

SAFETY DATA SHEETS

This SDS packet was issued with item:

078947422

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078947420 078947421



Tulaven™ 100 (tulathromycin injection)

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Tulaven™ 100 (tulathromycin injection)

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

Use of the substance/mixture : For bovine and swine respiratory disease, infectious bovine keratoconjunctivitis, and bovine foot rot.

1.3. Details of the supplier of the safety data sheet

Ceva Animal Health, LLC
8735 Rosehill Road, Suite 300
Lenexa, KS 66215

1.4. Emergency telephone number

Emergency number : Chemtrec 1 800 424 9300

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Sens. 1 H317
Eye Irrit. 2A H319

Full text of hazard classes and H-statements : see section 16

2.2. Label elements GHS US labeling

Hazard pictograms (GHS US)



GHS07

Signal word (GHS US)

: Warning

Hazard statements (GHS US)

: H317 - May cause an allergic skin reaction
: H319 - Causes serious eye irritation

Precautionary statements (GHS US)

:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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.
P321 - Specific treatment (see Section 4 of this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before use. P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local/regional/national/international regulation.

2.3. Other hazards

No additional information available.

2.4. Unknown acute toxicity (GHS US)

No data available.

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
1,2-Propanediol	(CAS-No.) 57-55-6	*	Not classified
Tulathromycin	(CAS-No.) 217500-96-4	10	Skin Sens. 1, H317 Eye Irrit. 2A, H319 Aquatic, Acute3, H402 Aquatic, Chronic3, H412
Citric acid	(CAS-No.) 77-92-9	**	Eye Irrit. 2A, H319 Comb. Dust
Hydrochloric acid	(CAS-No.) 7647-01-0	**	Skin Corr. 1, H314 Eye Dam. 1, H318
Monothioglycerol	(CAS-No.) 96-27-5	*	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic, Acute3, H402

* Proprietary

**For pH adjustment

Full text of hazard classes and H statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General	: Never give something by mouth to an unconscious person. If you feel unwell, get medical attention.
First-aid measures after inhalation	: Move to fresh air. Get medical attention if difficulty breathing or irritation persists.
First-aid measures after skin contact	: Flush with water for at least 15 minutes. Remove contaminated clothing. Get medical attention if irritation develops or persists.
First-aid measures after eye contact	: Immediately flush with plenty of water for at least 15 minutes. Get medical attention if eye irritation persists.
First-aid measures after ingestion	: Rinse the mouth with water. Do NOT induce vomiting. Get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General	: Skin sensitization. Causes serious eye irritation.
Symptoms/effects after inhalation	: Prolonged exposure may cause irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Causes severe irritation with redness and swelling of the conjunctiva.
Symptoms/effects after ingestion	: May cause adverse effects if ingested.

4.3. Indication of any immediate medical attention and special treatment needed

If exposed or concerned, get medical advice/attention. If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use foam, carbon dioxide, dry chemical or water spray.
Unsuitable extinguishing media	: Do not use water jet or heavy stream, as this may spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
Explosion hazard	: None known.

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear, including respiratory protection. In case of fire, keep unnecessary personnel away. Move containers from fire area if this can be done without risk. Use water spray for cooling exposed containers. Hazardous combustion products: nitrogen oxides, carbon oxides.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General Measures : Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).
Do not get in eyes, on skin, or on clothing. Keep unnecessary personnel away.

6.1.1. For non-emergency personnel

Use appropriate personal protective equipment (PPE). Evacuate unnecessary personnel.

6.1.2. For emergency responders

No action shall be taken involving any personal risk without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Provide adequate ventilation. Wear suitable personal protective equipment (see Section 8) during response.

6.2. Environmental precautions

Avoid dispersal of spilled material, runoff, and contact with soil, waterways, drains and sewers. Inform the relevant authorities in case of environmental release (sewers, waterways, soil, or air). Ensure emergency procedures to cope with accidental releases are in place to avoid contamination of the environment.

6.3. Methods and material for containment and cleaning up

For containment : Ensure adequate ventilation. Wear personal protective equipment (PPE). Stop the flow of material, if this is without risk. Prevent product from entering drains.

Methods for cleaning up : Small spill: Absorb spills with non-combustible absorbent material, and place it in a designated, labeled waste container. Clean surface thoroughly to remove residual contamination. Dispose of via licensed waste disposal contractor. Immediately contact appropriate personnel. Stop leak if it presents no risk.

