SAFETY DATA SHEET

Cloprostenol Formulation

Version 3.0  Revision Date: 2020/02/13  SDS Number: 25300-00013  Date of last issue: 2019/09/13  Date of first issue: 2014/10/24

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Cloprostenol Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td>sodium [1α(Z),2β(1E,3R*)]-7-[2-(3-chlorophenoxy)-3-hydroxybut-1-etyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</td>
<td>55028-72-3</td>
<td>&lt; 0.1</td>
<td></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.
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If swallowed
Get medical attention if irritation develops and persists.
If swallowed, DO NOT induce vomiting.

Most important symptoms and effects, both acute and delayed
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

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

Notes to physician
Treat symptomatically and supportively.

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 and personal protective equipment recommendations.

Environmental precautions
Discharge into the environment must be avoided.
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

Handling
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.
Avoidance of contact: Oxidizing agents
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.

Storage
Conditions for safe storage: Keep in properly labelled containers.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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-chlorophenoxo)-3-hydroxybut-1-eryl}-3,5-dihydroxycyclopentyl]hept-5-encate</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>Wipe limit 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: Organic vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Aqueous solution

Colour: clear

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reac-</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>tions</td>
<td></td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>
## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure
- Inhalation
- Skin contact
- Ingestion
- Eye contact

### Acute toxicity

Not classified based on available information.

#### Product:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute toxicity estimate:</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 5 mg/l</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

#### Components:

**Benzyl alcohol:**
- Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l

**sodium \[1\alpha(Z),2\beta(1E,3R^*)\]-[+/-]-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
  - TDLo (Monkey): 0.0025 - 0.025 mg/kg
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Application Route: Intramuscular
Target Organs: Lungs
Symptoms: Diarrhoea, 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:

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

Benzy 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 [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 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:

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

- **Target Organs**: Lungs
- **Assessment**: Causes damage to organs.

**STOT - repeated exposure**

Not classified based on available information.

Components:

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

- **Target Organs**: Ovary
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

Components:

**Benzyl alcohol**:

- **Species**: Rat
- **NOAEL**: 1.072 mg/l
- **Application Route**: inhalation (dust/mist/fume)
- **Exposure time**: 28 Days
- **Method**: OECD Test Guideline 412

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

- **Species**: Rat
- **NOAEL**: 0.05 mg/kg
- **LOAEL**: 0.15 mg/kg
- **Application Route**: Oral
- **Exposure time**: 3 Months
- **Target Organs**: Ovary

- **Species**: Rat
- **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.
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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: Embryofoetal 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
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

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
  - Hazardous to the ozone layer: Not applicable
  - 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
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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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable
Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance (Category Z)

Marine Pollution and Sea Disaster Prevention etc Law
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
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.

JP / EN