SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cloprostenol (with Propylene Glycol) Formulation

Manufacturer or supplier's details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</td>
<td>55028-72-3</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur. 
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
None known.

Protection of first-aiders
No special precautions are necessary for first aid responders.

Notes to physician
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media
None known.

Specific hazards during firefighting
Exposure to combustion products may be a hazard to health.

Hazardous combustion products
Carbon oxides

Specific extinguishing methods
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters
- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items...
employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types: Strong oxidizing agents.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [1α(Z),2β(1E,3R*)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</td>
<td>55028-72-3</td>
<td>TWA</td>
<td>0.01 ug/m3 (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: RSEN, Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 ug/100 cm2</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- No open handling permitted.
- Totally enclosed processes and materials transport systems are required.
- Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

Respiratory protection:
- If adequate local exhaust ventilation is not available or
exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type
: Particulates type

Hand protection

Material
: Chemical-resistant gloves

Remarks
: Consider double gloving.

Eye protection
: Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
: Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
: Aqueous solution

Color
: colorless

Odor
: characteristic

Odor Threshold
: No data available

pH
: No data available

Melting point/freezing point
: -6 °C

Initial boiling point and boiling range
: 99 °C

Flash point
: No data available

Evaporation rate
: No data available

Flammability (solid, gas)
: Not applicable
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Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: 1.02 - 1.08
Density: No data available
Solubility(ies)
  Water solubility: soluble
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
 Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: 1.56 - 1.62 mm²/s
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
  Inhalation
  Skin contact
  Ingestion
SAFETY DATA SHEET

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Eye contact

Acute toxicity
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Acute oral toxicity
LD50 (Mouse): 600 mg/kg
Acute inhalation toxicity
LC50 (Rat): > 2,871 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity
LD50 (Rat): > 5.000 mg/kg

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Acute oral toxicity
LD50 (Rat): > 25 mg/kg
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration)
LD50 (Rat): > 50 mg/kg
Application Route: Subcutaneous
LD50 (Rat): > 50 mg/kg
Application Route: Intramuscular
LD50 (Rat): 5 mg/kg
Application Route: Intravenous
Remarks: No mortality observed at this dose.
LD50 (Mouse): 350 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 54,7 mg/kg
Application Route: Intravenous
TDL0 (Monkey): 0,0025 - 0,025 mg/kg
Application Route: Intramuscular
Target Organs: Lungs
Symptoms: Diarrhea, Vomiting, Rapid respiration
TDL0 (Monkey): 0,0013 mg/kg
Application Route: Intramuscular
Target Organs: ovaries

Skin corrosion/irritation
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Species: Rabbit
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Cloprostenol (with Propylene Glycol) Formula-

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Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Remarks: Not classified due to lack of data. Can be absorbed through skin.

Serious eye damage/eye irritation
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Remarks: Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Assessment: Probability or evidence of low to moderate skin sensitization rate in humans

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Result: Sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Genotoxicity in vitro:  
- Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
  Test system: mouse lymphoma cells  
  Result: negative
- Test Type: Chromosomal aberration  
  Test system: Human lymphocytes  
  Result: equivocal

Genotoxicity in vivo:  
- Test Type: Micronucleus test  
  Species: Mouse  
  Cell type: Bone marrow  
  Application Route: Intraperitoneal  
  Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Remarks: Not classified due to lack of data.

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**4-Chloro-3-methylphenol:**

Effects on fertility:  
- Test Type: One-generation reproduction toxicity study  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative

Effects on fetal development:  
- Test Type: Reproduction/Developmental toxicity screening test  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Effects on fertility:  
- Test Type: Three-generation study  
  Species: Rat  
  Application Route: Oral
General Toxicity F1: NOAEL: 0.015 mg/kg body weight  
Fertility: NOAEL: > 0.04 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.  
Species: Cattle  
Application Route: Intramuscular  
General Toxicity Parent: LOAEL: 0.16 µg/kg  
Result: positive  
Remarks: Abortion  

Effects on fetal development  
Test Type: Development  
Species: Rabbit  
Application Route: Subcutaneous  
Teratogenicity: NOAEL: 0.250 µg/kg  
Result: No teratogenic effects.  
Test Type: Development  
Species: Rat  
Application Route: Oral  
Teratogenicity: NOAEL: 100 µg/kg  
Result: No teratogenic effects.  

Reproductive toxicity - Assessment  
May damage fertility.  

**STOT-single exposure**  
Not classified based on available information.  

**Components:**  

**4-Chloro-3-methylphenol:**  
Assessment  
May cause respiratory irritation.  

**Sodium [1α(Z),2β(1E,3R*),3α,5α](+/-)-7-[2-[(4-(3-chlorophenoxy)-3-hydroxybut-1-ENYL)-3,5-dihydroxycyclopentyl]hept-5-enoate:**  
Target Organs  
Lungs  
Assessment  
Causes damage to organs.  

**STOT-repeated exposure**  
Not classified based on available information.  

**Components:**  

**Sodium [1α(Z),2β(1E,3R*),3α,5α](+/-)-7-[2-[(4-(3-chlorophenoxy)-3-hydroxybut-1-ENYL)-3,5-dihydroxycyclopentyl]hept-5-enoate:**  
Target Organs  
Ovary  
Assessment  
Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**4-Chloro-3-methylphenol:**

- **Species:** Rat
- **NOAEL:** 200 mg/kg
- **LOAEL:** 400 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

- **Species:** Rat
- **NOAEL:** 0,05 mg/kg
- **LOAEL:** 0,15 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Ovary

- **Species:** Rat
- **NOAEL:** 0,0125 mg/kg
- **LOAEL:** 0,0125 mg/kg
- **Application Route:** Subcutaneous
- **Exposure time:** 30 Days
- **Target Organs:** Ovary

- **Species:** Monkey
- **NOAEL:** 0,05 mg/kg
- **LOAEL:** 0,15 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Heart, Testis

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Not applicable

**Experience with human exposure**

**Components:**

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

- **General Information:** Target Organs: Uterus (including cervix)
  - Symptoms: Embryo-fetal toxicity, Fetal mortality, menstrual irregularities, miscarriage
  - Target Organs: Lungs
Inhalation
Symptoms: Asthma, bronchospasm
Target Organs: Lungs
Remarks: May cause sensitization of susceptible persons by inhalation of aerosol or dust.
Target Organs: Uterus (including cervix)
Symptoms: Embryolethal effects, menstrual irregularities

Skin contact
Symptoms: Bronchospasm
Remarks: Can be absorbed through skin.
Target Organs: Uterus (including cervix)
Symptoms: Embryolethal effects.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
4-Chloro-3-methylphenol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Chlorella pyrenoidosa): 15 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Chlorella pyrenoidosa): 2,3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 0,15 mg/l
Exposure time: 28 d
Method: OECD Test Guideline 204

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0,32 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50: 22,86 mg/l
Exposure time: 60 h

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
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Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

Components:

4-Chloro-3-methylphenol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 78 %
Exposure time: 15 d
Method: OECD Test Guideline 301

Bioaccumulative potential

Components:

4-Chloro-3-methylphenol:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5,5 - 13

Partition coefficient: n-octanol/water: log Pow: 0,477

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-
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Date of last issue: 28.01.2020
Date of first issue: 14.11.2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

AR / Z8