

SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A



Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: Cloprostenol Sodium Solutions

SYNONYM(S): ESTRUMATE
ESTRUMATE SPOLANA
ESTRUMATE/UNIANDINE
ESTRUMATE SOLUTION FOR INJECTION
ESTRUMATE S
PLANATE
PLANATE SPOLANA
PLANATE/SUIMATE

MSDS NUMBER: SP000065

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Solution
Colorless to clear blue
Odor unknown
May cause developmental effects.
May cause reproductive effects.
May cause effects to:
cardiovascular system
respiratory system
female reproductive system
fetus

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s). The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture.

Cloprostenol sodium is a synthetic analog of prostaglandin. Prostaglandin compounds act on smooth muscles to induce abortions, and may cause side effects such as nausea, vomiting, and diarrhea. Cloprostenol sodium stimulates smooth muscles (e.g. alimentary tract and cardiovascular systems) and may cause abortions in humans. Inhalation or skin absorption may cause bronchospasms characterized by difficulty in breathing. Cloprostenol sodium has also been reported to cause a change in intraocular (internal eye) fluid pressure.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Cloprostenol sodium	55028-72-3	0.01 - 0.03

ADDITIONAL INFORMATION:

This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

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Latest Revision Date: 27-Jun-2012

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SECTION 4. FIRST AID MEASURES

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:

Store in a cool, dry, well ventilated area. Store in dark container or away from light. Store away from heat source.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):

OEB 4: 1-10 mcg/m³. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):

Internal Occupational Exposure Limit of 1 - 10 mcg/m³ (8-hr TWA) for Cloprostenol sodium.

OEB/OEL NOTATION(S):

This material has a notation of "S" for its ability to cause systemic toxicity through skin absorption.

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Body Protection:	<p>In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p> <p>In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p>

EXPOSURE LIMIT VALUES

See Internal Occupational Exposure Limit listed above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Solution
COLOR:	Colorless to clear blue
ODOR:	Odor unknown
SPECIFIC GRAVITY:	~1.0
SOLUBILITY:	
Water:	Soluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:

Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:

Open flames and high temperatures. Strong acids and bases. Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

ORAL:

Cloprostenol: Oral LD50: >25 mg/kg (rats)

In an acute oral study in rats, no deaths were observed. Adverse signs of toxicity included increased respiratory rate and abdominal discomfort. Complete recovery was observed within 4.5 hours of dosing.

The oral no effect level in marmosets is 50 ug/kg and 10 ug/kg in hamsters.

ADDITIONAL INFORMATION:

Cloprostenol: LD50 Intravenous: 54.7 mg/kg (mouse)

REPEAT DOSE TOXICITY DATA**SUBCHRONIC / CHRONIC TOXICITY:**

Cloprostenol did not cause mortality in marmosets or rhesus monkeys given oral and subcutaneous dosages ranging from 5 to 150 ug/kg/day for 14 to 103 days. Animals exhibited subdued behavior during the first hour after dosing. Vomiting, excessive salivation and diarrhea were observed. Subcutaneous administration in the marmoset appeared to exacerbate myocardial fibrosis and chronic cardiac inflammation; however, this disease process is common in marmosets. Similar findings were not observed in the rhesus monkey or in rats.

Repeat oral, dermal, intravenous, subcutaneous, and intramuscular dose toxicity studies were conducted in rats. Dosages ranged from 1.22 to 5000 ug/kg for 15 days to 105 days. Vacuolation of the luteal cells in the female rat ovaries was observed in all studies. In a three month oral study the no effect levels for was 50 ug/kg.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Cloprostenol (0.025 to 320 ug/kg/day) was evaluated in rats and rabbits. Premature delivery associated with impaired neonatal survival was observed. No teratogenic effects were evident. Dosages of 80 ug/kg/day and higher in rats caused termination of pregnancy. This effect was not seen at dosages of 30 to 50 ug/kg/day; however, induction of premature expulsion of uterine contents during late gestation was observed. In a multi-generation study in rats, no adverse effects were noted in rats given 15 mg/kg/day for eleven months. A dosage of 40 ug/kg/day resulted in premature expulsion of the uterine content, shortening of pregnancy, and decreased pup survival. In hamsters, oral administration of 60 ug/kg/day caused fertility changes in females. Intramuscular doses of 2400 ng/kg in female pigs reduced weight gain and viability in newborns. No adverse reactions or side effects were observed in pregnant swine given the recommended therapeutic dose of 175 ug.

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION**ECOTOXICITY DATA**

There are no ecotoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this material.

SECTION 13. DISPOSAL CONSIDERATIONS**MATERIAL WASTE:**

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:

Do not allow product to reach ground water, water courses, sewage or drainage systems.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION**TSCA LISTING**

This material or product is not subject to TSCA requirements.

U.S. STATE REGULATIONS

Check state requirements for ingredient listing.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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DEPARTMENT ISSUING MSDS:

Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:

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1, 8

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New regional format