SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Doxycycline Formulation

Version 1.2  Revision Date: 27.08.2021  SDS Number: 6105694-00003  Date of last issue: 09.04.2021  Date of first issue: 06.07.2020

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
Balıklıhasar Mah. Köyiçi Kümë Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone: +90 312 840 53 00
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification T.R. SEA No 28848
Skin corrosion, Category 1A: 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 T.R. SEA No 28848
Hazard 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 or mist.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
- P303 + P361 + P353 + P310 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- 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 or doctor/physician.
- P391 Collect spillage.

2.3 Other hazards
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>Doxycycline Hyclate</td>
<td>24390-14-5</td>
<td>Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 2; H411</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

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.
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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 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.
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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
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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 Hydrate</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**: 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. Equipment should conform to TS EN 143

- **Filter type**: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: powder
- **Colour**: light yellow
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: 1.5 - 3.5
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable

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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
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available

Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable

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 : No data available
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
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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.

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 (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.
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**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 contact 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

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.
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Components:

Doxycycline Hyclate:
Species : Rat
Application Route : Oral
Exposure time : 2 Years
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

Test Type: Fertility/early embryonic development
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
Not relevant
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12.6 Other adverse effects
No data available

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. (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)
ADN: 9
ADR: 9
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</table>

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
SAFETY DATA SHEET
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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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702 quantity 1

E1 ENVIRONMENTAL HAZARDS

Quantity 1 Quantity 2
100 t 200 t

Other regulations:
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16: Other information

Other information: The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025
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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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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; 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; 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; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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
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Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

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<thead>
<tr>
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<th>Code</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Corr. 1A</td>
<td>H314</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
<td>Calculation method</td>
</tr>
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</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.

TR / EN