SAFETY DATA SHEET

Tetracycline Hydrochloride Formulation

VERSION 1.4

Revision Date: 27.08.2021
SDS Number: 5479502-00005
Date of last issue: 09.04.2021
Date of first issue: 05.03.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Tetracycline Hydrochloride Formulation
Product code: Tetracycline hydrochloride, Tetracycline hydrochloride
Substance name: Tetracycline hydrochloride
EC-No.: 200-593-8

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: MSD
20 Spartan Road
1619 Spartan, South Africa
Telephone: +27119239300
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

- Reproductive toxicity, Category 1A
  - H360D: May damage the unborn child.
- Effects on or via lactation
  - H362: May cause harm to breast-fed children.
- Specific target organ toxicity - repeated exposure, Category 2, Gastrointestinal tract, Nervous system, Skin, Teeth
  - H373: May cause damage to organs through prolonged or repeated exposure if swallowed.
- Short-term (acute) aquatic hazard, Category 1
  - H400: Very toxic to aquatic life.
- Long-term (chronic) aquatic hazard, Category 1
  - H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms:
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Tetracycline Hydrochloride Formulation

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 and while nursing.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P391 Collect spillage.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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

3.1 Substances
Substance name : Tetracycline hydrochloride

EC-No. : 200-593-8

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>200-593-8</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : 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- : Carbon oxides
5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>TWA</td>
<td>0.5 mg/m^3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves

Skin and body protection

Work uniform or laboratory coat.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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.

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable
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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
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : Not applicable
Molecular weight : 480,9 g/mol
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
   Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
   Can react with strong oxidizing agents.

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

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

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 sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
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 foetal development:
- Test Type: Development
  - Result: Embryo-foetal toxicity, Specific developmental abnormalities, Skeletal malformations

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:
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)
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
12.1 Toxicity

**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

**Toxicity to microorganisms:**
- EC50: 0.08 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**M-Factor (Chronic aquatic toxicity):** 1

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

**Components:**

**Tetracycline hydrochloride:**
- **Partition coefficient: n-octanol/water:**
  - log Pow: -1.37
  - pH: 7

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**

**Assessment:**
- This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of
## 12.6 Other adverse effects

**Product:** Endocrine disrupting potential

- The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

**Product:**
- Dispose of in accordance with local regulations.
- According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
- Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

#### 14.1 UN number

- **ADN:** UN 3077
- **ADR:** UN 3077
- **RID:** UN 3077
- **IMDG:** UN 3077
- **IATA:** UN 3077

#### 14.2 UN proper shipping name

- **ADN:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)
- **ADR:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)
- **RID:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)
- **IMDG:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)
- **IATA:** Environmentally hazardous substance, solid, n.o.s. (Tetracycline hydrochloride)
14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes
IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : 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
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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
<table>
<thead>
<tr>
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Further information:

Sources of key data used to compile the Safety Data Sheet:


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.

ZA / EN