

## **Doxycycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 6105686-00010
 Date of first issue: 06.07.2020

#### **SECTION 1. IDENTIFICATION**

Product name : Doxycycline Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**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

Hazard pictograms





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.



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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 eye protection/ face 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.

P312 Call a POISON CENTER/ doctor if you feel unwell.

P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

### 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**

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



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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, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control center immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delayed

May be harmful if swallowed. 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).

Notes to physician : Treat symptomatically and supportively.

### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

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 prod-

ucts

Carbon oxides

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.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency 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.



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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.

#### **SECTION 7. HANDLING AND STORAGE**

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.

Conditions for safe storage : Keep in properly labeled 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:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

**Explosives** 



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#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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

**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

Respiratory protection If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection. Particulates type

Filter type

Hand protection Material

Chemical-resistant gloves

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.

Skin and body protection

Hygiene measures

Work uniform or laboratory coat.

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** powder

Color light yellow

Odor No data available

Odor Threshold No data available

1.5 - 3.5pН

Melting point/freezing point No data available



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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,

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

Vapor pressure : Not applicable

Relative vapor 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

Autoignition 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 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- : May form explosive dust-air mixture during processing,



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handling or other means. tions

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

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.



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#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

#### Components:

### **Doxycycline Hyclate:**

Remarks : No data available

May cause sensitization by skin contact.

May cause sensitization 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

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.



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#### **Components:**

**Doxycycline Hyclate:** 

Effects on fetal 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 Remarks: May cause photosensitization.

**Further information** 

**Components:** 

Skin contact

**Doxycycline Hyclate:** 

Remarks : Well tolerated in clinical use



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#### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

#### **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.

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

handling 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

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Doxycycline Hyclate)

Class 9 Packing group Ш



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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)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(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.

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/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

AICS : not determined

DSL : not determined

IECSC : not determined



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#### **SECTION 16. OTHER INFORMATION**

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**Further information** 

**Data Sheet** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

#### 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.



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