according to the OSHA Hazard Communication Standard



## **Tetracycline Hydrochloride**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 2.1 09/30/2023 5479501-00010 Date of first issue: 03/05/2020

#### **SECTION 1. IDENTIFICATION**

Product name : Tetracycline Hydrochloride

Product code : Tetracycline hydrochloride, Tetracycline hydrochloride

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Reproductive toxicity : Category 1A

Effects on or via lactation

Specific target organ toxicity - repeated exposure (Oral)

Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)

**GHS** label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, han-

dling or by other means, may form combustible dust concentra-

tions in air.

H360D May damage the unborn child. H362 May cause harm to breast-fed children.

H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated

exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

according to the OSHA Hazard Communication Standard



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and understood.

P260 Do not breathe dust.

P263 Avoid contact during pregnancy and while nursing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Substance

Substance name : Tetracycline hydrochloride

CAS-No. : 64-75-5

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Tetracycline hydrochloride	64-75-5	100

### **SECTION 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.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : 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.

according to the OSHA Hazard Communication Standard



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Rinse mouth thoroughly with water. ost important symptoms : May damage the unborn child.

Most important symptoms and effects, both acute and

delayed

May cause harm to breast-fed children.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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,

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 (CO2)

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec: :

tive 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

according to the OSHA Hazard Communication Standard



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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.

### **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 : Avoid contact during pregnancy and while nursing.

Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with 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. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

inert or nuisance dust 50 Million particles per cubic foot

according to the OSHA Hazard Communication Standard



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Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

15 mg/m<sup>3</sup>

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

5 mg/m<sup>3</sup>

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

15 Million particles per cubic foot

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

Dust, nuisance dust and par-

ticulates

10 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (Total dust)

Basis: CAL PEL

5 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m3 (OEB	Internal
			2)	

**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

according to the OSHA Hazard Communication Standard



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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.

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.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Crystalline powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : 417 °F / 214 °C

Initial boiling point and boiling

range

No data available

Flash point : No data available

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

according to the OSHA Hazard Communication Standard



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log Pow: -1.37

Density : No data available

Solubility(ies)

Water solubility : 0.231 g/l

Partition coefficient: n-

octanol/water pH: 7

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : 480.9 g/mol

Particle size : No data available

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

..

tions

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

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

### **Components:**

### Tetracycline hydrochloride:

according to the OSHA Hazard Communication Standard



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Acute oral toxicity : LD50 (Rat): 6,443 mg/kg

LD50 (Mouse): 2,759 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 128 mg/kg

Application Route: Intravenous

LD50 (Mouse): 157 mg/kg Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

## Tetracycline hydrochloride:

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

### Tetracycline hydrochloride:

Remarks : No data available

### Respiratory or skin sensitization

### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

### **Components:**

### Tetracycline hydrochloride:

Remarks : No data available

## Germ cell mutagenicity

Not classified based on available information.

### Components:

### Tetracycline hydrochloride:

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

Result: negative

Test Type: Cytogenetic assay

Test system: Chinese hamster ovary cells

Result: negative

Test Type: sister chromatid exchange assay

according to the OSHA Hazard Communication Standard



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Result: negative

Test Type: Mouse Lymphoma

Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

### Tetracycline hydrochloride:

Species : Rat
Application Route : Oral
Exposure time : 103 W
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 103 W
Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child. May cause harm to breast-fed children.

### **Components:**

## Tetracycline hydrochloride:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 400 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Development

Result: Embryo-fetal toxicity., Specific developmental

abnormalities., Skeletal malformations.

Reproductive toxicity - As-

sessment

Studies indicating a hazard to babies during the lactation

period, May damage the unborn child.

### **STOT-single exposure**

Not classified based on available information.

according to the OSHA Hazard Communication Standard



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### STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

### Components:

### Tetracycline hydrochloride:

Routes of exposure : Oral

Target Organs : Gastrointestinal tract, Nervous system, Skin, Teeth

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

## **Tetracycline hydrochloride:**

Species : Rat
NOAEL : 625 mg/kg
LOAEL : 1,250 mg/kg
Application Route : oral (feed)
Exposure time : 13 W
Target Organs : Liver

Symptoms : Reduced body weight

Species : Mouse

NOAEL : 3,750 mg/kg

LOAEL : 7,500 mg/kg

Application Route : oral (feed)

Exposure time : 13 W

Symptoms : Reduced body weight

### **Aspiration toxicity**

Not classified based on available information.

### Components:

### Tetracycline hydrochloride:

Not applicable

### Experience with human exposure

### **Components:**

### Tetracycline hydrochloride:

Ingestion : Target Organs: Teeth

Symptoms: Gastrointestinal disturbance, Nausea, Vomiting, Diarrhea, Liver effects, skin rash, central nervous system ef-

fects

Remarks: May cause sensitization of susceptible persons.

May cause photosensitization. Based on Human Evidence

according to the OSHA Hazard Communication Standard



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### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

### **Components:**

### Tetracycline hydrochloride:

Toxicity to algae/aquatic plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l

Exposure time: 72 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l

Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31

mg/

Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032

mg/l

Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l

Exposure time: 7 d

Toxicity to microorganisms : EC50: 0.08 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

No data available

**Bioaccumulative potential** 

## **Components:**

### Tetracycline hydrochloride:

Partition coefficient: n- : log Pow: -1.37

octanol/water pH: 7

Mobility in soil
No data available

Other adverse effects

No data available

### **SECTION 13. DISPOSAL CONSIDERATIONS**

### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste

according to the OSHA Hazard Communication Standard



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handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

**UNRTDG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(tetracycline hydrochloride)

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.

(Tetracycline hydrochloride)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Tetracycline hydrochloride)

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** 

**49 CFR** 

UN/ID/NA number : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Tetracycline hydrochloride)

Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171

Marine pollutant : yes(Tetracycline hydrochloride)

Remarks : Above applies only to containers over 119 gallons or 450

according to the OSHA Hazard Communication Standard



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liters.

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

#### 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.

#### **SECTION 15. REGULATORY INFORMATION**

### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 : The following components are subject to reporting levels

established by SARA Title III, Section 313:

Tetracycline hy- 64-75-5 100 %

drochloride

### **US State Regulations**

### Pennsylvania Right To Know

Tetracycline hydrochloride 64-75-5

#### California Prop. 65

WARNING: This product can expose you to chemicals including Tetracycline hydrochloride, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

AICS : not determined

DSL : not determined

IECSC : not determined

according to the OSHA Hazard Communication Standard



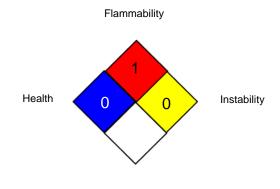
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### **SECTION 16. OTHER INFORMATION**

### **Further information**

#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contami-

nants (Title 8, Article 107)

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-

eral Dusts

CAL PEL / PEL : Permissible exposure limit OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance: 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

according to the OSHA Hazard Communication Standard



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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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 09/30/2023

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.

US / Z8