SAFETY DATA SHEET

Tetracycline Hydrochloride Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tetracycline Hydrochloride Formulation

Product code : Tetracycline hydrochloride, Tetracycline hydrochloride

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 : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity : Category 1A

Effects on or via lactation
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)
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 : 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/ while nursing.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P391 Collect spillage.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>Reproductive toxicity, Category 1A Effects on or via lactation, Specific target organ toxicity - repeated exposure (Oral) (Gastrointestinal tract, Nervous system, Skin, Teeth), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 90 &lt;= 100</td>
</tr>
</tbody>
</table>

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. 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.

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 products: Carbon oxides
Nitrogen oxides (NOx)
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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.
Emergency procedures

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.

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.

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,
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 
Organic peroxides 
Explosives 
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>TWA</td>
<td>0.5 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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 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

Appearance: Crystalline powder
Color: No data available
Odor: No data available
Odor Threshold: No data available
SAFETY DATA SHEET

Tetracycline Hydrochloride Formulation

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
Vapor pressure : Not applicable
Relative vapor 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
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 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.

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:
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
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

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

Reproductive toxicity - Assessment:
Studies indicating a hazard to babies during the lactation period, 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 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 effects
Remarks: May cause sensitization of susceptible persons. May cause photosensitization. Based on Human Evidence

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
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-: log Pow: -1,37
octanol/water  

**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.  
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**  

**UNRTDG**  
- **UN number**: UN 3077  
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)  
- **Class**: 9  
- **Packing group**: III  
- **Labels**: 9

**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.
SAFETY DATA SHEET

Tetracycline Hydrochloride Formulation

Version: 1.3  
Revision Date: 27.08.2021  
SDS Number: 5479489-00004  
Date of last issue: 10.10.2020
Date of first issue: 05.03.2020

Domestic regulation

ANTT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Tetracycline hydrochloride)
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.

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AIIIC - 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
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.