

Cloprostenol Formulation

Version 3.8 Revision Date: 08.12.2023 SDS Number: 25279-00021 Date of last issue: 30.11.2023
 Date of first issue: 24.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cloprostenol Formulation
 Other means of identification : ESTRUMATE® (A002698)
 ESTRUMATE SYNTHETIC PROSTAGLANDIN FOR CATTLE
 AND HORSES (36076)

Manufacturer or supplier's details

Company : MSD
 Address : Rua Coronel Bento Soares, 530
 Cruzeiro - Sao Paulo - Brazil CEP 12730-340
 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
 Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6	Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Eye irritation, Category 2A	>= 1 -< 5
Sodium	55028-72-3	Respiratory sensitiza-	< 0,1

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<p>[1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</p>		<p>tion, Category 1 Reproductive toxicity, Category 1B Specific target organ toxicity - single exposure (Lungs), Category 1 Specific target organ toxicity - repeated exposure (Ovary), Category 1</p>	
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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 (CO ₂) 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

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- 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/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.
- 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
Gases

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

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Color : clear

Odor : No data available

Odor 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 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

Density : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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

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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.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
 Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 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 [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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

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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:**Benzyl alcohol:**

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

Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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 [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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.

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Respiratory sensitization

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

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

Result	: Sensitizer
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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 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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.

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Components:**Benzyl alcohol:**

Species : Mouse
 Application Route : Ingestion
 Exposure time : 103 weeks
 Method : OECD Test Guideline 451
 Result : negative

Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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 fetal development : Test Type: Embryo-fetal development
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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 μ g/kg
 Result: positive
 Remarks: Abortion

Effects on fetal development : Test Type: Development
 Species: Rabbit
 Application Route: Subcutaneous
 Teratogenicity: NOAEL: 0,250 μ g/kg
 Result: No teratogenic effects.

Test Type: Development
 Species: Rat

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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:****Benzyl 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

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

Not applicable

Experience with human exposure**Components:****Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-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: Embryo-lethal effects., menstrual irregularities
Skin contact	:	Target Organs: Lungs Symptoms: bronchospasm Remarks: Can be absorbed through skin. Target Organs: Uterus (including cervix) Symptoms: Embryo-lethal effects.

SECTION 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	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770

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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.

Domestic regulation

ANTT

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : 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

Revision Date : 08.12.2023
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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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); EC_x - Concentration associated with x% response; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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 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; TECI - Thailand Existing Chemicals Inventory; 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

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.

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