

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Doxycycline Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

| | |
|------------|---------------------|
| Appearance | : powder |
| Colour | : light yellow |
| Odour | : No data available |

May be harmful if swallowed. Causes severe skin burns and eye damage. Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

GHS Classification

| | |
|-----------------------|--------------|
| Acute toxicity (Oral) | : Category 5 |
|-----------------------|--------------|

| | |
|---------------------------|--------------|
| Skin corrosion/irritation | : Category 1 |
|---------------------------|--------------|

| | |
|-----------------------------------|--------------|
| Serious eye damage/eye irritation | : Category 1 |
|-----------------------------------|--------------|

| | |
|-----------------------------------|--------------|
| Short-term (acute) aquatic hazard | : Category 1 |
|-----------------------------------|--------------|

| | |
|------------------------------------|--------------|
| Long-term (chronic) aquatic hazard | : Category 2 |
|------------------------------------|--------------|

GHS label elements

SAFETY DATA SHEET

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| | | |
|--------------------------|---|--|
| Hazard pictograms | : | Two hazard pictograms are shown in red diamonds. The first shows a hand with a drop of liquid falling on it, with the text 'G22' below. The second shows a dead tree with the text 'G400' below. |
| Signal word | : | Danger |
| Hazard statements | : | H303 May be harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects. |
| Precautionary statements | : | <p>Prevention:</p> <p>P260 Do not breathe dust. P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.</p> <p>Response:</p> <p>P301 + P330 + P331 + P316 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get emergency medical help immediately.</p> <p>P302 + P361 + P354 + P316 IF ON SKIN: Take off immediately all contaminated clothing. Immediately rinse with water for several minutes. Get emergency medical help immediately.</p> <p>P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately.</p> <p>P305 + P354 + P338 + P316 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get emergency medical help immediately.</p> <p>P363 Wash contaminated clothing before reuse.</p> <p>P391 Collect spillage.</p> <p>Storage:</p> <p>P405 Store locked up.</p> <p>Disposal:</p> <p>P501 Dispose of contents/ container to an approved waste disposal plant.</p> |

Physical and chemical hazards

Not classified based on available information.

Health hazards

May be harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage.

Environmental hazards

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

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Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------------|------------|-----------------------|
| Doxycycline Hydrate | 24390-14-5 | >= 50 - < 70 |

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.
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.

Most important symptoms and effects, both acute and delayed : Causes digestive tract burns.
May be harmful if swallowed.
Causes serious eye damage.
Causes severe burns.

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.

5. FIREFIGHTING MEASURES

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

SAFETY DATA SHEET

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| | |
|---|---|
| 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 |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for firefighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|---|--|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
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7. HANDLING AND STORAGE

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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Explosives

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|---------------------|------------|-------------------------------------|--|----------|
| Doxycycline Hyclate | 24390-14-5 | TWA | OEL = 100 µg/m3 (OEB 2) | Internal |

Engineering measures : Use feasible engineering controls to minimize exposure to

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
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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 |
| Eye/face 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. |
| Hand protection | |
| Material | : Chemical-resistant gloves |
| 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. |

9. 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 |
| Evaporation rate | : Not applicable |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

| | | |
|--|---|---|
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | 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. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | No data available |

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. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version 6.0 Revision Date: 2025/04/14 SDS Number: 6105661-00013 Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

| | |
|----------------------------------|---|
| Conditions to avoid | : Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : Oxidizing agents |
| Hazardous decomposition products | : No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

| | |
|-----------------|--|
| Exposure routes | : Inhalation Skin contact Ingestion Eye contact |
|-----------------|--|

Acute toxicity

May be harmful if swallowed.

Product:

| | |
|---------------------|--|
| Acute oral toxicity | : Acute toxicity estimate: 4,000 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. |
|---------|---|

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Doxycycline Hyclate:

| | |
|---------|---|
| Remarks | : No data available May irritate eyes. |
|---------|---|

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

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.

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) |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

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6105661-00013

Date of last issue: 2024/09/28
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Reproductive toxicity

Not classified based on available information.

Components:

Doxycycline Hydrate:

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 Hydrate:

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 Hydrate:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
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Further information

Components:

Doxycycline Hyclate:

||| Remarks : Well tolerated in clinical use

12. ECOLOGICAL INFORMATION

Ecotoxicity

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.

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Doxycycline Hyclate:

||| Partition coefficient: n-octanol/water : log Pow: 0.02

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| | | |
|---------------------------|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

IATA-DGR

| | | |
|--|---|---|
| UN/ID No. | : | UN 3077 |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate) |
| 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. (Doxycycline Hyclate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

| | | |
|----------------------|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Marine pollutant | : | no |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
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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.

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals

: This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

Version
6.0

Revision Date:
2025/04/14

SDS Number:
6105661-00013

Date of last issue: 2024/09/28
Date of first issue: 2020/07/06

Environmental Protection Law

||| List of Priority Controlled Chemicals : Not listed

||| List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Doxycycline Formulation

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Date of last issue: 2024/09/28
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lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.

CN / EN