

# Tetracycline Hydrochloride

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5479499-00010      Date of last issue: 04.04.2023  
Date of first issue: 05.03.2020

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## Section 1: Identification

Product name : Tetracycline Hydrochloride  
Product code : tetracycline hydrochloride, Tetracycline hydrochloride

### Manufacturer or supplier's details

Company : MSD  
Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand  
Telephone : 0800 800 543  
Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)  
E-mail address : EHSDATASTEWARD@msd.com

### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable


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## Section 2: Hazard identification

### GHS Classification

Reproductive toxicity : Category 1  
Effects on or via lactation  
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)  
Hazardous to the aquatic environment - acute hazard : Category 1  
Hazardous to the aquatic environment - chronic hazard : Category 1

### GHS label elements

Hazard pictograms :    
Signal word : Danger

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Hazard statements : 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.  
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
 P201 Obtain special instructions before use.  
 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.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

**Storage:**  
 P405 Store locked up.

**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.

**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	>= 90 -<= 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

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		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. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May damage the unborn child. 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, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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**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 Nitrogen oxides (NO <sub>x</sub> ) Chlorine compounds
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.
Hazchem Code	:	2Z

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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 : 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.

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- 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 labelled 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

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m <sup>3</sup> (OEB 2)	Internal

- 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** : 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** : Chemical-resistant gloves
- Material** : Chemical-resistant gloves
- 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.

### Section 9: Physical and chemical properties

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Appearance	:	Crystalline powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	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
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	0.231 g/l
Partition coefficient: n-octanol/water	:	log Pow: -1.37 pH: 7
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : 480.9 g/mol  
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

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **tetracycline hydrochloride:**

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:**

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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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****tetracycline hydrochloride:**

Remarks : No data available

**Chronic toxicity****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  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****tetracycline hydrochloride:**

Species : Rat  
Application Route : Oral



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Exposure time                   : 103 W  
Result                             : negative

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

**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 foetal develop-       : Test Type: Development  
ment                                 Result: Embryo-foetal toxicity, Specific developmental abnor-  
malities, Skeletal malformations

Reproductive toxicity - As-       : Studies indicating a hazard to babies during the lactation peri-  
sessment                             od, May damage the unborn child.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

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

**Components:****tetracycline hydrochloride:**

Exposure routes                   : 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)

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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, Diarrhoea, Liver effects, skin rash, central nervous system effects  
Remarks: May cause sensitisation of susceptible persons.  
May cause photosensitisation.  
Based on Human Evidence

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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/l  
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l  
Exposure time: 72 h

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EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l  
Exposure time: 7 d

M-Factor (Acute aquatic toxicity) : 10  
M-Factor (Chronic aquatic toxicity) : 1  
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-octanol/water : log Pow: -1.37  
pH: 7

**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.  
(tetracycline hydrochloride)  
Class : 9  
Packing group : III  
Labels : 9

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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 aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
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.

**National Regulations****NZS 5433**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(tetracycline hydrochloride)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 2Z  
Marine pollutant : no

**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**

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**HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

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**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**

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, Bioaccumu-

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lative 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.

NZ / EN