

# Oxytetracycline / Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 4156028-00015 Date of first issue: 17.04.2019

### **SECTION 1. IDENTIFICATION**

Product name : Oxytetracycline / Diclofenac 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** 

Skin corrosion/irritation : Category 3

Serious eye damage/eye

irritation

Category 2B

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - :

repeated exposure

Category 2 (Gastrointestinal tract, Blood, lymphatic system,

Liver, Prostate)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms :







Signal Word : Danger



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Hazard Statements : H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction.

H320 Causes eye irritation.

H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

**Precautionary Statements** 

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors. 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:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

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

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention

P362 + P364 Take off contaminated clothing and wash it 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

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
2-Pyrrolidone	616-45-5	>= 50 -< 70	



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Oxytetracycline	79-57-2	>= 20 -< 25
Magnesium oxide	1309-48-4	>= 1 -< 5
Sodium [2-[(2,6-	15307-79-6	>= 1 -< 2,5
dichlorophenyl)amino]phenyl]acetate		
Sodium hydroxymethanesulphinate	6035-47-8	>= 0,1 -< 1

#### **SECTION 4. FIRST AID MEASURES**

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. 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.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes mild skin irritation.

May cause an allergic skin reaction.

Causes eye irritation.

May damage fertility. May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

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

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides Chlorine compounds

Nitrogen oxides (NOx)

Sodium oxides

Specific extinguishing meth-Use extinguishing measures that are appropriate to local cir-



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ods 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.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

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

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 mist or vapors.

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.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.



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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** Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal	
	Further information: DSEN				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	
Magnesium oxide	1309-48-4	CMP (Fumes)	10 mg/m³	AR OEL	
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH	
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	TWA	100 μg/m3 (OEB 2)	Internal	
	Further information: Skin				

**Engineering measures** Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

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 Hand protection Combined particulates and organic vapor type

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



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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.

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.

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

Appearance : liquid

Color : brown, Greenish yellow

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : -33 °C

Initial boiling point and boiling

range

100,5 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : 1,15 - 1,19 (25 °C)

Density : No data available

Solubility(ies)



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Water solubility soluble

Partition coefficient: n-

octanol/water

Not applicable

No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, dynamic 50,3 - 50,7 mPa.s ( 25 °C)

Viscosity, kinematic No data available

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle size Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

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

Information on likely routes of: Inhalation

exposure

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute toxicity estimate: > 5.000 mg/kg Acute oral toxicity

Method: Calculation method

**Components:** 

2-Pyrrolidone:

LD50 (Rat): > 2.000 mg/kg Acute oral toxicity

Method: OECD Test Guideline 401

Assessment: The substance or mixture has no acute oral tox-



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icity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4.800 mg/kg

LD50 (Mouse): 2.240 mg/kg

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

Magnesium oxide:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2,1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg

LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 97 - 161 mg/kg

**Application Route: Intravenous** 

LD50 (Mouse): 92 - 147 mg/kg Application Route: Intravenous

Sodium hydroxymethanesulphinate:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials



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Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Skin corrosion/irritation

Causes mild skin irritation.

**Components:** 

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Oxytetracycline:

Remarks : No data available

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : irritating

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes eye irritation.

**Components:** 

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Oxytetracycline:

Remarks : No data available

Magnesium oxide:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : Mild eye irritation

Sodium hydroxymethanesulphinate:

Species : Rabbit

Result : No eye irritation



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Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

## Respiratory or skin sensitization

### Skin sensitization

May cause an allergic skin reaction.

### Respiratory sensitization

Not classified based on available information.

### Components:

### 2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

### Oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitizer

## Magnesium oxide:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

### Sodium hydroxymethanesulphinate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

### 2-Pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative



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Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: negative

Oxytetracycline:

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

Result: negative

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.

Magnesium oxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test



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Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: CHO Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell

mutagenicity tests.

