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

1.1 Product identifier

Trade name : Tulathromycin Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions : Not applicable

on use

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage. Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Reproductive toxicity, Category 2 H361: Suspected of damaging fertility or the un-

born child.

Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

exposure, Category 1 longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

orv 1

Long-term (chronic) aquatic hazard, Cat- H410: Very toxic to aquatic life with long lasting

egory 1 effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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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 re-

peated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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. P391 Collect spillage.

Hazardous components which must be listed on the label:

Tulathromycin Hydrochloric acid Sodium hydroxide 3-Mercaptopropane-1,2-diol

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.

Ecological information: 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.

Toxicological information: 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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Tulathromycin	217500-96-4	Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 2; H361 STOT RE 1; H372 (Liver, Eye) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity):	>= 10 - < 20
Hydrochloric acid	7647-01-0 231-595-7 017-002-01-X 01-2119484862-27	100 Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 STOT SE 3; H335 ———————————————————————————————————	>= 3 - < 5
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH014, EUH071	>= 1 - < 2

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		specific concentration limit Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0,5 - < 2 % Eye Irrit. 2; H319 0,5 - < 2 % EUH071 >= 2 %	
3-Mercaptopropane-1,2-diol	96-27-5 202-495-0	Acute Tox. 4; H302 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Irrit. 2; H315 Skin Sens. 1B; H317 Acute toxicity estimate Acute oral toxicity: 645 mg/kg Acute inhalation toxicity (dust/mist): 0,5001 mg/l Acute dermal toxicity: 670 mg/kg	>= 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 ad-

vice 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.

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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.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

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 prod: :

ucts

Carbon oxides

Chlorine compounds

Metal oxides

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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 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.

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 pro-

tective 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).

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 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.

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.

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Local/Total ventilation : Use only with adequate 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 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.

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 areas and containers

: Keep in properly labelled containers. Store locked up. Keep 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
Propylene glycol	57-55-6	TWA	25 ppm 79 mg/m3	FOR-2011- 12-06-1358
Tulathromycin	217500-96- 4	TWA	300 μg/m3 (OEB 2)	Internal
	Further information: DSEN			

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		Wipe limit	100 μg/100 cm2	Internal
Hydrochloric acid	7647-01-0	Т	5 ppm	FOR-2011-
			7 mg/m3	12-06-1358
		TWA	5 ppm	2000/39/EC
			8 mg/m3	
	Further information: Indicative			
		STEL	10 ppm	2000/39/EC
			15 mg/m3	
	Further information: Indicative			
Sodium hydroxide	1310-73-2	Т	2 mg/m3	FOR-2011-
			_	12-06-1358

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Hydrochloric acid	Workers	Inhalation	Long-term local ef- fects	8 mg/m3
	Workers	Inhalation	Acute local effects	15 mg/m3
Sodium hydroxide	Consumers	Inhalation	Long-term local ef- fects	1 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1 mg/m3

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

Substance name	Environmental Compartment	Value
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.)
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	Marine sediment	3,46 mg/kg dry weight (d.w.)
	Soil	33,1 mg/kg dry

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weight (d.w.)

8.2 Exposure controls

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

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

Remarks Consider double gloving.

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, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Filter type Combined particulates and acidic gas/vapour type (E-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state liquid

Colour Colorless to pale yellow

Odour slight

Odour Threshold No data available

Melting point/freezing point 190 - 192 °C

Initial boiling point and boiling : No data available

range

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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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 5,1 - 5,7

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : > 1.000 mg/l

Partition coefficient: n-

octanol/water

: log Pow: -1,41

Vapour pressure : No data available

Relative density : No data available

Density : 1,07 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 806,09 g/mol

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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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 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

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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): 645 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,5 - 1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): 670 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

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Sodium hydroxide:

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

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Sodium hydroxide:

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

3-Mercaptopropane-1,2-diol:

Species : Rabbit

Result : No eye irritation

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

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

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Hydrochloric acid:

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

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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

Carcinogenicity

Not classified based on available information.

Components:

Tulathromycin:

Carcinogenicity - Assess-

ment

: No data available

Hydrochloric acid:

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

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.

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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

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

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Exposure time : 3 Months
Target Organs : Liver

Symptoms : Liver disorders

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Liver, Eye

Symptoms : Liver disorders, Eye disease

Citric acid:

Species : Rat

NOAEL : 4.000 mg/kg
LOAEL : 8.000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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.

Experience with human exposure

Components:

Tulathromycin:

Ingestion : Symptoms: Diarrhoea, Nausea, Abdominal pain, Vomiting

SECTION 12: Ecological information

12.1 Toxicity

Components:

Tulathromycin:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

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Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0,044

mg/l

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

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- :

icity)

100

Toxicity to microorganisms : 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

M-Factor (Chronic aquatic

toxicity)

100

Citric acid:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1.535 mg/l

Exposure time: 24 h

3-Mercaptopropane-1,2-diol:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 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

12.3 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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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.

12.7 Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID 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.

(Tulathromycin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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RID ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Environmentally hazardous substance, liquid, n.o.s. **IATA**

(Tulathromycin)

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 Ш Classification Code M6 Hazard Identification Number : 90 Labels 9

ADR

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

RID

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

IMDG

Packing group Ш Labels 9 F-A, S-F **EmS Code**

IATA (Cargo)

Packing instruction (cargo

964 aircraft)

Packing instruction (LQ) Y964 Packing group Ш

Labels Miscellaneous

IATA (Passenger)

Packing instruction (passen-964

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

rid

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High : Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

IECSC : not determined

DSL : not determined

AICS : not determined

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.

Full text of H-Statements

H290 : May be corrosive to metals. H302 : Harmful if swallowed. H311 : Toxic in contact with skin.

H314 : Causes severe skin burns and eye damage.

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.

H331 : Toxic if inhaled.

H335 : May cause respiratory irritation.

H361 : Suspected of damaging fertility or the unborn child.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

EUH014 : Reacts violently with water. EUH071 : Corrosive to the respiratory tract.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Met. Corr. : Corrosive to metals Repr. : Reproductive toxicity Skin Corr. : Skin corrosion

Skin Corr.

Skin Irrit.

Skin irritation

Skin Sens.

Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure

2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first

list of indicative occupational exposure limit values

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

2000/39/EC / TWA : Limit Value - eight hours 2000/39/EC / STEL : Short term exposure limit FOR-2011-12-06-1358 / : Long term exposure limit

TWA

FOR-2011-12-06-1358 / T : Ceiling

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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; REACH - Regulation (EC) No 1907/2006 of the European

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 Agen-

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

Classification of the mixture:

Classification procedure: Skin Irrit. 2 Calculation method H315 Eye Dam. 1 H318 Calculation method Skin Sens. 1 H317 Calculation method Repr. 2 H361 Calculation method STOT RE 1 H372 Calculation method Calculation method Aquatic Acute 1 H400 Aquatic Chronic 1 H410 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.

NO / EN