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.
If swallowed: Get medical attention if irritation develops and persists. 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.

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

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>
</tbody>
</table>

Further information: RSEN, Skin

Wipe limit 0.1 ug/100 cm2 Internal

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:

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.

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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Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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: Diarrhoea, 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:

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

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:
- 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
- Method: OECD Test Guideline 405
- Result: Irritation to eyes, reversing within 21 days

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:
- 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-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
- Result: Sensitiser

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

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol:</td>
</tr>
<tr>
<td><strong>Genotoxicity in vitro</strong></td>
</tr>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Result: negative</td>
</tr>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
</tr>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)&lt;br&gt;Species: Mouse&lt;br&gt;Application Route: Intraperitoneal injection&lt;br&gt;Result: negative</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>
</tr>
<tr>
<td><strong>Genotoxicity in vitro</strong></td>
</tr>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Result: negative</td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test&lt;br&gt;Test system: mouse lymphoma cells&lt;br&gt;Result: negative</td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration&lt;br&gt;Test system: Human lymphocytes&lt;br&gt;Result: equivocal</td>
</tr>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
</tr>
<tr>
<td>Test Type: Micronucleus test&lt;br&gt;Species: Mouse&lt;br&gt;Cell type: Bone marrow&lt;br&gt;Application Route: Intraperitoneal&lt;br&gt;Result: negative</td>
</tr>
</tbody>
</table>

Carcinogenicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol:</td>
</tr>
<tr>
<td><strong>Species</strong></td>
</tr>
<tr>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
</tr>
<tr>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td>103 weeks</td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td>OECD Test Guideline 451</td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
<tr>
<td>negative</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>
</tr>
<tr>
<td><strong>Remarks</strong></td>
</tr>
<tr>
<td>Not classified due to lack of data.</td>
</tr>
</tbody>
</table>

Reproductive toxicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol:</td>
</tr>
</tbody>
</table>
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 fetal 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 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:

Benzy1 alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

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
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-etyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

General Information:
- Target Organs: Uterus (including cervix)
- Symptoms: Embryo-fetal 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 [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

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.
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Date of first issue: 2014/10/24

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations


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