SAFETY DATA SHEET
Cloprostenol Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cloprostenol Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

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.

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>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</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; 0.3</td>
</tr>
</tbody>
</table>

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.
### 5. FIREFIGHTING 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 firefighters | Wear self-contained breathing apparatus for firefighting if necessary.  
|                             | Use personal protective equipment. |  

### 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : Use only with adequate ventilation.
Advice on safe handling: 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 labelled containers. Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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*),3α,5α]-(+/-)-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>Wipe limit</td>
<td>0.1 ug/100 cm2</td>
<td>Internal</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.
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Filter type: Organic vapour type
Hand protection: Chemical-resistant gloves
Material: Consider double gloving.
Remarks: Wear safety glasses with side shields or goggles.
Eye protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution
Colour: clear
Odour: No data available
Odour Threshold: No data available
pH: 5.6 - 6.1 (20 - 25 °C)
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper: No data available
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flammability limit

Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 1
Density : No data available
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.
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## Cloprostenol Formulation

<table>
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<td>2014/10/24</td>
</tr>
</tbody>
</table>

### Product:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Acute toxicity estimate/Exposure time/Test atmosphere/Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 2,000 mg/kg/Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 5 mg/l/4 h/dust/mist/Calculation method</td>
</tr>
</tbody>
</table>

### Components:

#### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>LD50 (Rat): 1,620 mg/kg/Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>LD50 (Rat): &gt; 25 mg/kg/Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): &gt; 50 mg/kg/Calculation method</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 50 mg/kg/Calculation method</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 5 mg/kg/Calculation method</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>LD50 (Mouse): 350 mg/kg</td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td>LD50 (Mouse): 54.7 mg/kg</td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>TDL0 (Monkey): 0.0025 - 0.025 mg/kg</td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td>Target Organs: Lungs</td>
<td>Symptoms: Diarrhoea, Vomiting, Rapid respiration</td>
</tr>
<tr>
<td>TDL0 (Monkey): 0.0013 mg/kg</td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td>Target Organs: ovaries</td>
<td></td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation

Not classified based on available information.
Components:

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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:

Benzyl alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
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:
Result: Sensitiser

Germ cell mutagenicity
Not classified based on available information.
Components:

Benzyl alcohol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
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:

Benzyl alcohol:
Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
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:
Remarks : Not classified due to lack of data.

Reproductive toxicity
Not classified based on available information.

Components:

Benzyl alcohol:
Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

Sodium \([1\alpha(Z),2\beta(1E,3R^*)-\{\pm\}]-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 foetal 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 \([1\alpha(Z),2\beta(1E,3R^*)-\{\pm\}]-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 \([1\alpha(Z),2\beta(1E,3R^*),3\alpha,5\alpha]-(+/-)-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:
Benzy alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Sodium \([1\alpha(Z),2\beta(1E,3R^*),3\alpha,5\alpha]-(+/-)-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: 0.15 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^*),3\alpha,5\alpha]-(+/-)-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^*),3\alpha,5\alpha]-(+/-)-7-[2-(4-(3-chlorophenoxy)-3-hydroxybut-1-enyl)-3,5-dihydroxycyclopentyl]hept-5-enoate:\n
**General Information:**
- Target Organs: Uterus (including cervix)
- Symptoms: Embryo-foetal toxicity, foetal mortality, menstrual irregularities, miscarriage
- Target Organs: Lungs
- Symptoms: Asthma, bronchospasm

**Inhalation:**
- Target Organs: Lungs
- Symptoms: bronchospasm, Asthma
- Remarks: May cause sensitisation 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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Benzyl alcohol:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants:** EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Sodium \([1\alpha(Z),2\beta(1E,3R^*),3\alpha,5\alpha]-(+/-)-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**

**Components:**

**Benzyl alcohol:**

Biodegradability: Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

**Bioaccumulative potential**

**Components:**

**Benzyl alcohol:**

Partition coefficient: \(n\)-octanol/water: log Pow: 1.05

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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.

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.
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AIC - 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
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.

ID / EN