Carcinogenicity

Not classified based on available information.

**Components:** 

2-Pyrrolidone:

Species : Mouse
Application Route : Ingestion
Exposure time : 18 month(s)
Result : negative

Remarks : Based on data from similar materials

Oxytetracycline:

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

Species : Rat Application Route : Oral



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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

Magnesium oxide:

Species : Mouse
Application Route : Ingestion
Exposure time : 96 weeks
Result : negative

Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

**Components:** 

2-Pyrrolidone:

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

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

**Application Route: Ingestion** 

Result: positive

Reproductive toxicity - As-

sessment

: Clear evidence of adverse effects on sexual function and

fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal

experiments.

Oxytetracycline:

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

Species: Rat



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Application Route: Oral

Fertility: NOAEL: 18 mg/kg body weight

Result: No effects on fertility., No effect on reproduction capacity., No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

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

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 1.500 mg/kg body weight

Result: No teratogenic effects. Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Mouse

Application Route: Oral

General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 2.100 mg/kg body weight

Result: No teratogenic effects. Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-fetal toxicity.: LOAEL: 41,5 mg/kg body weight Result: Postimplantation loss., No fetal abnormalities.

Test Type: Embryo-fetal development

Species: Dog

Application Route: Intramuscular

Embryo-fetal 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.

Magnesium oxide:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test



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Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Test Type: Fertility Effects on fertility

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 4 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 5 mg/kg body weight Result: Embryo-fetal toxicity., No teratogenic effects.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

### Sodium hydroxymethanesulphinate:

Effects on fertility Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Test Type: Embryo-fetal development Effects on fetal development :

Species: Rat

**Application Route: Ingestion** Method: OECD Test Guideline 414

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.



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### **Components:**

## Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

### 2-Pyrrolidone:

Species : Rat
NOAEL : 207 mg/kg
Application Route : Ingestion
Exposure time : 3 Months

Method : OECD Test Guideline 408

### 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

### Magnesium oxide:

Species : Rat

NOAEL : >= 1.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days



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Method : OECD Test Guideline 407

Remarks : Based on data from similar materials

## Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat

LOAEL : 0,25 mg/kg

Application Route : Oral Exposure time : 98 w

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog LOAEL : 1 mg/kg Application Route : Oral Exposure time : 12 w Target Organs : Blood

Species : Baboon
NOAEL : 0,5 mg/kg
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 52 w

Target Organs : Gastrointestinal tract, Blood Symptoms : constipation, Diarrhea

### Sodium hydroxymethanesulphinate:

Species : Rat

NOAEL : 600 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

### **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.

## Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhea, constipation, heartburn,

Ulceration, Dizziness, Headache, Breathing difficulties, Rash

## **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

### **Components:**

#### 2-Pyrrolidone:



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Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1.000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Oxytetracycline:

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)
Toxicity to microorganisms

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

Magnesium oxide:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h



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Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 80,1 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0,32 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials



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Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 13,5 mg/l

Exposure time: 35 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 5,6 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 1.000 mg/l

Exposure time: 4 h

Remarks: Based on data from similar materials

## Persistence and degradability

### **Components:**

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

### Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

### Bioaccumulative potential

### **Components:**

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0,71

octanol/water Method: OECD Test Guideline 107

## Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n-

octanol/water

log Pow: 4,51

# Mobility in soil

No data available

#### Other adverse effects

No data available



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#### **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 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

Class 9 Packing group Ш 9 Labels Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

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

(Oxytetracycline)

9 Class Packing group Ш

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

964

Environmentally hazardous yes

**IMDG-Code** 

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Oxytetracycline)

Class 9 Packing group Ш 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.



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#### **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

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

**Revision Date** 30.09.2023 dd.mm.yyyy Date format

**Further information** 

Sources of key data used to

compile the Material 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/

### Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV) AR OEL Argentina. Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average AR OEL / CMP TLV (Threshold Limit Value)

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;



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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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