

## Oxytetracycline / Diclofenac Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 4156031-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Skin corrosion/irritation : Category 3

Serious eye damage/eye irritation : Category 2B

Skin sensitisation : 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

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- Hazard pictograms : 
- Signal word : Danger
- 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:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe mist or vapours.  
P264+P265 Wash hands thoroughly after handling. Do not touch eyes.  
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.  
P318 IF exposed or concerned, get medical advice.  
P333 + P317 If skin irritation or rash occurs: Get medical help.  
P337 + P317 If eye irritation persists: Get medical help.  
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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

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Chemical name	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	616-45-5	$\geq 50 - < 70$
oxytetracycline	79-57-2	$\geq 20 - < 25$
Magnesium oxide	1309-48-4	$\geq 1 - < 5$
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	$\geq 1 - < 2.5$
Sodium hydroxymethanesulphinate	6035-47-8	$\geq 0.1 - < 1$

### 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

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Sodium oxides

- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency 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 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 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.
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### 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 the mist or vapours.  
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.
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- Conditions for safe storage : Take care to prevent spills, waste and minimize release to the environment.  
Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.
- Materials to avoid : Store in accordance with the particular national regulations.  
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 (Form of exposure)	Control parameters / Permissible concentration	Basis
oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Magnesium oxide	1309-48-4	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m <sup>3</sup> (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 : Combined particulates and organic vapour type
- Hand protection : Chemical-resistant gloves
- Material
- 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.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye

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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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	brown, Greenish yellow
Odour	:	characteristic
Odour 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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1.15 - 1.19 (25 °C)
Density	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-	:	Not applicable

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octanol/water  
Auto-ignition temperature : No data available

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

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 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 toxicity

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

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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 toxicity  
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 hydroxymethanesulphinat:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402



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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  
Method : OECD Test Guideline 405  
Result : No eye irritation  
Remarks : Based on data from similar materials

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

Result : Mild eye irritation

##### **Sodium hydroxymethanesulphinate:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

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Remarks : Based on data from similar materials

### 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

##### 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  
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

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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  
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

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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 humans.

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

### **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 foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive

Reproductive toxicity - Assessment : 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.

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### **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 capacity, No significant adverse effects were reported

Effects on foetal development : 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 - Assessment : 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

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Effects on foetal development : 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 development : 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 - Assessment : 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

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### **STOT - single exposure**

Not classified based on available information.

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### STOT - repeated exposure

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

### 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:**



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Species : Rat  
NOAEL :  $\geq 1,000$  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 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, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **2-Pyrrolidone:**

- 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 toxicity) : 10
- Toxicity to microorganisms : EC50: 17.9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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NOEC: 0.2 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity) : 10

### **Magnesium oxide:**

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
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 toxicity) : NOEC: 0.32 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### **Sodium hydroxymethanesulphinat:**

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

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 microorganisms : EC50: > 1,000 mg/l  
Exposure time: 4 h  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 13.5 mg/l  
Exposure time: 35 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 5.6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
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 hydroxymethanesulphinat:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 77 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

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### Bioaccumulative potential

#### Components:

##### 2-Pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0.71  
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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## 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.

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## 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 aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

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### IMDG-Code

UN number	: UN 3082
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

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

## 15. REGULATORY INFORMATION

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

#### 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 : 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 Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AllC - 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

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x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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