If in eyes, hold eyes open, flood with water for at least 15 minutes. Seek medical assistance if required.

Skin: If skin contact occurs remove contaminated clothing and wash skin thoroughly with soap and water. Seek medical assistance if required.

Inhaled: Seek medical assistance if required.

First Aid Facilities: No specific first aid facilities required.

ADVICE TO DOCTOR: Treat symptomatically as required.

5. FIRE-FIGHTING MEASURES

This material is not considered a fire hazard. Use standard fire fighting techniques to extinguish fires involving this material. Use water spray, dry chemical, carbon dioxide or foam.

6. ACCIDENTAL RELEASE MEASURES

Clear immediate area of unprotected personnel. Clean up spilled material with absorbent ensuring no contact with skin during operation. Flush contaminated area with water and detergent.

Dispose of waste in accordance with local, state or federal laws.

7. HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing.

Storage: Store below 25°C (77°F) (Air conditioning). Protect from light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards: No exposure standard allocated

Engineering Controls: Not applicable

Personal Protection:

Wear gloves when handling product.

Avoid spraying or splashing of the preparation.

Avoid inhalation of aerosol spray or vapour of the preparation.

Avoid eating, drinking or smoking in area of product or during handling of product.

Avoid contamination of work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odour

Clear, colourless solution free from particulate matter with a mild amine odor.

Boiling Point

Not determined

Vapour Pressure

Not determined

Flash Point

Not determined

Solubility in Water

Aqueous solution

Melting Point

Not determined

Specific Gravity

1.00 - 1.05

Flammability Limits

Not determined

Other Properties

Not applicable

10. STABILITY AND REACTIVITY

Reactivity

Stable under normal conditions of use.

Conditions to avoid

Protect from light

Incompatibilities

None known

Hazardous decomposition products

None known

Hazardous polymerization

Will not occur

11. TOXICOLOGICAL INFORMATION

Toxicology summary

The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

Compound	Type	Rout	Specie	Result
Cloprostenol sodium	LD5	IV	Rat	>5 mg/kg
Cloprostenol sodium	LD5	SC	Rat	>5 mg/kg
Cloprostenol sodium	LD5	Oral	Rat	>310 mg/kg

Eye

No data available

Skin

No data available

Inhalation

No data available

Ingestion

See Acute toxicity table

Mutagenicity

R-cloprostenol, an enantiomer of cloprostenol, is not genotoxic.

Subchronic effects

Three month oral toxicity studies were performed in rats and marmosets. In rats, ovarian vasculization was seen at doses of 0.150 mg/kg/day. The same dose induced myocardial changes and a statistical increase in testicular weights in marmosets.

Chronic effects/ carcinogenicity

No data available

Carcinogen status

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Reproductive effects

In a three generation study carried out in rats, doses of up to 0.040 mg/kg did not induce effects on reproductive performance. The only effects seen were slight reduction in neonatal viability attributable to the prematurity of the offspring.

Teratogenicity	In a series of reproductive studies, it was shown that the sensitivity of the rat to termination of pregnancy resulting from luteolysis varies according to the point in pregnancy when the compound is administered. The dose of 0.025 mg/kg did not terminate pregnancy. <i>In vitro</i> studies using human luteal tissues have determined that cloprostenol may not be luteolytic in humans.
At increased risk from exposure	No teratogenic effects were seen in rats following oral administration or in rabbits following subcutaneous administration of cloprostenol.
Additional information	Women of child bearing age, asthmatics or other people with bronchial disease Cloprostenol has the potential to induce abortion or acute bronchostriction.

12. ECOLOGICAL INFORMATION

Environmental overview	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
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13. DISPOSAL CONSIDERATIONS

Disposal procedure	Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.
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14. TRANSPORT INFORMATION

General shipping instructions	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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15. REGULATORY INFORMATION

EU Classification	Toxic to Reproduction: Category 2
EU Labelling	T
GHS Label Pictogram(s)	



Risk phrases	R61 - May cause harm to the unborn child.
Safety phrases	S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - obtain special instructions before use.
Canadian WHMIS	Class D, Division 2, Subdivision A

16. OTHER INFORMATION

Issue date: 26 September 2018
Replaces MSDS dated: 11 May, 2016
Replaces MSDS dated: 11 February 2013
Replaces MSDS dated: 19 January, 2009

End of SDS