

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxytetracycline / Diclofenac Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 2

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.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

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)	ENCS No.
2-Pyrrolidone	616-45-5	>= 40 - < 50	5-112
oxytetracycline	79-57-2	20	9-271
Benzyl alcohol	100-51-6	>= 1 - < 10	3-1011
Magnesium oxide	1309-48-4	>= 1 - < 10	1-465

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

Sodium hydroxymethanesulphinate	149-44-0	$\geq 0.1 - < 1$	2-1633
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	$\geq 0.25 - < 1$	3-3082

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.
- 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 : May cause an allergic skin reaction.
 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-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
 Nitrogen oxides (NO_x)
- 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

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

Special protective equipment for firefighters : so.
Evacuate area.
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

7. HANDLING AND STORAGE

Handling

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.
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.

Avoidance of contact : Oxidizing agents

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

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.

Storage

- 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
oxytetracycline	79-57-2	TWA	500 µg/m ³ (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 µg/100 cm ²	Internal
Benzyl alcohol	100-51-6	OEL-C	25 mg/m ³	JP OEL JSOH
	Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.			
Magnesium oxide	1309-48-4	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m ³ (OEB 2)	Internal
	Further information: Skin			

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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 | : | |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|--|---|------------------------------------|
| Physical state | : | liquid |
| Colour | : | light brown |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Boiling point, initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 8.3 - 9.0
(as aqueous solution) |
| Evaporation rate | : | No data available |

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : 47.62 mm²/s

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Density : 1.05 - 1.18 g/cm³

Relative vapour density : No data available

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 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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Product:

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
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
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): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

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 hydroxymethanesulphinat:

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

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

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 hydroxymethanesulphinat:

Species : Rat
Result : No skin irritation

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

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

||Result : irritating

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 hydroxymethanesulphinat:

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

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

||Result : Mild eye irritation

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

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

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.

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)

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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.

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

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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 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 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 mutagenicity tests.

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

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 / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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 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

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

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.

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.

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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 foetal development : 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
 Method: OECD Test Guideline 422
 Result: negative
 Remarks: Based on data from similar materials

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 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 development : Test Type: Embryo-foetal 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.

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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.

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
---------	---------

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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
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 hydroxymethanesulphinate:

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

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
---------	-------

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

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

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:

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 / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

II

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

M-Factor (Chronic aquatic toxicity) : 10

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
 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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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 hydroxymethanesulphinate:

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

II**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 (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

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
 Date of first issue: 2017/02/20

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 hydroxymethanesulphinate:

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

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

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

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
 Do not dispose of waste into sewer.
 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.

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

IATA-DGR

UN/ID No. : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

(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.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Oxytetracycline / Diclofenac Liquid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 1313813-00017 Date of last issue: 2022/10/01
Date of first issue: 2017/02/20

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Benzyl alcohol	>=1 - <10	-
magnesium oxide	>=1 - <10	From April 1st, 2026

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
benzyl alcohol	-
magnesium oxide	From April 1st, 2026

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Until March 31st, 2023

Not applicable

From April 1st, 2023

Class I Designated Chemical Substances

Chemical name	Administration number	Concentration (%)
(4S,4aR,5S,5aR,6S,12aS)-4-(Dimethylamino)-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracen-2-carboxamide	648	20

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**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/>

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)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	1313813-00017	Date of first issue: 2017/02/20

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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; KECl - 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; TECl - 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.

JP / EN