: Large spill: Stop leak if it presents no risk. Prevent all possible penetration into sewers, waterways, cellars or confined areas. Absorb spills with non-combustible absorbent material, and place it in a designated, labeled waste container. Dispose of via licensed waste disposal contractor. Immediately contact appropriate personnel. Note: see section 1 for emergency contact information and section 13 for waste disposal. Immediately contact appropriate personnel.

6.4. Reference to other sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin, eyes, and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and when leaving work. Avoid breathing vapors, mist, or spray. Avoid prolonged exposure. Avoid accidental injection. Put on appropriate personal protective equipment (see section 8).
Use only with adequate ventilation. Wear appropriate respirator when ventilator system is inadequate. Empty containers or liners may retain product residues. This material and its container must be disposed of in a safe manner.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store as directed by product packaging (see section 10) in a well-ventilated place.
Do not store in direct sunlight. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Thioglycerol (96-27-5)

Not applicable

Tulathromycin (217500-96-4)

Not applicable

Citric acid (77-92-9)

Not applicable

Hydrochloric acid (7647-01-0)

ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
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OSHA	OSHA PEL (Ceiling)	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
NIOSH	NIOSH REL C [ppm]	5 ppm
1,2-Propanediol (57-55-6)		
AIHA	WEEL TWA	10 mg/m ³

8.2. Exposure controls

Appropriate engineering controls	: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. Emergency eye wash fountains and emergency showers are should be in the immediate vicinity of any potential exposure.
Hand protection	: Chemical-resistant, impermeable gloves complying with an approved standard should be worn at all times during handling chemical products.
Skin and Body Protection	: Wear suitable personal protective clothing. Wear impervious protective clothing to prevent skin contact.
Eye/ Face protection	: Safety eyewear complying with an approved standard should be used to avoid exposure to liquid splashes, mists, gases or dusts.
Respiratory Protection	: In case of inadequate ventilation, wear suitable respiratory equipment. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear a properly fitted respirator with a protection factor complying with an approved standard.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless to slightly yellow
Odor	: No data available
Odor threshold	: No data available
pH	: 5.4
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Flammability-Lower Limit	: No data available
Flammability-Upper Limit	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available

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Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

This product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

Contact with incompatible materials. Heat, flames, and sparks. Sunlight.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

No additional information available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Chronic effects	: Not classified

11.2. Information on toxicological effects-Ingredients

Tulaven	
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	11 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h
Thioglycerol (96-27-5)	
ATE US (oral)	500 mg/kg body weight
ATE US (dermal)	300 mg/kg body weight
Tulathromycin (217500-96-4)	
ATE US (oral)	500 mg/kg body weight
Citric acid (77-92-9)	
LD50 oral rat	5 g/kg

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ATE US (oral)	5000 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
1,2-Propanediol (57-55-6)	
LD50 oral rat	20 g/kg
LD50 dermal rabbit	20800 mg/kg
ATE US (oral)	20000 mg/kg body weight
ATE US (dermal)	20800 mg/kg body weight
Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

SECTION 12: Ecological information

12.1. Toxicity

Citric acid (77-92-9)	
LC50 - Fish [1]	1516 mg/l (Exposure time: 96 h - Species: <i>Lepomis macrochirus</i> [static])
1,2-Propanediol (57-55-6)	
LC50 - Fish [1]	51600 mg/l (Exposure time: 96 h - Species: <i>Oncorhynchus mykiss</i> [static])
EC50 - Crustacea [2]	> 1000 mg/l (Exposure time: 48 h - Species: <i>Daphnia magna</i> [Static])
LC50 - Fish [2]	41 – 47 ml/l (Exposure time: 96 h - Species: <i>Oncorhynchus mykiss</i> [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Citric acid (77-92-9)	
Partition coefficient n-octanol/water (Log Pow)	-1.72 (at 20 °C)
1,2-Propanediol (57-55-6)	
BCF - Fish [1]	< 1

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT : Not regulated
In accordance with IMDG : Not regulated
In accordance with IATA : Not regulated
In accordance with TDG : Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

Thioglycerol (96-27-5))

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Citric acid (77-92-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

1,2-Propanediol (57-55-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

1,2-Propanediol (57-55-6)

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

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SECTION 16: Other information

Date of Preparation : 07/15/2021

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment-Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful 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
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.