

SAFETY DATA SHEET



Cloprostenol (with Propylene Glycol) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5266452-00012 Date of last issue: 04.12.2024
Date of first issue: 14.11.2019

SECTION 1. IDENTIFICATION

Product identifier : Cloprostenol (with Propylene Glycol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

GHS label elements in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
4-Chloro-3-methylphenol	59-50-7	Acute Tox. (Oral), 4 Skin Corr., 1C Eye Dam., 1 Skin Sens., 1B STOT SE, 3 Aquatic Acute, 1 Aquatic Chronic, 3	>= 0,1 - < 0,25
Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-	55028-72-3	Resp. Sens., 1 Repr., 1B STOT SE, (Lungs) , 1 STOT RE, (Ovary) , 1	< 0,1

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[dihydroxycyclopentyl]hept-5-enoate

SECTION 4. FIRST AID MEASURES

If inhaled	: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types: Strong oxidizing agents Gases

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
4-Chloro-3-methylphenol	59-50-7	TWA	200 µg/m ³ (OEB 2)	Internal
		Wipe limit	100 µg/100 cm ²	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 µg/m ³ (OEB 5)	Internal
Further information: RSEN, Skin				
		Wipe limit	0.1 µg/100 cm ²	Internal

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 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

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

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Remarks Eye protection	: Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: 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

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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 mm ² /s
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	: Inhalation Skin contact Ingestion Eye contact
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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

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

Acute oral toxicity	: LD50 (Rat): > 25 mg/kg Remarks: No mortality observed at this dose.
Acute toxicity (other routes of administration)	: LD50 (Rat): > 50 mg/kg Application Route: Subcutaneous
	: LD50 (Rat): > 50 mg/kg Application Route: Intramuscular
	: 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:

4-Chloro-3-methylphenol:

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

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.
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Serious eye damage/eye irritation

Not classified based on available information.

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Components:

4-Chloro-3-methylphenol:

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

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

Remarks	:	Not classified due to lack of data.
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Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

4-Chloro-3-methylphenol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig

Assessment	:	Probability or evidence of low to moderate skin sensitization rate in humans
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Sodium [1 α (Z),2 β (1E,3R*),3 α ,5 α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

Result	:	Sensitizer
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Germ cell mutagenicity

Not classified based on available information.

Components:

4-Chloro-3-methylphenol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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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
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Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

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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 [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:

4-Chloro-3-methylphenol:

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

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

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

||| Effects on fertility : Test Type: Three-generation study
Species: Rat
Application Route: Oral
General Toxicity F1: NOAEL: 0,015 mg/kg body weight
Fertility: NOAEL: > 0,04 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Species: Cattle
Application Route: Intramuscular
General Toxicity Parent: LOAEL: 0,16 µg/kg
Result: positive
Remarks: Abortion

Effects on fetal development : Test Type: Development

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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

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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

Experience with human exposure

Components:

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

General Information	:	Target Organs: Uterus (including cervix) Symptoms: Embryo-fetal toxicity., Fetal mortality., menstrual irregularities, miscarriage
Inhalation	:	Target Organs: Lungs Symptoms: Asthma, bronchospasm Remarks: May cause sensitization of susceptible persons by inhalation of aerosol or dust.
Skin contact	:	Target Organs: Uterus (including cervix) Symptoms: Embryo-lethal effects., menstrual irregularities Remarks: Can be absorbed through skin. Target Organs: Uterus (including cervix) Symptoms: Embryo-lethal effects.

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Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella pyrenoidosa): 15 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC10 (Chlorella pyrenoidosa): 2,3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,32 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: 22,86 mg/l Exposure time: 60 h

Sodium [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

Persistence and degradability**Components:****4-Chloro-3-methylphenol:**

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

Components:

4-Chloro-3-methylphenol:

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 5,5 - 13
Partition coefficient: n-octanol/water	:	log Pow: 0,477

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

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(LINACH)

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

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

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
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Further information

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

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 other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - 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

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1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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