

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Cloprostenol Formulation

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

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions : Not applicable
on use

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Precautionary statements :

Prevention:

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 Acute toxicity estimate Acute oral toxicity: 1.200 mg/kg	>= 1 - < 10
Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-	55028-72-3 259-439-3	Resp. Sens. 1; H334	< 0,1

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate	Repr. 1B; H360F STOT SE 1; H370 (Lungs) STOT RE 1; H372 (Ovary)
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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- | | |
|----------------------------|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| If inhaled | : If inhaled, remove to fresh air.
Get medical attention if symptoms occur. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse. |
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | |
|-------|--|
| Risks | : May cause an allergic skin reaction. |
|-------|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | |
|-----------|---|
| Treatment | : Treat symptomatically and supportively. |
|-----------|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | |
|------------------------------|---|
| Suitable extinguishing media | : Water spray
Alcohol-resistant foam |
|------------------------------|---|

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. 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

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 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.

6.3 Methods and material 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 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 | : | Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Avoid contact with eyes.
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. Contaminated work clothing should not be allowed out of the workplace.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version 6.1 Revision Date: 14.04.2025 SDS Number: 25305-00028 Date of last issue: 03.12.2024
Date of first issue: 24.10.2014

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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/m3 (OEB 5)	Internal
Further information: RSEN, Skin				
		Wipe limit	0.1 ug/100 cm2	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg

8.2 Exposure controls

Engineering measures

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostamol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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

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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	:	Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	Aqueous solution
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

range

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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 5,6 - 6,1 (20 - 25 °C)

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : 1

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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: > 2.000 mg/kg
Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

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:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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 sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
Result	: positive

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

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 : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl alcohol:

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Sodium [1 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: equivocal

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Intraperitoneal
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Benzyl alcohol:

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

Sodium [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 foetal development : Test Type: Embryo-foetal 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Method : OECD Test Guideline 412

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:

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 [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

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Experience with human exposure

Components:

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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: 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

12.1 Toxicity

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: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

12.3 Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H302	:	Harmful if swallowed.
H317	:	May cause an allergic skin reaction.
H319	:	Causes serious eye irritation.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360F	:	May damage fertility.
H370	:	Causes damage to organs.
H372	:	Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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;

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cloprostenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
6.1	14.04.2025	25305-00028	Date of first issue: 24.10.2014

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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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/>

Classification of the mixture:

Skin Sens. 1

H317

Classification procedure:

Calculation method

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.

NO / EN