

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Chlorhexidine Formulation

Version 1.10      Revision Date: 30.09.2023      SDS Number: 5322110-00011      Date of last issue: 04.04.2023  
Date of first issue: 25.11.2019

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Chlorhexidine Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

##### GHS label elements

Hazard pictograms :



Signal word : None

Hazard statements : H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

**Response:**

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P391 Collect spillage.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 5 - < 10
Chlorhexidine	55-56-1	>= 5 - < 10
Linalyl acetate	115-95-7	>= 0.1 - < 0.25

#: Voluntarily-disclosed substance

## 4. 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.
- 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.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
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 : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- 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).
- Notes to physician : Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
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- Local/Total ventilation : Use only with adequate ventilation.  
Advice on safe handling : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
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  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	IN OEL
		STEL	1,000 ppm	ACGIH
Chlorhexidine	55-56-1	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: RSEN				
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

#### 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 : Combined particulates and organic vapour type
- Hand protection
- Material : Chemical-resistant gloves

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Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	light pink
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	5.0 - 6.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

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flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### 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.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### **Ethanol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

##### **Chlorhexidine:**

Acute oral toxicity : LD50 Oral (Mouse): 1,260 mg/kg  
LD50 Oral (Rabbit): 1,100 mg/kg  
LD50 Oral (Rat): 2,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 21 mg/kg  
Application Route: Intravenous

##### **Linalyl acetate:**

Acute oral toxicity : LD50 (Rat): > 9,000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Ethanol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

##### **Linalyl acetate:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

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### Components:

#### **Ethanol:**

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

#### **Chlorhexidine:**

Species : Rabbit  
Result : Mild eye irritation

#### **Linalyl acetate:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days  
Remarks : Based on data from similar materials

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Ethanol:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : negative

#### **Linalyl acetate:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : positive

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

### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Ethanol:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative



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

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: equivocal

### **Chlorhexidine:**

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

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test  
Species: Mouse  
Result: negative

Test Type: Cytogenetic assay  
Species: Hamster  
Result: negative

### **Linalyl acetate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Chlorhexidine:**

Species : Rat

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Application Route : oral (drinking water)  
Exposure time : 2 Years  
Frequency of Treatment : daily  
NOAEL : 38 mg/kg body weight  
Result : negative

Species : Rat  
Application Route : oral (drinking water)  
Exposure time : 2 Years  
Frequency of Treatment : daily  
NOAEL : 158 mg/kg body weight  
Result : negative

### Reproductive toxicity

Not classified based on available information.

### Components:

#### **Ethanol:**

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

#### **Chlorhexidine:**

Effects on fertility : Species: Rat  
Fertility: NOAEL: 100 mg/kg body weight

Effects on foetal development : Species: Rat  
Developmental Toxicity: NOAEL: 300 mg/kg body weight

Species: Rabbit  
Developmental Toxicity: NOAEL: 40 mg/kg body weight

#### **Linalyl acetate:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

### **STOT - single exposure**

Not classified based on available information.

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### STOT - repeated exposure

Not classified based on available information.

#### Components:

##### **Chlorhexidine:**

Target Organs : Liver  
Assessment : May cause damage to organs through prolonged or repeated exposure.

##### **Linalyl acetate:**

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.  
Remarks : Based on data from similar materials

### Repeated dose toxicity

#### Components:

##### **Ethanol:**

Species : Rat  
NOAEL : 1,280 mg/kg  
LOAEL : 3,156 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

##### **Chlorhexidine:**

Species : Rat  
NOAEL : 158 mg/kg  
Application Route : Oral  
Exposure time : 2 yr

Species : Rabbit  
LOAEL : 250 mg/kg  
Application Route : Dermal  
Exposure time : 13 Weeks  
Target Organs : Skin, Liver

##### **Linalyl acetate:**

Species : Rat  
NOAEL : > 30 - 300 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days  
Remarks : Based on data from similar materials

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Skin contact  
Exposure time : 91 Days  
Remarks : Based on data from similar materials

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### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Chlorhexidine:**

General Information : Symptoms: Headache  
Inhalation : Target Organs: Lungs  
Symptoms: Asthmatic appearance, bronchospasm, discomfort in the chest, upper respiratory tract infection  
Ingestion : Target Organs: Gastrointestinal tract  
Symptoms: Gastrointestinal disturbance, Gastrointestinal tract damage

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Ethanol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 ( Chlorella vulgaris (Fresh water algae)): 275 mg/l  
Exposure time: 72 h

EC10 ( Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l  
Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.6 mg/l  
Exposure time: 9 d  
Species: Daphnia magna (Water flea)

#### **Chlorhexidine:**

Toxicity to fish : (Fish): 2.088 mg/l  
Exposure time: 96 h  
Method: ECOSAR (Ecological Structure Activity Relationships)

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.222 mg/l  
Exposure time: 48 h  
Method: ECOSAR (Ecological Structure Activity Relationships)

Toxicity to algae/aquatic : ErC50 ( Pseudokirchneriella subcapitata (green algae)): 1.124



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### Bioaccumulative potential

#### Components:

##### **Ethanol:**

Partition coefficient: n-octanol/water : log Pow: -0.35

##### **Chlorhexidine:**

Partition coefficient: n-octanol/water : log Pow: 4.85

##### **Linalyl acetate:**

Partition coefficient: n-octanol/water : log Pow: 3.9  
Method: OECD Test Guideline 107

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

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## 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.

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## 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Chlorhexidine)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### **IATA-DGR**

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Chlorhexidine)  
Class : 9  
Packing group : III

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Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Chlorhexidine)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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## 15. REGULATORY INFORMATION

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

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

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

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## 16. OTHER INFORMATION

Revision Date : 30.09.2023

### Further information

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

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
IN OEL : India. Permissible levels of certain chemical substances in

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work environment.

ACGIH / STEL : Short-term exposure limit  
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition 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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