

# Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.0 2024/09/28 1313810-00019 Date of first issue: 2017/02/20

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

### 2. HAZARDS IDENTIFICATION

**GHS Classification** 

Serious eye damage/eye irri-

tation

Category 2A

Skin sensitisation : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms

> (!)



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.



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H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn child. 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.

P261 Avoid breathing mist or vapours.
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 protection/ 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/ attention.

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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name   | CAS-No.  | Concentration (% w/w) |  |
|-----------------|----------|-----------------------|--|
| 2-Pyrrolidone   | 616-45-5 | >= 30 -< 60           |  |
| oxytetracycline | 79-57-2  | >= 10 -< 25           |  |
| Benzyl alcohol  | 100-51-6 | >= 1 -< 10            |  |



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| Magnesium oxide                     | 1309-48-4  | < 10         |
|-------------------------------------|------------|--------------|
| Sodium [2-[(2,6-                    | 15307-79-6 | >= 0.25 -< 1 |
| dichlorophenyl)amino]phenyl]acetate |            |              |
| Sodium hydroxymethanesulphinate     | 149-44-0   | < 1          |

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.

Get medical attention.

In case of contact, immediately flush skin with soap and plenty In case of skin contact

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. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

delayed

Causes serious eye irritation.

May damage fertility. May damage the unborn child.

Protection of first-aiders First Aid responders should pay attention to self-protection.

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

Exposure to combustion products may be a hazard to health.

fighting

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)



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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.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emergency 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.

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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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.

#### 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.

Avoid breathing mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.



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Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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

environment.

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:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components   | CAS-No.   | Value type<br>(Form of                       | Control parameters / Permissible | Basis    |  |  |
|--|---|--|----------------------------------|----------|--|--|
|  |   | exposure)                                    | concentration                    |          |  |  |
| oxytetracycline  | 79-57-2   | TWA  | 500 μg/m3 (OEB<br>2)             | Internal |  |  |
|  | Further inform  | Further information: DSEN                    |                                  |          |  |  |
|  |   | Wipe limit                                   | 100 µg/100 cm <sup>2</sup>       | Internal |  |  |
| Magnesium oxide  | 1309-48-4   | NAB (Inhala-<br>ble particu-<br>late matter) | 10 mg/m3                         | ID OEL   |  |  |
|  | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |  |                                  |          |  |  |
|  |   | TWA (Inhal-<br>able particu-<br>late matter) | 10 mg/m3                         | ACGIH    |  |  |
| Sodium [2-[(2,6-<br>dichloro-<br>phenyl)amino]phenyl]acetate | 15307-79-6  | TWA  | 100 μg/m3 (OEB<br>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 expo-

sure assessment demonstrates exposures outside the rec-



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ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour 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

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 work-

ing 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** liquid

Colour light brown

Odour No data available

Odour Threshold No data available

pН 8.3 - 9.0

(as aqueous solution)

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

No data available Flash point

No data available Evaporation rate

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available



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Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.05 - 1.18 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 47.62 mm2/s

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation



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exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

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

Method: Calculation method

**Components:** 

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

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

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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity



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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): > 2,000 mg/kg

Method: OECD Test Guideline 423

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

icity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

oxytetracycline:

Remarks : No data available



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Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

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

Result : irritating

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

oxytetracycline:

Remarks : No data available

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

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

Method : OECD Test Guideline 405



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### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

## 2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : 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 : Sensitiser

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Magnesium oxide:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

## Sodium hydroxymethanesulphinate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

### Germ cell mutagenicity

Not classified based on available information.



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#### 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

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.



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Benzyl alcohol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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

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

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: positive

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



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cytogenetic assay) Species: Mouse

. Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity 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
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

### Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

### Magnesium oxide:

Species : Mouse
Application Route : Ingestion



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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: MouseApplication Route: OralExposure time: 2 YearsResult: 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 foetal develop-

ment

Test Type: Embryo-foetal 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

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



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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.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Magnesium oxide:

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

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion



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Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

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

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

Effects on fertility : Test Type: Fertility

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 4 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

nent

Test Type: Development

Species: Rat

Application Route: Oral

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

Test Type: Development

Species: Rabbit Application Route: Oral

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

Reproductive toxicity - As-

sessmen

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

Effects on foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.



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#### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

#### 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: DogNOAEL: 125 mg/kgLOAEL: 250 mg/kgApplication Route: OralExposure time: 12 MonthsTarget Organs: Testis

Remarks : Significant toxicity observed in testing

Species : Rat NOAEL : 40 mg/kg



# Oxytetracycline / Diclofenac Liquid Formulation

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LOAEL : 100 mg/kg
Application Route : Intraperitoneal
Exposure time : 14 Days
Target Organs : Kidney

Benzyl alcohol:

Species : Rat

NOAEL : 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Magnesium oxide:

Species : Rat

NOAEL : >= 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

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, Diarrhoea

Sodium hydroxymethanesulphinate:

Species : Rat NOAEL : 600 m

NOAEL : 600 mg/kg Application Route : Ingestion Exposure time : 13 Weeks

Method : OECD Test Guideline 408



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**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, Diarrhoea, constipation, heart-

burn, Ulceration, Dizziness, Headache, Breathing difficulties,

Rash

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

2-Pyrrolidone:

LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : 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



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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-

city)

M-Factor (Chronic aquatic :

toxicity)

Toxicity to microorganisms

EC50: 17.9 mg/l

10

10

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

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Magnesium oxide:

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

Exposure time: 96 h

Remarks: Based on data from similar materials



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aquatic invertebrates

Toxicity to daphnia and other : 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

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

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l



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aquatic invertebrates Exposure time: 48 h

Method: OECD Test Guideline 202

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

plants Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox- : NOEC (Danio rerio (zebra fish)): 13.5 mg/l

icity) Exposure time: 35 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : EC10 (Daphnia magna (Water flea)): 8 mg/l

aquatic invertebrates (Chron- Exposure time: 21 d

ic toxicity) Method: OECD Test Guideline 211

Toxicity to microorganisms : NOEC: 10 mg/l

Exposure time: 4 h

#### Persistence and degradability

## **Components:**

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

**Bioaccumulative potential** 

**Components:** 

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107



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Benzyl alcohol:

Partition coefficient: n- : log Pow: 1.05

octanol/water

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

Partition coefficient: n- : log Pow: 4.51

octanol/water

Sodium hydroxymethanesulphinate:

Partition coefficient: n- : log Pow: < 0.3

octanol/water

Mobility in soil
No data available

Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### 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 : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

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

(oxytetracycline)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen- : 964



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ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

Marine pollutant

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

yes

(oxytetracycline)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F

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.

## 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable



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control, Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

Revision Date : 2024/09/28

**Further information** 

Sources of key data used to compile the Safety Data

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/

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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 Develop-



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ment; 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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