according to the OSHA Hazard Communication Standard



Oxytetracycline (10%) Liquid Formulation

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SECTION 1. IDENTIFICATION

Product name : Oxytetracycline (10%) Liquid Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin irritation : Category 2

Eye irritation : Category 2A

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Other hazards

None known.

GHS label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H360D May damage the unborn child.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing mist or vapors. P264 Wash skin thoroughly after handling.

P272 Contaminated work clothing must not be allowed out of

according to the OSHA Hazard Communication Standard



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the workplace.

P280 Wear protective gloves, protective clothing, eye protection

and 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 attention. P333 + P313 If skin irritation or rash occurs: Get medical atten-

tion.

P337 + P313 If eye irritation persists: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before

reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|--------------------------------------|----------------------|-----------------------|-----------------|
| Propylene glycol | 57-55-6* | >= 45 - <= 70 | TSC |
| Oxytetracycline | 79-57-2* | >= 7 - <= 13 | TSC |
| Glycerine | 56-81-5* | >= 5 - <= 10 | TSC |
| Ethanolamine | 141-43-5* | >= 0.5 - <= 1.5 | TSC |
| Sodium hy- droxymethanesulphinate | 6035-47-8* | >= 0.1 - <= 1 | TSC |

^{*} Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water

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for at least 15 minutes while removing 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.

Causes skin irritation.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delaved

May cause an allergic skin reaction. Causes serious eye irritation.

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).

Treat symptomatically and supportively. Notes to physician

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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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

according to the OSHA Hazard Communication Standard



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Avoid release to the environment. Environmental precautions

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

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.

Avoid breathing mist or vapors.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Take care to prevent spills, waste and minimize release to the

environment.

Keep in properly labeled containers. Conditions for safe storage

> Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Do not store with the following product types: Materials to avoid

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

according to the OSHA Hazard Communication Standard



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|---------------------------|-------------------------------------|--|-----------|
| Propylene glycol | 57-55-6 | TWA | 10 mg/m ³ | US WEEL |
| Oxytetracycline | 79-57-2 | TWA | 500 μg/m3 (OEB 2) | Internal |
| | Further information: DSEN | | | |
| | | Wipe limit | 100 μg/100 cm ² | Internal |
| Ethanolamine | 141-43-5 | TWA | 3 ppm | ACGIH |
| | | STEL | 6 ppm | ACGIH |
| | | TWA | 3 ppm 8 mg/m ³ | NIOSH REL |
| | | ST | 6 ppm 15 mg/m³ | NIOSH REL |
| | | TWA | 3 ppm 6 mg/m³ | OSHA Z-1 |

Use appropriate engineering controls and manufacturing **Engineering measures**

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection General and local exhaust ventilation is recommended to

> maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air

supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions.

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection

Work uniform or laboratory coat.

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

according to the OSHA Hazard Communication Standard



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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : light yellow

amber

translucent

Odor : No data available

Odor Threshold : No data available

pH : 8.0 - 9.0

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.050 - 1.250 g/cm³

according to the OSHA Hazard Communication Standard



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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

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 reac- : Can react with strong oxidizing agents.

ions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

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

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l

Exposure time: 4 h
Test atmosphere: vapor

according to the OSHA Hazard Communication Standard



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Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

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

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Ethanolamine:

Acute oral toxicity : LD50 (Rat): 1,089 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l

Exposure time: 4 h
Test atmosphere: vapor
Method: Expert judgment

Remarks: Based on national or regional regulation.

Assessment: Not corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 mg/kg

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Ш

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 skin irritation.

Components:

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Oxytetracycline:

Remarks : No data available

Glycerine:

Species : Rabbit

Result : No skin irritation

Ethanolamine:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

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:

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Oxytetracycline:

Remarks : No data available

according to the OSHA Hazard Communication Standard



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Glycerine:

Species Rabbit

Result No eye irritation

Ethanolamine:

Species Rabbit

Result Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

Species

Result No eye irritation

: OECD Test Guideline 405 Method

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:

Propylene glycol:

Test Type : Maximization Test : Skin contact Routes of exposure Species : Guinea pig Result : negative

Oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result Sensitizer

Ethanolamine:

Test Type : Maximization Test Routes of exposure Skin contact Species : Guinea pig Result : negative

Sodium hydroxymethanesulphinate:

: Maximization Test Test Type Skin contact
Guinea pig
OECD Test Guideline 406
negative Routes of exposure Species Method

Result

Remarks : Based on data from similar materials

according to the OSHA Hazard Communication Standard



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Germ cell mutagenicity

Not classified based on available information.

Components:

Propylene glycol:

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

Result: negative

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

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.

Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

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Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Ethanolamine:

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

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

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 muta-

genicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:

Species : Rat Application Route : Ingestion

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Exposure time : 2 Years
Result : negative

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 hu-

mans.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Glycerine:

Species : Rat

Application Route : Ingestion

Exposure time : 2 Years

Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Oxytetracycline:

according to the OSHA Hazard Communication Standard



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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 - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

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Application Route: Ingestion

Result: negative

Ethanolamine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

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: negative

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 - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : No significant health effects observed in animals at concentra-

tions of 0.2 mg/l/6h/d or less.

