

# **Doxycycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 3.0
 06.04.2024
 6105693-00011
 Date of first issue: 06.07.2020

**Section 1: Identification** 

**Product identifier** : Doxycycline Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Skin corrosion/irritation : Category 1

Serious eye damage/eye irri-

tation

Category 1

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 2

GHS Label elements, including precautionary statements

Hazard pictograms :



\*\*\*

Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.



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Precautionary statements : Prevention:

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection/ hearing protection.

Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth.

Do NOT induce vomiting. Immediately call a POISON

CENTER/ doctor.

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.

P304 + P340 + P310 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. 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.

P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### Other hazards which do not result in classification

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

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

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

#### Section 4: First-aid measures

#### Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.



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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 contact, immediately flush eyes with plenty of water In case of eye contact

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

Risks Causes serious eye damage.

Causes severe burns.

Causes digestive tract 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).

Indication of any immediate medical attention and special treatment needed

**Treatment** Treat symptomatically and supportively.

#### Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

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 prod: :

ucts

Carbon oxides

### Special protective actions for fire-fighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.



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Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

#### Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

**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.

#### Methods and materials for containment and cleaning up

Methods for cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## Section 7: Handling and storage

### 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



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practice, based on the results of the workplace exposure as-

sessment

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.

#### Conditions for safe storage, including any incompatibilities

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

### Section 8: Exposure controls/personal protection

#### **Control parameters**

#### **Occupational Exposure Limits**

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

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection : Wear safety glasses with side shields or goggles.



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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 protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

Particulates type

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Material : Chemical-resistant gloves

Section 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

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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



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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

## Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

## **Section 11: Toxicological information**

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute toxicity estimate: > 2,000 mg/kg Acute oral toxicity

Method: Calculation method



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#### **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.

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:** 



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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)

#### Reproductive toxicity

Not classified based on available information.

#### **Components:**

ment

#### **Doxycycline Hyclate:**

Effects on foetal develop-

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.



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## 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**

### **Toxicity**

#### **Components:**

## **Doxycycline Hyclate:**

Toxicity to algae/aquatic : EC10 (Anabaena flos-aquae): 0.251 mg/l

plants 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.



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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

Section 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information** 

International Regulations

**UNRTDG** 

UN number : UN 3077

UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

9

(Doxycycline Hyclate)

Transport hazard class(es)

Packing group : III
Labels : 9
Environmental hazards : yes

IATA-DGR

UN/ID No. : UN 3077

UN proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Doxycycline Hyclate)

Transport hazard class(es)

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

956 956

9

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Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Doxycycline Hyclate)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

## Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **Section 15: Regulatory information**

#### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

: Not applicable

Fire Safety (Petroleum and Flammable Materials)

Regulations

: Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

## **Section 16: Other information**

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**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 Agen-

cy, http://echa.europa.eu/



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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.

Date format : dd.mm.yyyy

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, 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; 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

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.

SG / EN