

# SAFETY DATA SHEET



## Oxytetracycline Solid Formulation

Version 5.0      Revision Date: 14.04.2025      SDS Number: 6008051-00013      Date of last issue: 07.02.2025  
Date of first issue: 05.06.2020

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### SECTION 1. IDENTIFICATION

Product identifier : Oxytetracycline Solid 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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Skin corrosion : Category 1

Serious eye damage : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.  
H317 May cause an allergic skin reaction.  
H360D May damage the unborn child.

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H410 Very toxic to aquatic life with long lasting effects.

### Precautionary Statements

#### : Prevention:

P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### : Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.  
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P391 Collect spillage.

#### : Storage:

P405 Store locked up.

### Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Oxytetracycline	79-57-2	Skin Sens., 1A Repr., 1A Aquatic Acute, 1 Aquatic Chronic, 1	>= 70 - < 90

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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	When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
In case of skin contact	: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	: Causes digestive tract burns. May cause an allergic skin reaction. Causes serious eye damage. May damage the unborn child. Causes severe burns.
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.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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.

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

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**SECTION 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. 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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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**SECTION 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.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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

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Hygiene measures	<p>environment.</p> <p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Contaminated work clothing should not be allowed out of the workplace.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>
Conditions for safe storage	<p>: Keep in properly labeled containers.</p> <p>Store locked up.</p> <p>Keep tightly closed.</p> <p>Store in accordance with the particular national regulations.</p>
Materials to avoid	<p>: Do not store with the following product types:</p> <p>Strong oxidizing agents</p> <p>Self-reactive substances and mixtures</p> <p>Organic peroxides</p> <p>Explosives</p> <p>Gases</p>

## 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
Oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

Engineering measures	<p>: Use feasible engineering controls to minimize exposure to compound.</p> <p>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</p>
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### Personal protective equipment

Respiratory protection	<p>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</p>
Filter type	<p>: Particulates type</p>
Hand protection	<p>: Chemical-resistant gloves</p>
Material	
Eye protection	<p>: Wear safety glasses with side shields or goggles.</p> <p>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</p> <p>Wear a faceshield or other full face protection if there is a</p>

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potential for direct contact to the face with dusts, mists, or aerosols.  
Skin and body protection : Work uniform or laboratory coat.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder  
Color : light yellow  
Odor : No data available  
Odor Threshold : No data available  
pH : 1,5 - 3,0  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : No data available  
Flash point : Not applicable  
Evaporation rate : Not applicable  
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.  
Flammability (liquids) : Not applicable  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available  
Vapor pressure : Not applicable  
Relative vapor density : Not applicable  
Relative density : No data available  
Density : No data available  
Solubility(ies)  
Water solubility : No data available  
Partition coefficient: n-octanol/water : No data available  
Autoignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity  
Viscosity, kinematic : Not applicable

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

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## SECTION 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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## 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:

#### Oxytetracycline:

Acute oral toxicity	:	LD50 (Rat): 4.800 mg/kg  LD50 (Mouse): 2.240 mg/kg Remarks: Evidence of phototoxicity was observed
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Rat): 4.840 mg/kg Application Route: Intramuscular  LD50 (Mouse): 3.500 mg/kg Application Route: Subcutaneous

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**Skin corrosion/irritation**

Causes severe burns.

**Components:****Oxytetracycline:**

||| Remarks : No data available

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Oxytetracycline:**

||| Remarks : No data available

**Respiratory or skin sensitization****Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Oxytetracycline:**

||| Test Type : Human repeat insult patch test (HRIPT)  
||| Result : Sensitizer

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Oxytetracycline:**

||| Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
||| Result: negative  
  
||| Test Type: Mouse Lymphoma  
||| Metabolic activation: Metabolic activation  
||| Result: positive  
  
||| Test Type: sister chromatid exchange assay  
||| Test system: Chinese hamster ovary cells  
||| Result: equivocal  
  
||| Test Type: Chromosomal aberration  
||| Result: negative  
  
||| Genotoxicity in vivo : Test Type: Micronucleus test  
||| Species: Mouse  
||| Cell type: Bone marrow  
||| Application Route: Oral  
||| Result: equivocal

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Test Type: in vivo assay  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

Not classified based on available information.

**Components:****Oxytetracycline:**

Species : Mouse  
Application Route : Oral  
Exposure time : 104 weeks  
Result : negative

Species : Rat  
Application Route : Oral  
Exposure time : 103 weeks  
Result : equivocal  
Target Organs : Adrenal gland, Pituitary gland  
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**Reproductive toxicity**

May damage the unborn child.

**Components:****Oxytetracycline:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 18 mg/kg body weight  
Result: No effects on fertility., No effect on reproduction capacity., No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: LOAEL: 48 mg/kg body weight  
Result: Postimplantation loss., Skeletal malformations.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight

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Embryo-fetal toxicity.: NOAEL: 1.500 mg/kg body weight  
Result: No teratogenic effects.  
Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight  
Embryo-fetal toxicity.: NOAEL: 2.100 mg/kg body weight  
Result: No teratogenic effects.  
Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intramuscular  
Embryo-fetal toxicity.: LOAEL: 41,5 mg/kg body weight  
Result: Postimplantation loss., No fetal abnormalities.

Test Type: Embryo-fetal development  
Species: Dog  
Application Route: Intramuscular  
Embryo-fetal toxicity.: LOAEL: 20,75 mg/kg body weight  
Result: Skeletal and visceral variations ., Postimplantation loss.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### Oxytetracycline:

Species	:	Rat
LOAEL	:	198 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Bone
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
LOAEL	:	7.990 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Bone
Remarks	:	No significant adverse effects were reported

Species	:	Dog
NOAEL	:	125 mg/kg

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LOAEL	:	250 mg/kg
Application Route	:	Oral
Exposure time	:	12 Months
Target Organs	:	Testis
Remarks	:	Significant toxicity observed in testing
Species	:	Rat
NOAEL	:	40 mg/kg
LOAEL	:	100 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	14 Days
Target Organs	:	Kidney

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Oxytetracycline:**

Ingestion	:	Symptoms: Gastrointestinal disturbance, tooth discoloration
		Remarks: May cause birth defects.

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Oxytetracycline:**

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 621 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
		EC50 (Moina macrocopa (Water flea)): 126,7 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena): 0,032 mg/l Exposure time: 72 h
		NOEC (Anabaena): 0,0031 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 (activated sludge): 17,9 mg/l Exposure time: 3 h

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Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC (activated sludge): 0,2 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

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### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

### Domestic regulation

#### ANTT

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

### 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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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

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

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

DSL : not determined

AICS : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
Date format : dd.mm.yyyy

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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; 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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