according to GB/T 16483 and GB/T 17519



Tulathromycin Formulation

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tulathromycin Formulation

Other means of identification : AROVYN INJECTABLE SOLUTION (90779)

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid

Colorless to pale yellow

Odour : slight

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irri-

tation

Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 1

according to GB/T 16483 and GB/T 17519



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Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms









Signal word : Danger

Hazard statements : H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H318 Causes serious eye damage.

H361 Suspected of damaging fertility or the unborn child.

H372 Causes 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.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. 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 protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse

P391 Collect spillage.

Storage:

P405 Store locked up.

according to GB/T 16483 and GB/T 17519



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Disposal:

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes skin irritation. Causes serious eye damage. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | |
|----------------------------|-------------|-----------------------|--|
| Tulathromycin | 217500-96-4 | >= 10 -< 20 | |
| Hydrochloric acid | 7647-01-0 | >= 3 -< 5 | |
| Citric acid | 77-92-9 | >= 1 -< 10 | |
| Sodium hydroxide | 1310-73-2 | >= 1 -< 2 | |
| 3-Mercaptopropane-1,2-diol | 96-27-5 | >= 0.25 -< 1 | |

4. FIRST AID MEASURES

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

vice 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

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 immediately.

If swallowed, DO NOT induce vomiting.

Get medical attention.

according to GB/T 16483 and GB/T 17519



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Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Causes skin irritation.

delayed

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

Suspected of damaging fertility or the unborn child.

Causes 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Chlorine compounds

Metal oxides

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

90

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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

parriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

according to GB/T 16483 and GB/T 17519



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cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

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.

Use only with adequate ventilation.

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

sessment

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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

according to GB/T 16483 and GB/T 17519



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| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis | | |
|-------------------|----------------|-------------------------------------|--|----------|--|--|
| Tulathromycin | 217500-96-4 | TWA | 300 μg/m3 (OEB 2) | Internal | | |
| | Further inform | Further information: DSEN | | | | |
| | | Wipe limit | 100 μg/100 cm2 | Internal | | |
| Hydrochloric acid | 7647-01-0 | MAC | 7.5 mg/m3 | CN OEL | | |
| | | С | 2 ppm | ACGIH | | |
| Sodium hydroxide | 1310-73-2 | MAC | 2 mg/m3 | CN OEL | | |
| | | С | 2 mg/m3 | ACGIH | | |

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist,

handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and acidic gas/vapour type

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.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

eye flushing systems and safety showers close to the work-

ing 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.

according to GB/T 16483 and GB/T 17519



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> 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance liquid

Colour Colorless to pale yellow

Odour slight

Odour Threshold No data available

Hq 5.1 - 5.7

Melting point/freezing point 190 - 192 °C

Initial boiling point and boiling

range

No data available

Flash point No data available

Evaporation rate No data available

Not applicable Flammability (solid, gas)

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

No data available Vapour pressure

Relative vapour density No data available

Relative density No data available

1.07 g/cm³ Density

Solubility(ies)

Water solubility > 1,000 mg/l

Partition coefficient: n-

octanol/water

Auto-ignition temperature No data available

log Pow: -1.41

according to GB/T 16483 and GB/T 17519



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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 : 806.09 g/mol

Particle characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

: None known.

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

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Method: Calculation method

Components:

Tulathromycin:

Acute oral toxicity : LD50 (Dog): > 1,000 mg/kg

Target Organs: Gastrointestinal tract

LD50 (Rat): > 2,000 mg/kg

Target Organs: Gastrointestinal tract

according to GB/T 16483 and GB/T 17519



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

Target Organs: Gastrointestinal tract

Hydrochloric acid:

Acute inhalation toxicity : LC50 (Rat): 8.3 mg/l

Exposure time: 30 min
Test atmosphere: dust/mist

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

3-Mercaptopropane-1,2-diol:

Acute oral toxicity : LD50 (Rat): 648 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 673 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Tulathromycin:

Species : Rabbit

Result : No skin irritation

Hydrochloric acid:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 431

Result : Corrosive after 3 minutes or less of exposure

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Sodium hydroxide:

according to GB/T 16483 and GB/T 17519



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Result : Corrosive after 3 minutes or less of exposure

3-Mercaptopropane-1,2-diol:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Tulathromycin:

Species : Rabbit

Result : Irreversible effects on the eye

Hydrochloric acid:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : Irreversible effects on the eye

Citric acid:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Sodium hydroxide:

Result : Irreversible effects on the eye Remarks : Based on skin corrosivity.

3-Mercaptopropane-1,2-diol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Tulathromycin:

Test Type : Maximisation Test Exposure routes : Skin contact

according to GB/T 16483 and GB/T 17519



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Species : Guinea pig

Assessment : May cause sensitisation by skin contact.