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Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male NOAEL : >= 1,700 mg/kgApplication Route : Ingestion Exposure time : 2 y

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 Exposure time Oral 13 Weeks Target Organs Bone

Remarks No significant adverse effects were reported

Application Route
Exposure time
Target Organs
Remarks Dog 125 mg/kg 250 mg/kg Oral : 12 Months Testis

Significant toxicity observed in testing

Species : Rat

NOAEL : 40 mg/kg

LOAEL : 100 mg/kg

Application Route : Intraperitoneal

112 Days

Kidney Target Organs Kidney

Glycerine:

Species Rat NOAEL : 0.167 mg/l LOAEL : 0.622 mg/l

: inhalation (dust/mist/fume) Application Route

Exposure time : 13 Weeks

Species : Rat

NOAEL 8,000 - 10,000 mg/kg

Application Route Ingestion Exposure time 2 y

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Species Rabbit NOAEL 5,040 mg/kg Application Route Skin contact Exposure time 45 Weeks

Ethanolamine:

Species Rat

NOAEL : > 120 mg/kgApplication Route : Ingestion Exposure time > 75 Days

Remarks Based on data from similar materials

Species Rat

NOAEL >= 0.15 mg/l

inhalation (dust/mist/fume) Application Route

Exposure time 28 Davs

OECD Test Guideline 412 Method

Sodium hydroxymethanesulphinate:

Species Rat NOAEL

600 mg/kg Application Route Ingestion Exposure time 90 Days

OECD Test Guideline 408 Method

Based on data from similar materials Remarks

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.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

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plants Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to microorganisms NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

Exposure time: 7 d

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 (Moina macrocopa (Water flea)): 126.7 mg/l

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena): 0.032 mg/l

Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50 (activated sludge): 17.9 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC (activated sludge): 0.2 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,955 mg/l

Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l

> Exposure time: 16 h Method: DIN 38 412 Part 8

Ethanolamine:

Toxicity to fish LC50 (Cyprinus carpio (Carp)): 349 mg/l

Exposure time: 96 h

according to the OSHA Hazard Communication Standard



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Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 65 mg/l

Exposure time: 48 h

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l

Exposure time: 41 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other: aguatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.85 mg/l

Exposure time: 21 d

Toxicity to microorganisms EC10 (Pseudomonas putida): > 1,000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

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

aquatic invertebrates

Toxicity to daphnia and other : 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 tox-

icity)

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 (Chron-

ic 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

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Remarks: Based on data from similar materials

Persistence and degradability

Components:

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 %

Exposure time: 28 d

Method: OECD Test Guideline 301F

Glycerine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

Ethanolamine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 21 d

Method: OECD Test Guideline 301A

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:

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

Glycerine:

Partition coefficient: n- : log Pow: -1.75

octanol/water

Ethanolamine:

Partition coefficient: n- : log Pow: -2.3

octanol/water Method: OECD Test Guideline 107

Mobility in soilNo data available

according to the OSHA Hazard Communication Standard



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Other adverse effects

No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Oxytetracycline)

9 Class Packing group Ш 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 Ш

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous yes

964

964

IMDG-Code

UN number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(Oxytetracycline)

Class 9 Ш Packing group Labels 9 F-A, S-F **EmS Code** Marine pollutant ves

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

according to the OSHA Hazard Communication Standard



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49 CFR

UN/ID/NA number : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Oxytetracycline)

Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171

Marine pollutant : yes(Oxytetracycline)

Remarks : Above applies only to containers over 119 gallons or 450

liters

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : Respiratory or skin sensitization

Reproductive toxicity Skin corrosion or irritation

Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

| Propylene glycol | 57-55-6 |
|-----------------------|-----------|
| Water | 7732-18-5 |
| Oxytetracycline | 79-57-2 |
| Glycerine | 56-81-5 |
| Polyvinyl pyrrolidone | 9003-39-8 |
| Ethanolamine | 141-43-5 |
| Hydrochloric acid | 7647-01-0 |

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California Prop. 65

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

California List of Hazardous Substances

Polyvinyl pyrrolidone 9003-39-8 Ethanolamine 141-43-5

California Permissible Exposure Limits for Chemical Contaminants

Glycerine 56-81-5 Ethanolamine 141-43-5

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

AICS : not determined

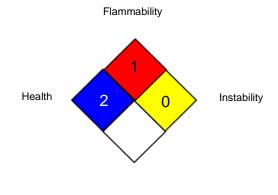
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



Special hazard

HMIS® IV:



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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

according to the OSHA Hazard Communication Standard



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NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded

at any time during a workday

OSHA Z-1 / TWA : 8-hour time weighted average

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance: ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 06/20/2025

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided

according to the OSHA Hazard Communication Standard



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relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8