

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Oxytetracycline / Diclofenac Liquid Formulation

Version 5.0      Revision Date: 09/28/2024      SDS Number: 1313819-00019      Date of last issue: 09/30/2023  
Date of first issue: 02/20/2017

### SECTION 1. IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Liquid Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation : Category 2A  
Skin sensitization : Category 1  
Reproductive toxicity : Category 1A

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H360FD May damage fertility. May damage the unborn child.

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 vapors.  
P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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 attention.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.

P337 + P313 If eye irritation persists: Get medical attention.

P363 Wash contaminated clothing before reuse.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	616-45-5	>= 30 - < 50
Oxytetracycline	79-57-2	>= 20 - < 30
Benzyl alcohol	100-51-6	>= 1 - < 5
Magnesium oxide	1309-48-4	>= 1 - < 5
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	>= 0.1 - < 1
Sodium hydroxymethanesulphinate	149-44-0	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

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- |   |   |   |
|---|---|---|
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.          |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>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.   |

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### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water. |

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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.  
Avoid breathing 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.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration	
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
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Magnesium oxide	1309-48-4	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (fume, total particulate)	15 mg/m <sup>3</sup>	OSHA Z-1
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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**  
**Material** : Chemical-resistant gloves

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.  
**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

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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	:	light brown
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	8.3 - 9.0 (as aqueous solution)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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	:	No data available
Density	:	1.05 - 1.18 g/cm <sup>3</sup>
Solubility(ies) Water solubility	:	soluble

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Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	47.62 mm <sup>2</sup> /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

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### SECTION 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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### SECTION 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
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#### 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-
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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

### 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 inhalation toxicity

### 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



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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 toxicity  
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

#### 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.

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### 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 hydroxymethanesulphinat:**

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

### **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)

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Result : Sensitizer

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

### 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

### 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  
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

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### 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.

### 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

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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 hydroxymethanesulphinat:**

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  
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

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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 humans.

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

### 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  
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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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### 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 - 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.

##### **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 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.

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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 - Assessment : 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 fetal development : Test Type: Embryo-fetal 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  
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  
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



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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 - Assessment : Suspected of damaging the unborn child.

### **Sodium hydroxymethanesulphinat:**

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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive

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

### **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.

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### 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

##### **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
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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, Diarrhea

### Sodium hydroxymethanesulphinat:

Species : Rat  
NOAEL : 600 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks  
Method : OECD Test Guideline 408

### 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

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### SECTION 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
Toxicity to microorganisms	:	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

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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 mg/l  
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 (Chronic 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

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

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## Oxytetracycline / Diclofenac Liquid Formula- tion

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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 (Pimephales promelas (fathead minnow)): 0.32 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

### Sodium hydroxymethanesulphinat:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l 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 toxicity)	:	NOEC (Danio rerio (zebra fish)): 13.5 mg/l Exposure time: 35 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10 (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	NOEC: 10 mg/l Exposure time: 4 h

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### 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-octanol/water : log Pow: -0.71  
Method: OECD Test Guideline 107

##### **Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

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

Partition coefficient: n-octanol/water : log Pow: 4.51

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

Partition coefficient: n-octanol/water : log Pow: < 0.3

#### **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 : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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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 : 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

##### 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

UN/ID/NA number : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : CLASS 9



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ERG Code : 171  
Marine pollutant : yes(Oxytetracycline)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization  
Reproductive toxicity  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

2-Pyrrolidone	616-45-5
Water	7732-18-5
Oxytetracycline	79-57-2
Polyvinyl pyrrolidone	9003-39-8
Benzyl alcohol	100-51-6
Magnesium oxide	1309-48-4

#### California Prop. 65

WARNING: This product can expose you to chemicals including Oxytetracycline, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

Polyvinyl pyrrolidone	9003-39-8
Magnesium oxide	1309-48-4

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### California Permissible Exposure Limits for Chemical Contaminants

Magnesium oxide

1309-48-4

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

AICS : not determined

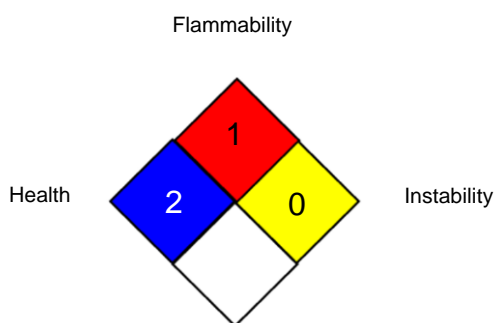
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
ACGIH / TWA : 8-hour, time-weighted average  
OSHA Z-1 / TWA : 8-hour time weighted average  
US WEEL / TWA : 8-hr TWA

AllC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with

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x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

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

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.

US / Z8