

# Ilium Tula Injection

## Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: 3

Chemwatch: 5436-74

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Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

L.GHS.AUS.EN.E

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

#### Product Identifier

Product name	Ilium Tula Injection
Chemical Name	Not Applicable
Synonyms	Ilium Tulathromycin Injection; APVMA number 88512
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	To be used as directed on product label. Use according to manufacturer's directions.
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#### Details of the manufacturer or supplier of the safety data sheet

Registered company name	Troy Laboratories Pty Ltd
Address	37 Glendenning Road Glendenning NSW 2761 Australia
Telephone	02 8808 3600
Fax	02 9677 9300
Website	<a href="http://www.Troylab.com.au">www.Troylab.com.au</a>
Email	admin@troylab.com.au

#### Emergency telephone number

Association / Organisation	Ixom Emergency Response Service
Emergency telephone number(s)	1800 033 111 (24 hours)
Other emergency telephone number(s)	Not Available

### SECTION 2 Hazards identification

#### Classification of the substance or mixture

Poisons Schedule	S4
Classification <sup>[1]</sup>	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 1
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	
Signal word	Danger

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## Hazard statement(s)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.

## Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.

## Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

## Precautionary statement(s) Storage

Not Applicable

## Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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## SECTION 3 Composition / information on ingredients

## Substances

See section below for composition of Mixtures

## Mixtures

CAS No	%[weight]	Name
57-55-6	30-60	<u>propylene glycol</u>
217500-96-4	1-10	<u>tulathromycin</u>
77-92-9	1-3	<u>citric acid</u>
Not Available	balance	Ingredients determined not to be hazardous
Not Available		includes
7732-18-5	30-60	<u>water</u>

**Legend:** 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; \* EU IOELVs available

## SECTION 4 First aid measures

## Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes or combustion products are inhaled remove from contaminated area.</li> <li>▶ Lay patient down. Keep warm and rested.</li> <li>▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> </ul>

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	<ul style="list-style-type: none"> <li>▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> <li>▶ Transport to hospital, or doctor.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Seek medical advice.</li> </ul>

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

Propylene glycol is primarily a CNS depressant in large doses and may cause hypoglycaemia, lactic acidosis and seizures.

- ▶ The usual measures are supportive care and decontamination (Ipecac/ lavage/ activated charcoal/ cathartics), within 2 hours of exposure should suffice.
- ▶ Check the anion gap, arterial pH, renal function and glucose levels.

*Ellenhorn and Barceloux: Medical Toxicology*

**SECTION 5 Firefighting measures****Extinguishing media**

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- ▶ foam.
- ▶ dry chemical powder.
- ▶ carbon dioxide.

**Special hazards arising from the substrate or mixture**

<b>Fire Incompatibility</b>	None known.
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**Advice for firefighters**

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ The material is not readily combustible under normal conditions.</li> <li>▶ However, it will break down under fire conditions and the organic component may burn.</li> <li>▶ Not considered to be a significant fire risk.</li> <li>▶ Heat may cause expansion or decomposition with violent rupture of containers.</li> <li>▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acrid smoke.</li> </ul> <p>Decomposes on heating and produces toxic fumes of: carbon dioxide (CO<sub>2</sub>) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>
<b>HAZCHEM</b>	Not Applicable

**SECTION 6 Accidental release measures****Personal precautions, protective equipment and emergency procedures**

See section 8

**Environmental precautions**

See section 12

**Methods and material for containment and cleaning up**

<b>Minor Spills</b>	▶ Clean up all spills immediately.
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	<ul style="list-style-type: none"> <li>▶ Avoid breathing vapours and contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Contain and absorb spill with sand, earth, inert material or vermiculite.</li> <li>▶ Wipe up.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul>
<b>Major Spills</b>	<p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water course.</li> <li>▶ Stop leak if safe to do so.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Neutralise/decontaminate residue (see Section 13 for specific agent).</li> <li>▶ Collect solid residues and seal in labelled drums for disposal.</li> <li>▶ Wash area and prevent runoff into drains.</li> <li>▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.</li> <li>▶ If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

Personal Protective Equipment advice is contained in Section 8 of the SDS.

## SECTION 7 Handling and storage

### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ <b>DO NOT allow clothing wet with material to stay in contact with skin</b></li> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Other information</b>	<p>Consider storage under inert gas.</p> <ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ No smoking, naked lights or ignition sources.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	100mL clear glass vial with a rubber stopper and aluminium seal.
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid reaction with oxidising agents, bases and strong reducing agents.</li> <li>▶ Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.</li> </ul>

## SECTION 8 Exposure controls / personal protection

### Control parameters

#### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	propylene glycol	Propane-1,2-diol: particulates only	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	propylene glycol	Propane-1,2-diol total: (vapour & particulates)	150 ppm / 474 mg/m3	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
propylene glycol	Not Available	Not Available


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Ingredient	Original IDLH	Revised IDLH
tulathromycin	Not Available	Not Available
citric acid	Not Available	Not Available
water	Not Available	Not Available

## MATERIAL DATA

## Exposure controls

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].</li> </ul>
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.</li> <li>▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.</li> </ul> <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none"> <li>· frequency and duration of contact,</li> <li>· chemical resistance of glove material,</li> <li>· glove thickness and</li> <li>· dexterity</li> </ul> <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none"> <li>· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.</li> <li>· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.</li> <li>· Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.</li> <li>· Contaminated gloves should be replaced.</li> </ul> <p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> <li>· Excellent when breakthrough time &gt; 480 min</li> <li>· Good when breakthrough time &gt; 20 min</li> <li>· Fair when breakthrough time &lt; 20 min</li> <li>· Poor when glove material degrades</li> </ul> <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> <li>· