SAFETY DATA SHEET

Cloprostenol (with Propylene Glycol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	5266462-00011	Date of first issue: 14.11.2019

Section 1: Identification

Product identifier : Cloprostenol (with Propylene Glycol) Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive
Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Not a hazardous substance or mixture.

GHS Label elements, including precautionary statements

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.	Concentration (% w/w)
4-Chloro-3-methylphenol	59-50-7	>= 0.1 -< 0.25
Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate	55028-72-3	< 0.1

Section 4: First-aid measures

Description of necessary 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

Risks	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.

Indication of any immediate medical attention and special treatment needed

Treatment	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides

Special protective actions for fire-fighters

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

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

Methods for 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.

Section 7: Handling and storage

Precautions for safe handling

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, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
4-Chloro-3-methylphenol	59-50-7	TWA	200 µg/m3 (OEB 2)	Internal
		Wipe limit	100 µg/100 cm2	Internal
Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate	55028-72-3	TWA	0.01 ug/m3 (OEB 5)	Internal
	Further information: RSEN, Skin			
		Wipe limit	0.1 ug/100 cm2	Internal

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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 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.
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		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.

Section 9: Physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	colourless
Odour	:	characteristic
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	-6 °C
Initial boiling point and boiling range	:	99 °C
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
Vapour pressure	:	No data available

Relative vapour 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
Auto-ignition 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 characteristics		
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:

4-Chloro-3-methylphenol:

Acute oral toxicity	:	LD50 (Mouse): 600 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 2.871 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rat): > 5,000 mg/kg

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 TDLo (Monkey): 0.0025 - 0.025 mg/kg 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:

4-Chloro-3-methylphenol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	Corrosive after 1 to 4 hours of exposure

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:

4-Chloro-3-methylphenol:

Species : Rabbit
Result : Irreversible effects on the eye
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:

4-Chloro-3-methylphenol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

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:

4-Chloro-3-methylphenol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
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:

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:

4-Chloro-3-methylphenol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
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:

4-Chloro-3-methylphenol:

Assessment	:	May cause respiratory irritation.

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:

4-Chloro-3-methylphenol:

Species	:	Rat
NOAEL	:	200 mg/kg
LOAEL	:	400 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days

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

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

Section 12: Ecological information

Toxicity

Components:

4-Chloro-3-methylphenol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1.5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.32 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 22.86 mg/l
Exposure time: 60 h

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:

4-Chloro-3-methylphenol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 78 %
Exposure time: 15 d
Method: OECD Test Guideline 301

Bioaccumulative potential

Components:

4-Chloro-3-methylphenol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5.5 - 13

Partition coefficient: n-octanol/water : log Pow: 0.477

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	:	Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations	:	Not applicable

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

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

Section 16: Other information

Revision Date	:	28.09.2024

Further information

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

Full text of other abbreviations

AIIC - 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 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tem-

perature; 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.

SG / EN