

Oxytetracycline / Diclofenac Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4156038-00014 Date of last issue: 04.04.2023
Date of first issue: 17.04.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Oxytetracycline / Diclofenac Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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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.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

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

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD	>= 50 - < 70
oxytetracycline	79-57-2 201-212-8	Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute)	>= 20 - < 25

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		aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6 239-346-4	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) Aquatic Chronic 2; H411	>= 1 - < 2,5
Sodium hydroxymethanesulphinate	6035-47-8	Muta. 2; H341 Repr. 2; H361d	>= 0,1 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause an allergic skin reaction.
Causes serious eye irritation.

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May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)
Sodium oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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).

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Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep in properly labelled containers. Store locked up. Keep

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areas and containers tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
oxytetracycline	79-57-2	TWA	500 µg/m ³ (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Magnesium oxide	1309-48-4	OEL-RL	10 mg/m ³ (Magnesium)	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m ³
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17,1 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5,2 mg/kg bw/day

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	Consumers	Ingestion	Acute systemic effects	33,3 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
2-Pyrrolidone	Fresh water	0,5 mg/l
	Freshwater - intermittent	0,5 mg/l
	Marine water	0,05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0,4205 mg/kg dry weight (d.w.)
	Soil	0,0612 mg/kg dry weight (d.w.)
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

8.2 Exposure controls**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

Eye/face 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.

Hand protection
 Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

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Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	liquid
Colour	:	brown, Greenish yellow
Odour	:	characteristic
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	-33 °C
Initial boiling point and boiling range	:	100,5 °C
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1,15 - 1,19 (25 °C)
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	50,3 - 50,7 mPa.s (25 °C)
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

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Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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: > 2.000 mg/kg
Method: Calculation method

Components:**2-Pyrrolidone:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

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Method: OECD Test Guideline 402
 Assessment: The substance or mixture has no acute dermal toxicity

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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

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

Not classified based on available information.

Components:**2-Pyrrolidone:**

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

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Remarks : No data available

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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 serious eye irritation.

Components:**2-Pyrrolidone:**

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

oxytetracycline:

Remarks : No data available

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

Result : Mild eye irritation

Sodium hydroxymethanesulphinate:

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

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**2-Pyrrolidone:**

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

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Test Type : Human repeat insult patch test (HRIPT)

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Result : Sensitiser

Sodium hydroxymethanesulphinate:

Test Type : Maximisation Test
 Exposure routes : Skin contact
 Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : negative
 Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:**2-Pyrrolidone:**

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

Test Type: In vitro mammalian cell gene mutation test
 Method: OECD Test Guideline 476
 Result: negative
 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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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

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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.

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

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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

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

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Mouse
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**2-Pyrrolidone:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: positive
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

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Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral

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- Fertility: NOAEL: 18 mg/kg body weight
 Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported
- Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
 Result: Postimplantation loss., Skeletal malformations
- Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight
 Embryo-foetal toxicity: NOAEL: 1.500 mg/kg body weight
 Result: No teratogenic effects
 Remarks: Maternal toxicity observed.
- Test Type: Embryo-foetal development
 Species: Mouse
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight
 Embryo-foetal toxicity: NOAEL: 2.100 mg/kg body weight
 Result: No teratogenic effects
 Remarks: Maternal toxicity observed.
- Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Intramuscular
 Embryo-foetal toxicity: LOAEL: 41,5 mg/kg body weight
 Result: Postimplantation loss., No foetal abnormalities
- Test Type: Embryo-foetal development
 Species: Dog
 Application Route: Intramuscular
 Embryo-foetal toxicity: LOAEL: 20,75 mg/kg body weight
 Result: Skeletal and visceral variations, Postimplantation loss.
- Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

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

- Effects on fertility : Test Type: Fertility
 Species: Rat, male and female
 Application Route: Oral
 Fertility: NOAEL: 4 mg/kg body weight
 Result: No effects on fertility
- Effects on foetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 1 mg/kg body weight
 Result: Embryo-foetal toxicity, No teratogenic effects

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Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL: 5 mg/kg body weight
 Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

Sodium hydroxymethanesulphinate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 422
 Result: negative
 Remarks: Based on data from similar materials

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs 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

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Species : Rat

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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

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

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

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

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

Sodium hydroxymethanesulphinat:

Species : Rat
 NOAEL : 600 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

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Method : OECD Test Guideline 408
 Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****oxytetracycline:**

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

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

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 12: Ecological information**12.1 Toxicity****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

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Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Anabaena): 0,032 mg/l
Exposure time: 72 h

NOEC (Anabaena): 0,0031 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic 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

M-Factor (Chronic aquatic toxicity) : 10

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

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 80,1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC: 0,32 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

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

Sodium hydroxymethanesulphinate:

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

12.2 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

12.3 Bioaccumulative potential

Components:

2-Pyrrolidone:

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

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

Partition coefficient: n-octanol/water : log Pow: 4,51

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

SECTION 14: Transport information**14.1 UN number**

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)

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ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxytetracycline)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxytetracycline)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxytetracycline)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(oxytetracycline)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
 Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9

ADR
 Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9
 Tunnel restriction code : (-)

RID
 Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9

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

IATA (Cargo)
 Packing instruction (cargo aircraft) : 964
 Packing instruction (LQ) : Y964
 Packing group : III
 Labels : Miscellaneous

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IATA (Passenger)

Packing instruction (passenger aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous	:	yes
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ADR

Environmentally hazardous	:	yes
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RID

Environmentally hazardous	:	yes
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IMDG

Marine pollutant	:	yes
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IATA (Passenger)

Environmentally hazardous	:	yes
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IATA (Cargo)

Environmentally hazardous	:	yes
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14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks	:	Not applicable for product as supplied.
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SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS	:	not determined
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DSL	:	not determined
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IECSC	:	not determined
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15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H301	: Toxic if swallowed.
H315	: Causes skin irritation.
H317	: May cause an allergic skin reaction.
H319	: Causes serious eye irritation.
H341	: Suspected of causing genetic defects.
H360D	: May damage the unborn child.
H360FD	: May damage fertility. May damage the unborn child.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H411	: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Irrit.	: Eye irritation
Muta.	: Germ cell mutagenicity
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
ZA OEL	: South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	: Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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

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tative) 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

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/>

Classification of the mixture:

Eye Irrit. 2	H319
Skin Sens. 1	H317
Repr. 1A	H360FD
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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