Result : Causes sensitisation.

Hydrochloric acid:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : negative

3-Mercaptopropane-1,2-diol:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Tulathromycin:

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

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: Rat Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Hydrochloric acid:

Genotoxicity in vitro : Test Type: Saacharomyces cerevisiae, miotic recombination

according to GB/T 16483 and GB/T 17519



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assay (in vitro)

Result: negative

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

3-Mercaptopropane-1,2-diol:

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: 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

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Tulathromycin:

Carcinogenicity - Assess-

: No data available

ment

Hydrochloric acid:

Species : Rat
Application Route : Inhalation
Exposure time : 128 weeks
Result : negative

according to GB/T 16483 and GB/T 17519



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Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Tulathromycin:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Oral

Fertility: NOAEL: 100 mg/kg body weight

Result: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 15 mg/kg body weight

Teratogenicity: NOAEL: 15 mg/kg body weight

Result: Postimplantation loss.

Test Type: Embryo-foetal development

Application Route: Oral

General Toxicity Maternal: NOAEL: 15 mg/kg body weight

Teratogenicity: NOAEL: 15 mg/kg body weight

Result: Maternal toxicity observed.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

Citric acid:

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

3-Mercaptopropane-1,2-diol:

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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

according to GB/T 16483 and GB/T 17519



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STOT - single exposure

Not classified based on available information.

Components:

Tulathromycin:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Hydrochloric acid:

Assessment : May cause respiratory irritation.

Citric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Tulathromycin:

Exposure routes : Oral Target Organs : Liver, Eye

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Tulathromycin:

Species : Rat

NOAEL : 5 mg/kg

Application Route : Oral

Exposure time : 3 Months

Target Organs : Liver

Symptoms : Liver disorders

Species: DogNOAEL: 5 mg/kgApplication Route: OralExposure time: 3 MonthsTarget Organs: Liver, Eye

Symptoms : Liver disorders, Eye disease

Citric acid:

Species : Rat

 NOAEL
 : 4,000 mg/kg

 LOAEL
 : 8,000 mg/kg

according to GB/T 16483 and GB/T 17519



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Application Route : Ingestion Exposure time 10 Days

3-Mercaptopropane-1,2-diol:

Species Rat

LOAEL : > 100 mg/kg: Ingestion : 55 Days Application Route Exposure time

Method : OECD Test Guideline 422

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Tulathromycin:

Ingestion Symptoms: Diarrhoea, Nausea, Abdominal pain, Vomiting

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Tulathromycin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.044

mg/l

plants

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.014

mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.0023 mg/l

according to GB/T 16483 and GB/T 17519



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> End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Anabaena flos-aquae): 0.00035 mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0028 mg/l End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Synechococcus leopoliensis (blue-green algae)):

0.0012 mg/l End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

M-Factor (Chronic aquatic 100

toxicity)

Toxicity to microorganisms

100

EC50: 41.1 mg/l Exposure time: 3 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

EC10: 0.667 mg/l Exposure time: 3 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

Hydrochloric acid:

Ecotoxicology Assessment

Toxic to aquatic life. Acute aquatic toxicity

Remarks: Based on national or regional regulation.

Citric acid:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

3-Mercaptopropane-1,2-diol:

according to GB/T 16483 and GB/T 17519



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Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 - 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 (Raphidocelis subcapitata (freshwater green alga)): >

10 - 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Raphidocelis subcapitata (freshwater green alga)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (activated sludge): > 1 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Persistence and degradability

Components:

Tulathromycin:

Biodegradability : Result: Not readily biodegradable.

Exposure time: 29 d

Method: OECD Test Guideline 301B

Citric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

3-Mercaptopropane-1,2-diol:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

according to GB/T 16483 and GB/T 17519



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Bioaccumulative potential

Components:

Tulathromycin:

Partition coefficient: n- : log Pow: -1.41

octanol/water pH: 7

Citric acid:

Partition coefficient: n- : log Pow: -1.72

octanol/water

3-Mercaptopropane-1,2-diol:

Partition coefficient: n- : log Pow: -0.84

octanol/water Method: OECD Test Guideline 117

Mobility in soil

No data available

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

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.

(Tulathromycin)

Class : 9

according to GB/T 16483 and GB/T 17519



Tulathromycin Formulation

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Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen- : 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Class : 9
Packing group : III
Labels : 9
Marine pollutant : no

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.

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

according to GB/T 16483 and GB/T 17519



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18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

IECSC not determined

DSL not determined

AICS not determined

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

compile the Safety Data

eChem Portal search results and European Chemicals Agen-

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

Ceiling limit ACGIH / C

CN OEL / MAC Maximum allowable concentration

according to GB/T 16483 and GB/T 17519



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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

Disclaimer

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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