SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	28.09.2024	4156026-00016	Date of first issue: 17.04.2019

SECTION 1. IDENTIFICATION

Product identifier : Oxytetracycline / Diclofenac Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Skin irritation : Category 3

Eye irritation : Category 2B

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

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:

P201 Obtain special instructions before use.
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.
P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
2-Pyrrolidone	616-45-5	Eye Irrit., 2B Repr., 1B	>= 50 -< 70
Oxytetracycline	79-57-2	Skin Sens., 1A Repr., 1A Aquatic Acute, 1 Aquatic Chronic, 1	>= 20 -< 25
Magnesium oxide	1309-48-4		>= 1 -< 5
Sodium [2-[(2,6-dichloro-	15307-79-6	Acute Tox. (Oral), 3 Skin Irrit., 2	>= 1 -< 2,5

phenyl)amino]phenyl]acetate		Eye Irrit., 2B Repr., 2 STOT RE, (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) , 1 Aquatic Acute, 3 Aquatic Chronic, 2	
Sodium hydroxymethanesulphinate	6035-47-8	Muta., 2 Repr., 2	>= 0,1 -< 1

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 plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes mild skin irritation. May cause an allergic skin reaction. Causes eye irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine compounds Nitrogen oxides (NOx) 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling	:	Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oxytetracycline	79-57-2	TWA	500 µg/m3 (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 µg/100 cm^2	Internal
Magnesium oxide	1309-48-4	TWA (Inhalable particulate matter)	10 mg/m^3	ACGIH
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m3 (OEB 2)	Internal
	Further information: Skin			

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Color	:	brown, Greenish yellow
Odor	:	characteristic
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	-33 °C
Initial boiling point and boiling range	:	100,5 °C
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1,15 - 1,19 (25 °C)
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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 characteristics		
Particle size	:	Not applicable

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.

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

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

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 hydroxymethanesulphinate:

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 Remarks: Based on data from similar materials

Skin corrosion/irritation

Causes mild skin irritation.

Components:

2-Pyrrolidone:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Oxytetracycline:

Remarks	:	No data available

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

Result	:	irritating

Sodium hydroxymethanesulphinate:

Species	:	Rat
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Serious eye damage/eye irritation

Causes eye irritation.

Components:

2-Pyrrolidone:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 7 days

Oxytetracycline:

Remarks	:	No data available

Magnesium oxide:

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

Remarks : Based on data from similar materials

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

Result : Mild eye irritation

Sodium hydroxymethanesulphinate:

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

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)
Result : Sensitizer

Magnesium oxide:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Sodium hydroxymethanesulphinate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative

Oxytetracycline:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Result: negative Test Type: Mouse Lymphoma Metabolic activation: Metabolic activation Result: positive Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: equivocal Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: equivocal Test Type: in vivo assay Species: Mouse Application Route: Intraperitoneal injection Result: negative
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Magnesium oxide:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471

Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

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

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: CHO Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: positive Remarks: Based on data from similar materials
Germ cell mutagenicity - Assessment	:	Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	18 month(s)
Result	:	negative
Remarks	:	Based on data from similar materials

Oxytetracycline:

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

Species	:	Rat
Application Route	:	Oral
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 fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: positive
Reproductive toxicity - As-	:	Clear evidence of adverse effects on sexual function and

sessment		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. 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.

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 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 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 fetal development	:	Test Type: Embryo-fetal 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.

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:

Species	:	Rat
NOAEL	:	>= 1.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Method	:	OECD Test Guideline 407
Remarks	:	Based on data from similar materials

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

Species	:	Rat
LOAEL	:	0,25 mg/kg
Application Route	:	Oral
Exposure time	:	98 w
Target Organs	:	Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

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

Species	:	Baboon
NOAEL	:	0,5 mg/kg
LOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	52 w
Target Organs	:	Gastrointestinal tract, Blood
Symptoms	:	constipation, Diarrhea

Sodium hydroxymethanesulphinate:

Species	:	Rat
NOAEL	:	600 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Oxytetracycline:

Ingestion	:	Symptoms: Gastrointestinal disturbance, tooth discoloration Remarks: May cause birth defects.

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

Ingestion	:	Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:

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
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

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 (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 hydroxymethanesulphinate:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 13,5 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 5,6 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC50: > 1.000 mg/l Exposure time: 4 h Remarks: Based on data from similar materials

Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials

Sodium hydroxymethanesulphinate:

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

Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n-octanol/water	:	log Pow: -0,71 Method: OECD Test Guideline 107

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

Partition coefficient: n-	:	log Pow: 4,51

octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class	:	9
Packing group	:	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

ANTT

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class	:	9
Packing group	:	III
Labels	:	9
Hazard Identification Number	:	90

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

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
Brazil. List of chemicals controlled by the Federal Police	:	Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	:	28.09.2024
Date format	:	dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals 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.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and 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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