

Oxytetracycline Solid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 6008071-00010 6.1 Date of first issue: 05.06.2020

Section 1: Identification

Product name Oxytetracycline Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone 0800 800 543

0800 764 766 (0800 POISON) Emergency telephone number: 0800 243 622 (0800

CHEMCALL)

EHSDATASTEWARD@msd.com E-mail address

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

Section 2: Hazard identification

GHS Classification

Skin corrosion/irritation Category 1

Serious eye damage/eye irri-

tation

Category 1

Skin sensitisation Category 1

Reproductive toxicity Category 1

Hazardous to the aquatic

environment - acute hazard

Hazardous to the aquatic

environment - chronic hazard

Category 1

Category 1

GHS label elements

Hazard pictograms





Signal word Danger



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 60.09.2023 60.08071-00010 Date of first issue: 05.06.2020

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

H317 May cause an allergic skin reaction. H360D May damage the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

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)
oxytetracycline	79-57-2	>= 70 -< 90



Oxytetracycline Solid Formulation

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

 6.1
 30.09.2023
 6008071-00010
 Date of first issue: 05.06.2020

Section 4: 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.

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, 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

If swallowed

May cause an allergic skin reaction.

Causes serious eye damage.

May damage the unborn child.

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



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

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

Use personal protective equipment.

: 2Z

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 pro-

tective 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 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

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 as-



Oxytetracycline Solid Formulation

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

 6.1
 30.09.2023
 6008071-00010
 Date of first issue: 05.06.2020

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.

Contaminated work clothing should not be allowed out of the

workplace.

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 : 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

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB	Internal	
			2)		
	Further information: DSEN				
		Wipe limit	100 μg/100 cm 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 expo-

sure assessment demonstrates exposures outside the rec-



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

ommended guidelines, use respiratory protection.

Filter type
Hand protection

: Particulates type

Meterial

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 : Work uniform or laboratory coat.

Section 9: Physical and chemical properties

Appearance : powder

Colour : light yellow

Odour : No data available

Odour Threshold : No data available

pH : 1.5 - 3.0

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



Oxytetracycline Solid Formulation

Version SDS Number: Date of last issue: 04.04.2023 **Revision Date:** 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

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.

No data available

Molecular weight No data available

No data available Particle size

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, 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

Exposure routes Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

oxytetracycline:

Acute oral toxicity LD50 (Rat): 4,800 mg/kg

LD50 (Mouse): 2,240 mg/kg



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of:

administration)

LD50 (Rat): 4,840 mg/kg

Application Route: Intramuscular

LD50 (Mouse): 3,500 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Causes severe burns.

Components:

oxytetracycline:

Remarks : No data available

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

oxytetracycline:

Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitiser

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

oxytetracycline:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Result: negative



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Test Type: Mouse Lymphoma

Metabolic activation: Metabolic activation

Result: positive

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: equivocal

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral Result: equivocal

Test Type: in vivo assay

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

oxytetracycline:

Species : Mouse
Application Route : Oral
Exposure time : 104 weeks
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 103 weeks
Result : equivocal

Target Organs : Adrenal gland, Pituitary gland

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

Carcinogenicity - Assess-

ment

: Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

May damage the unborn child.



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Components:

oxytetracycline:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Fertility: NOAEL: 18 mg/kg body weight

Result: No effects on fertility, No effect on reproduction capac-

ity, No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight

Result: No teratogenic effects

Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight

Result: No teratogenic effects Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development

Species: Dog

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Repeated dose toxicity

Components:

oxytetracycline:

Species : Rat

LOAEL : 198 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone

Remarks : No significant adverse effects were reported

Species : Mouse LOAEL : 7,990 mg/kg

Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 125 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 12 Months
Target Organs : Testis

Remarks : Significant toxicity observed in testing

Species : Rat

NOAEL : 40 mg/kg

LOAEL : 100 mg/kg

Application Route : Intraperitoneal

Exposure time : 14 Days

Target Organs : Kidney

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

oxytetracycline:

Ingestion : Symptoms: Gastrointestinal disturbance, tooth discoloration

Remarks: May cause birth defects.

Section 12: Ecological information

Ecotoxicity

Components:

oxytetracycline:



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 621 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena): 0.032 mg/l

Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

M-Factor (Chronic aquatic

Toxicity to microorganisms

toxicity)

10

10

EC50: 17.9 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 0.2 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

No data available

Bioaccumulative potential

No data available

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.



Oxytetracycline Solid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

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.

(oxytetracycline)

Class 9 Ш Packing group Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3077

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(oxytetracycline)

Class 9 Packing group Ш

Labels Miscellaneous

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous yes

IMDG-Code

UN number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(oxytetracycline)

Class 9 Packing group Ш Labels 9 **EmS Code** F-A, S-F yes Marine pollutant

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

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(oxytetracycline)

9 Class Ш Packing group Labels 9 Hazchem Code 2Z



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

Marine pollutant : no

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

HSNO Approval Number

not allocated

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

DSL : not determined

AICS : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 30.09.2023

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/

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 Con-



Oxytetracycline Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 6008071-00010 Date of first issue: 05.06.2020

centration 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.

NZ / EN