SAFETY DATA SHEET

Doxycycline Formulation

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

1.1 Product identifier
   Trade name : Doxycycline Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

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)
   Skin corrosion, Category 1 : H314: Causes severe skin burns and eye damage.
   Serious eye damage, Category 1 : H318: Causes serious eye damage.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 2 : H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Description of pictograms :

   Signal word : Danger

   Hazard statements :
   H314 : Causes severe skin burns and eye damage.
   H410 : Very toxic to aquatic life with long lasting effects.

   Precautionary statements :
   Prevention:
   P260 : Do not breathe dust.
   P273 : Avoid release to the environment.
SAFETY DATA SHEET

Doxycycline Formulation

Version: 1.2
Revision Date: 27.08.2021
SDS Number: 6105696-00003
Date of last issue: 09.04.2021
Date of first issue: 06.07.2020

P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 + P310  IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
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.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>EC-No.</td>
<td>Index-No.</td>
<td>Registration number</td>
</tr>
<tr>
<td>Doxycycline Hyclate</td>
<td>24390-14-5</td>
<td></td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Causes serious eye damage. Causes severe burns.
Causes digestive tract burns.

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 products: Carbon oxides

5.3 Advice for firefighters
Special protective equipment: In the event of fire, wear self-contained breathing apparatus.
for firefighters
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: Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the 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

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>Doxycycline Hyclate</td>
<td>24390-14-5</td>
<td>TWA</td>
<td>OEL = 100 µg/m³ (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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>1.5 - 3.5</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
</tbody>
</table>
## SELECTION 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

<table>
<thead>
<tr>
<th>Hazardous reactions</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
<td></td>
</tr>
</tbody>
</table>

### 10.4 Conditions to avoid

<table>
<thead>
<tr>
<th>Conditions to avoid</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat, flames and sparks. Avoid dust formation.</td>
<td></td>
</tr>
</tbody>
</table>

### 10.5 Incompatible materials

<table>
<thead>
<tr>
<th>Materials to avoid</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxidizing agents</td>
<td></td>
</tr>
</tbody>
</table>

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation Skin contact Ingestion Eye contact</td>
<td></td>
</tr>
</tbody>
</table>
Acute toxicity
Not classified based on available information.

**Product:**
Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

**Components:**
Doxycycline Hyclate:
Acute oral toxicity : LD50 (Rat): 2.000 mg/kg
LD50 (Mouse): 1.870 mg/kg
LD50 (Dog): 500 mg/kg
Acute toxicity estimate: 2.000 mg/kg
Method: Calculation method

Acute toxicity (other routes of administration) : LD50 (Rat): 222 mg/kg
Application Route: Intravenous

**Skin corrosion/irritation**
Causes severe burns.

**Components:**
Doxycycline Hyclate:
Remarks : No data available
May irritate skin.

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**
Doxycycline Hyclate:
Remarks : No data available
May irritate eyes.

**Respiratory or skin sensitisation**

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

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

**Components:**
Doxycycline Hyclate:
Remarks : No data available
May cause sensitisation by skin contact.
May cause sensitisation of susceptible persons by skin con-
tact or by inhalation of dust.

Germ cell mutagenicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Result: Weakly positive
Remarks: Based on data from similar materials

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster cells
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
200 mg/kg body weight

Symptoms: females
Target Organs: Uterus (including cervix)
Remarks: Benign tumor(s)

Reproductive toxicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat, females
Application Route: Oral
General Toxicity Maternal: NOAEL: 250 mg/kg body weight
Result: No adverse effects

Species: Rat, male
Application Route: Oral
General Toxicity Maternal: NOAEL: 50 mg/kg body weight
Symptoms: male reproductive effects
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

**Doxycycline Hyclate:**
- **Species:** Rat
- **NOAEL:** 25 mg/kg
- **Application Route:** Oral
- **Exposure time:** 28 d
- **Symptoms:** Thyroid effects

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

**Doxycycline Hyclate:**
- **General Information:** May cause
- **Target Organs:** Teeth
- **Symptoms:** Gastrointestinal disturbance
- **Skin contact:** Remarks: May cause photosensitisation.

Further information

Components:

**Doxycycline Hyclate:**
- **Remarks:** Well tolerated in clinical use

SECTION 12: Ecological information

12.1 Toxicity

Components:

**Doxycycline Hyclate:**
- **Toxicity to algae/aquatic plants:** EC10 (Anabaena flos-aquae): 0.251 mg/l
- **End point:** Growth rate
- **Exposure time:** 72 h
Ecotoxicology Assessment

Acute aquatic toxicity: Very toxic to aquatic life.

Chronic aquatic toxicity: Toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

Doxycycline Hyclate:
Partition coefficient: n-octanol/water: log Pow: 0,02

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 0.1% or higher.

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
SAFETY DATA SHEET

Doxycycline Formulation

Version 1.2 Revision Date: 27.08.2021 SDS Number: 6105696-00003 Date of last issue: 09.04.2021 Date of first issue: 06.07.2020

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. (Doxycycline Hyclate)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
IATA : Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)

14.3 Transport hazard class(es)

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
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 H-Statements

H302 : Harmful if swallowed.
H400 : Very toxic to aquatic life.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

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 - 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; LGD - Lethal Dose; LD50 - Lethal Concentration to 50% of a test population; LC50 - Lethal Concentration 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICS - 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Road; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

**Classification of the mixture:**

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Corr. 1 H314</td>
</tr>
<tr>
<td>Eye Dam. 1 H318</td>
</tr>
<tr>
<td>Aquatic Acute 1 H400</td>
</tr>
<tr>
<td>Aquatic Chronic 2 H411</td>
</tr>
</tbody>
</table>

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