# SAFETY DATA SHEET

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

# Cloprostenol (with Propylene Glycol) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 6.1 | 28.09.2024 | 5306572-00013 | Date of first issue: 14.11.2019 |

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

### 1.1 Product identifier

Trade name : Cloprostenol (with Propylene Glycol) Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

### 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)**

Not a hazardous substance or mixture.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

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

**Additional Labelling**

EUH210 Safety data sheet available on request.

EUH208 Contains 4-Chloro-3-methylphenol. May produce an allergic reaction.

### 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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| 4-Chloro-3-methylphenol | 59-50-7<br>200-431-6<br>604-014-00-3 | Acute Tox. 4; H302<br>Skin Corr. 1C; H314<br>Eye Dam. 1; H318<br>Skin Sens. 1B; H317<br>STOT SE 3; H335<br>Aquatic Acute 1; H400<br>Aquatic Chronic 3; H412<br>M-Factor (Acute aquatic toxicity): 1<br>Acute toxicity estimate<br>Acute oral toxicity: 600 mg/kg | >= 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<br>259-439-3 | Resp. Sens. 1; H334<br>Repr. 1B; H360F<br>STOT SE 1; H370 (Lungs)<br>STOT RE 1; H372 (Ovary) | < 0.1 |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

| | | |
|---|---|---|
| Protection of first-aiders | : | No special precautions are necessary for first aid responders. |
| If inhaled | : | If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur. |
| In case of skin contact | : | Wash with water and soap as a precaution.<br>Get medical attention if symptoms occur. |
| In case of eye contact | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water. |

### 4.2 Most important symptoms and effects, both acute and delayed

| | | |
|---|---|---|
| Risks | : | May produce an allergic 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |

### 5.2 Special hazards arising from the substance or mixture

| | | |
|---|---|---|
| Specific hazards during firefighting | : | 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 | : | 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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

| | | |
|---|---|---|
| Personal precautions | : | 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.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 | : | Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- |

sessment
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.

### 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**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Propylene glycol | 57-55-6 | OELV - 8 hrs (TWA) (particles) | 10 mg/m3 | IE OEL |
| | | OELV - 8 hrs (TWA) (total (vapour and particles)) | 150 ppm<br>470 mg/m3 | IE OEL |
| 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 |

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

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| Propylene glycol | Workers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Workers | Inhalation | Long-term systemic effects | 168 mg/m3 |
| | Consumers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Consumers | Inhalation | Long-term systemic effects | 50 mg/m3 |
| 4-Chloro-3-methylphenol | Workers | Inhalation | Long-term systemic effects | 6.289 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 3.567 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1.551 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 1.783 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0.892 mg/kg bw/day |

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

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Propylene glycol | Fresh water | 260 mg/l |
| | Freshwater - intermittent | 183 mg/l |
| | Marine water | 26 mg/l |
| | Sewage treatment plant | 20000 mg/l |
| | Fresh water sediment | 572 mg/kg dry weight (d.w.) |
| | Marine sediment | 57.2 mg/kg dry weight (d.w.) |
| | Soil | 50 mg/kg dry weight (d.w.) |
| 4-Chloro-3-methylphenol | Fresh water | 0.015 mg/l |
| | Intermittent use/release | 0.015 mg/l |
| | Marine water | 0.002 mg/l |
| | Sewage treatment plant | 2.286 mg/l |
| | Fresh water sediment | 13.981 mg/kg dry weight (d.w.) |
| | Marine sediment | 13.981 mg/kg dry weight (d.w.) |
| | Soil | 6.399 mg/kg dry weight (d.w.) |

### 8.2 Exposure controls

**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**

| | | |
|---|---|---|
| Eye/face protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>Equipment should conform to I.S. EN 143 |
| Filter type | : | Particulates type (P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | Aqueous solution |
| Colour | : | colourless |
| Odour | : | characteristic |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | -6 °C |
| Initial boiling point and boiling range | : | 99 °C |

| | | |
|---|---|---|
| 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 | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | 1.56 - 1.62 mm2/s |
| Solubility(ies) | | |
| Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | 1.02 - 1.08 |
| 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 |

## 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.

**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 : LD50 (Rat): > 50 mg/kg

administration)

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.<br>Can be absorbed through skin. |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**4-Chloro-3-methylphenol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irreversible effects on the eye |

**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

### 11.2 Information on other hazards

**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. |

**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)<br>Symptoms: Embryo-foetal toxicity, foetal mortality, menstrual irregularities, miscarriage<br>Target Organs: Lungs<br>Symptoms: Asthma, bronchospasm |
| Inhalation | : | Target Organs: Lungs<br>Symptoms: bronchospasm, Asthma<br>Remarks: May cause sensitisation of susceptible persons by |

| | | |
|---|---|---|
| | | inhalation of aerosol or dust.<br>Target Organs: Uterus (including cervix)<br>Symptoms: Embryolethal effects, menstrual irregularities |
| Skin contact | : | Target Organs: Lungs<br>Symptoms: bronchospasm<br>Remarks: Can be absorbed through skin.<br>Target Organs: Uterus (including cervix)<br>Symptoms: Embryolethal effects |

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**4-Chloro-3-methylphenol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1.5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| Toxicity to microorganisms | : | EC50 : 22.86 mg/l<br>Exposure time: 60 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0.32 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

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

**Ecotoxicology Assessment**

| | | |
|---|---|---|
| Acute aquatic toxicity | : | Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : | Toxic effects cannot be excluded |

### 12.2 Persistence and degradability

**Components:**

**4-Chloro-3-methylphenol:**

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

### 12.3 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

### 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

## 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.

| | | |
|---|---|---|
| Contaminated packaging | : | Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer.<br>Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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 |
| **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 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

Regulation (EC) 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

REACH - List of substances subject to authorisation (Annex XIV) : 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

**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. |

**Full text of H-Statements**

| | | |
|---|---|---|
| H302 | : | Harmful if swallowed. |
| H314 | : | Causes severe skin burns and eye damage. |
| H317 | : | May cause an allergic skin reaction. |
| H318 | : | Causes serious eye damage. |
| H334 | : | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | : | May cause respiratory irritation. |
| H360F | : | May damage fertility. |
| H370 | : | Causes damage to organs. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H400 | : | Very toxic to aquatic life. |
| H412 | : | Harmful to aquatic life with long lasting effects. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Dam. | : | Serious eye damage |
| Repr. | : | Reproductive toxicity |
| Resp. Sens. | : | Respiratory sensitisation |
| Skin Corr. | : | Skin corrosion |
| Skin Sens. | : | Skin sensitisation |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| STOT SE | : | Specific target organ toxicity - single exposure |
| IE OEL | : | Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |
| IE OEL / OELV - 8 hrs (TWA) | : | Occupational exposure limit value (8-hour reference period) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 La-

boratory 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; 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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/ |

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.

IE / EN