SECTION 1. IDENTIFICATION

Product name: Cloprostenol (with Propylene Glycol) Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.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 the Hazardous Products Regulations
Not a hazardous substance or mixture.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>12.9518</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>No data available</td>
<td>55028-72-3</td>
<td>0.0229</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cloprostenol (with Propylene Glycol) Formulation

Version 2.8  Revision Date: 09/30/2023  SDS Number: 5266431-00010  Date of last issue: 04/04/2023
Date of first issue: 11/14/2019

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 (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 fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 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 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 : 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.
Conditions for safe storage : Keep in properly labeled containers.
Materials to avoid : Do not store with the following product types: Strong oxidizing agents Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Sodium [(α(Z),β(E,3R*),3α,5α)-(+-/-)-7-[2-{4-(3-chlorophenoxy)-3-hydroxybut-1-eryl}-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: Particulates 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: Aqueous solution

Color: colorless

Odor: characteristic
**Odor 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

**Vapor pressure**: No data available

**Relative vapor 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

**Autoignition 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 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:

Propylene glycol:
Acute oral toxicity: LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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: 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:**

**Propylene glycol:**
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:**

**Propylene glycol:**
Species: Rabbit
Result: No eye irritation
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 sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

Propylene glycol:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- 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: Sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
  - Test Type: Chromosome aberration test in vitro
    - Method: OECD Test Guideline 473
    - 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
Carcinogenicity
Not classified based on available information.

Components:

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
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:
Remarks: Not classified due to lack of data.

Reproductive toxicity
Not classified based on available information.

Components:

Propylene glycol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
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:
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
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cloprostenol (with Propylene Glycol) Formulation

Version 2.8  Revision Date: 09/30/2023  SDS Number: 5266431-00010  Date of last issue: 04/04/2023  Date of first issue: 11/14/2019

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:

Propylene glycol:
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y

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
Cloprostenol (with Propylene Glycol) Formulation

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-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: 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

Ecotoxicity

Components:

Propylene glycol:
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
- Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 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:

Propylene glycol:
- Biodegradability: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Propylene glycol:
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
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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
## SAFETY DATA SHEET
according to the Hazardous Products Regulations

### Cloprostenol (with Propylene Glycol) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.8</td>
<td>09/30/2023</td>
<td>5266431-00010</td>
<td>04/04/2023</td>
<td>11/14/2019</td>
</tr>
</tbody>
</table>

CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.

CA ON OEL / TWA : Time-Weighted Average Limit (TWA)

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); 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; IECCSC - Inventory of Existing Chemicals 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


Revision Date : 09/30/2023

Date format : mm/dd/yyyy

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.
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cloprostenol (with Propylene Glycol) Formulation

Version  2.8  Revision Date:  09/30/2023  SDS Number:  5266431-00010  Date of last issue:  04/04/2023
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CA / Z8