SAFETY DATA SHEET

Cloprostenol (with Propylene Glycol) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cloprostenol (with Propylene Glycol) Formulation

Manufacturer or supplier's details
Company name of supplier : MSD
Address : 2000 Galloping Hill Road
           Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATATESTEWARD@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
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>Sodium [1α(Z),2β(1E,3R*),3α,5α-(-/+)7-[2-{4-(3-chlorophenoxy)-3-hydroxybut-1-etyl]-3,5-dihydroxypropyl}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 fire fighting: 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 spills 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.
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Technical measures
See Engineering measures under EXPOSURE CONTROLS/PERSONAL 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.

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.

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>Wipe limit</td>
<td>0.1 ug/100 cm²</td>
<td>Internal</td>
<td></td>
<td></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: 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Color</td>
<td>colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>-6 °C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>99 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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<td>14.11.2019</td>
</tr>
</tbody>
</table>

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
Eye contact
Acute 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:**

**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

  - 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

- TDLo (Monkey): 0.0025 - 0.025 mg/kg
  - Application Route: Intramuscular
  - Target Organs: Lungs
  - Symptoms: Diarrhea, Vomiting, Rapid respiration

- TDLo (Monkey): 0.0013 mg/kg
  - Application Route: Intramuscular
  - Target Organs: ovaries

**Skin corrosion/irritation**
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.
- Can be absorbed through skin.

**Serious eye damage/eye irritation**
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.
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Sodium \([\text{1α}(Z),2\beta(1\text{E},3\text{R}^*),3\alpha,5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:\)
Result : Sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

Sodium \([\text{1α}(Z),2\beta(1\text{E},3\text{R}^*),3\alpha,5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:\)

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 \([\text{1α}(Z),2\beta(1\text{E},3\text{R}^*),3\alpha,5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:\)
Remarks : Not classified due to lack of data.

Reproductive toxicity
Not classified based on available information.

Components:

Sodium \([\text{1α}(Z),2\beta(1\text{E},3\text{R}^*),3\alpha,5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:\)
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:**

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:

Sodium \([1\alpha(Z),2\beta(1E,3R^\ast),3\alpha,5\alpha]-\langle+/\rangle-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.05 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Ovary</td>
</tr>
</tbody>
</table>

Species : Rat
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 \([1\alpha(Z),2\beta(1E,3R^\ast),3\alpha,5\alpha]-\langle+/\rangle-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

Not applicable

Experience with human exposure

Components:

Sodium \([1\alpha(Z),2\beta(1E,3R^\ast),3\alpha,5\alpha]-\langle+/\rangle-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
Symptoms: Asthma, bronchospasm

Inhalation : Target Organs: Lungs
Symptoms: bronchospasm, Asthma
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 : Target Organs: Lungs
Symptoms: bronchospasm
Remarks: Can be absorbed through skin.
Target Organs: Uterus (including cervix)
Symptoms: Embryolethal effects.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
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
Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability
No data available

Bioaccumulative potential
No data available

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.
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Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIIC - 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 Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
# SAFETY DATA SHEET

**Cloprostenol (with Propylene Glycol) Formula-**

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<tr>
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</tbody>
</table>

1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 10.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8