

## Section 1 - Identification of Chemical Product and Company

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Freecall: 1800 665 866

**Chemical nature:** Tulathromycin injection  
**Trade Name:** **Tulieve Injection**  
**APVMA No.:** 88653  
**Product Use:** Antibiotic injection for treatment of various conditions in pigs and cattle.  
**Creation Date:** **November, 2020**  
**This version issued:** **November, 2020** and is valid for 5 years from this date.  
**Poisons Information Centre: Phone 13 1126 from anywhere in Australia**

## Section 2 - Hazards Identification

### Statement of Hazardous Nature

This product is classified as: Xi, Irritating. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

**SUSMP Classification:** S4

**ADG Classification:** None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

**UN Number:** None allocated



### GHS Signal word: WARNING

Skin Sensitisation Category 1

Serious eye irritation Category 2/2A

#### HAZARD STATEMENT:

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

#### PREVENTION

P261: Avoid breathing fumes, mists, vapours or spray.

P262: Do not get in eyes, on skin, or on clothing.

P264: Wash contacted areas thoroughly after handling.

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves, protective clothing and eye or face protection.

#### RESPONSE

P363: Wash contaminated clothing before reuse.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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.

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

P337+P313: If eye irritation persists: Get medical advice.

P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

#### STORAGE

P410: Protect from sunlight.

P411+P235: Store at temperatures not exceeding 30°C. Keep cool.

#### DISPOSAL

P501: If they can not be recycled, dispose of contents to an approved waste disposal plant and containers to landfill (see Section 13 of this SDS).

## SAFETY DATA SHEET

## Emergency Overview

**Physical Description & Colour:** Liquid, no data regarding colour.

**Odour:** No data.

**Major Health Hazards:** may cause serious damage to eyes, possible skin sensitiser. This is an antibiotic preparation. Any person with a history of allergies to this class of substances should avoid all contact with this product as it may cause sensitisation. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

## Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc, mg/mL	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Tulathromycin	217500-96-4	100	not set	not set
Propylene glycol	57-55-6	500	10	not set
Other non hazardous ingredients	secret	to 1 mL	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

## Section 4 - First Aid Measures

### General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

**Self Injection:** Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed liquid. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

**Inhalation:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

**Skin Contact:** Wash gently and thoroughly with water (use non-abrasive soap if necessary) for 5 minutes or until chemical is removed.

**Eye Contact:** Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes or until the product is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately. Take special care if exposed person is wearing contact lenses.

**Ingestion:** If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

## Section 5 - Fire Fighting Measures

**Fire and Explosion Hazards:** The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

**Extinguishing Media:** In case of fire, use carbon dioxide, dry chemical, foam or water fog.

**Fire Fighting:** When fighting fires involving significant quantities of this product, wear a splash suit complete with self contained breathing apparatus.

**Flash point:** No data

**Upper Flammability Limit:** No data.

**Lower Flammability Limit:** No data.

**Autoignition temperature:** No data.

**Flammability Class:** No data.

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## Section 6 - Accidental Release Measures

**Accidental release:** This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

## Section 7 - Handling and Storage

**Handling:** Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

**Storage:** This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

## Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Propylene glycol	10	not set

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

**Ventilation:** This product should only be used where there is ventilation that is adequate to keep exposure below the TWA levels. If necessary, use a fan.

**Eye Protection:** Protective glasses or goggles must be worn when this product is being used. Failure to protect your eyes may lead to severe harm to them or to general health. Emergency eye wash facilities must also be available in an area close to where this product is being used.

**Skin Protection:** If you believe you may have a sensitisation to this product or any of its declared ingredients, you should prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

**Protective Material Types:** We suggest that protective clothing be made from the following materials: butyl rubber.

**Respirator:** Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Eyebaths or eyewash stations and safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

## Section 9 - Physical and Chemical Properties:

<b>Physical Description &amp; colour:</b>	Liquid, no data regarding colour.
<b>Odour:</b>	No data.
<b>Boiling Point:</b>	Not available.
<b>Freezing/Melting Point:</b>	No specific data. Liquid at normal temperatures.
<b>Volatiles:</b>	No data.
<b>Vapour Pressure:</b>	No data.
<b>Vapour Density:</b>	No data.
<b>Specific Gravity:</b>	1.061-1.068
<b>Water Solubility:</b>	Soluble.
<b>pH:</b>	No data.
<b>Volatility:</b>	No data.
<b>Odour Threshold:</b>	No data.
<b>Evaporation Rate:</b>	No data.

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**Coeff Oil/water Distribution:** No data  
**Autoignition temp:** No data.

### Section 10 - Stability and Reactivity

**Reactivity:** This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

**Conditions to Avoid:** Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

**Incompatibilities:** strong acids, strong bases, strong oxidising agents.

**Fire Decomposition:** Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

**Polymerisation:** This product will not undergo polymerisation reactions.

### Section 11 - Toxicological Information

**Local Effects:**

**Target Organs:** There is no data to hand indicating any particular target organs.

### Classification of Hazardous Ingredients

**Ingredient**

**Risk Phrases**

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

### Potential Health Effects

**Inhalation:**

**Short Term Exposure:** Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

**Long Term Exposure:** No data for health effects associated with long term inhalation.

**Skin Contact:**

**Short Term Exposure:** Classified as a potential sensitiser by skin contact. Exposure to a skin sensitiser, once sensitisation has occurred, may manifest itself as skin rash or inflammation, and in some individuals this reaction can be severe. In addition product may be irritating, but is unlikely to cause anything more than mild transient discomfort.

**Long Term Exposure:** No data for health effects associated with long term skin exposure.

**Eye Contact:**

**Short Term Exposure:** This product is a severe eye irritant. Symptoms may include stinging and reddening of eyes and watering which may become copious. Other symptoms such as swelling of eyelids and blurred vision may also become evident. If exposure is brief, symptoms should disappear once exposure has ceased. However, lengthy exposure or delayed treatment is likely to cause permanent damage.

**Long Term Exposure:** No data for health effects associated with long term eye exposure.

**Ingestion:**

**Short Term Exposure:** Significant oral exposure is considered to be unlikely. Available data shows that this product is not harmful. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

**Long Term Exposure:** No data for health effects associated with long term ingestion.

**Carcinogen Status:**

**SWA:** No significant ingredient is classified as carcinogenic by SWA.

**NTP:** No significant ingredient is classified as carcinogenic by NTP.

**IARC:** No significant ingredient is classified as carcinogenic by IARC.

### Section 12 - Ecological Information

Insufficient data to be sure of status.

## SAFETY DATA SHEET

### Section 13 - Disposal Considerations

**Disposal:** Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

### Section 14 - Transport Information

**UN Number:** This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

### Section 15 - Regulatory Information

**AICS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Tulathromycin, is mentioned in the SUSMP.

### Section 16 - Other Information

**This SDS contains only safety-related information. For other data see product literature.**

#### Acronyms:

<b>ADG Code</b>	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 <sup>th</sup> edition)
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>SWA</b>	Safe Work Australia, formerly ASCC and NOHSC
<b>CAS number</b>	Chemical Abstracts Service Registry Number
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
<b>IARC</b>	International Agency for Research on Cancer
<b>NOS</b>	Not otherwise specified
<b>NTP</b>	National Toxicology Program (USA)
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines & Poisons
<b>UN Number</b>	United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (Feb 2016)

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### SAFETY DATA SHEET