

# SAFETY DATA SHEET



## Tulathromycin Injectable

Version 1.1      Revision Date: 01/04/2021      SDS Number: 122000016563      Date of last issue: 06/24/2020  
Date of first issue: 06/24/2020

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### SECTION 1. IDENTIFICATION

#### Product information

Product Name : Tulathromycin Injectable  
Synonyms : Increxxa™  
Araxilis™  
SDS Number : 122000016563

**Use** : veterinary medicine

#### Company

Elanco US Inc.  
2500 Innovation Way  
Greenfield, IN 46140  
USA  
+1-877-Elanco1(+1-877-3526261)  
elanco\_sds@elanco.com

**In case of emergency:** CHEMTREC International: +1 703-527-3887 (24 hours)

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Eye irritation : Category 2A  
Skin sensitisation : Category 1

#### GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/ eye protection/ face protection.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and 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.

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### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Tulathromycin	217500-96-4	10
Citric acid	77-92-9	2

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### SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : Not an expected entry route.

In case of skin contact : If skin reactions occur, contact a physician.

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : In case of accidental ingestion, contact your regional poison center or physician immediately.

Most important symptoms and effects, both acute and delayed : No information available.

Notes to physician : No information available.

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### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Fire may cause evolution of:  
Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

Further information : Prevent fire extinguishing water from contaminating surface water or the ground water system.

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

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Use with adequate ventilation.
- Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.  
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Place in closed containers. Label for proper disposal.

### SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:  
Avoid formation of aerosol.  
Use with local exhaust ventilation.  
Avoid contact with skin, eyes and clothing.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propane-1,2-diol	57-55-6	TWA	10 mg/m <sup>3</sup>	US WEEL

#### Personal protective equipment

- Respiratory protection : Recommended Filter type:  
Organic vapor with prefilter  
  
None required for consumer use of this product.
- Hand protection  
Material : Chemically resistant gloves.
- Remarks : None required for consumer use of this product.
- Eye protection : Safety glasses  
None required for consumer use of this product.
- Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.  
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

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Wear suitable protective equipment.  
Please consult label for end-user requirements.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid  
Density : ca. 1 g/cm<sup>3</sup> (68 °F / 20 °C)  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Explosive properties : No data available  
Oxidizing properties : No data available  
Impact sensitivity : No data available  
Minimum ignition energy : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : No data available  
Chemical stability : No data available  
Possibility of hazardous reactions : No data available  
Conditions to avoid : No data available  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

##### Product:

Acute oral toxicity : Acute toxicity estimate (ATE): > 5,000 mg/kg  
Method: Calculation method  
Acute dermal toxicity : Acute toxicity estimate (ATE): > 5,000 mg/kg  
Method: Calculation method

##### Components:

**Citric acid:**

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Acute oral toxicity : LD50 (Rat): 3,000 mg/kg

### Skin corrosion/irritation

#### Components:

##### **Tulathromycin:**

Result : Mild skin irritation

##### **Citric acid:**

Species : Rabbit  
Exposure time : 72 h  
Method : OECD 404  
Result : Mild skin irritation

### Serious eye damage/eye irritation

#### Components:

##### **Tulathromycin:**

Result : Eye irritation

##### **Citric acid:**

Species : Rabbit  
Result : Eye irritation  
Exposure time : 72 h  
Assessment : Causes serious eye irritation.  
Method : OECD 405

### Respiratory or skin sensitisation

#### Components:

##### **Tulathromycin:**

Result : May cause sensitisation by skin contact.

Assessment : An acute toxic effect is not expected.

### Germ cell mutagenicity

#### Components:

##### **Citric acid:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

### Carcinogenicity

**IARC** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is

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on OSHA's list of regulated carcinogens.

**NTP**      No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Components:**

**Tulathromycin:**

Repeated dose toxicity - Assessment : An acute toxic effect is not expected.

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### SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Tulathromycin:**

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

**Citric acid:**

Toxicity to microorganisms : EC0 (Bacteria): 10,000 mg/l  
Method: DIN 38412

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

**Persistence and degradability**

**Components:**

**Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98 %  
Exposure time: 2 d  
Method: OECD 302B

Biochemical Oxygen Demand (BOD) : 575 - 675 mg/g

Chemical Oxygen Demand (COD) : 700 - 800 mg/g

**Bioaccumulative potential**

**Components:**

**Citric acid:**

Bioaccumulation : Remarks: Does not bioaccumulate.

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Partition coefficient: n-octanol/water : log Pow: -1.61  
Method: experimental

### Mobility in soil

No data available

### Other adverse effects

### Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic.

However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### National Regulations

#### 49 CFR

Not regulated as a dangerous good

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## SECTION 15. REGULATORY INFORMATION

### EPCRA - Emergency Planning and Community Right-to-Know Act

#### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Hydrochloric acid	7647-01-0	5000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

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### 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** : Serious eye damage or eye irritation  
Respiratory or skin sensitisation

**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

#### Massachusetts Right To Know

Hydrochloric acid 7647-01-0

#### Pennsylvania Right To Know

Propane-1,2-diol 57-55-6

#### New York City Hazardous Substances

Hydrochloric acid 7647-01-0

### International Regulations

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

TSCA : Not On TSCA Inventory

### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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## SECTION 16. OTHER INFORMATION

### Further information

### Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
US WEEL / TWA : 8-hr TWA

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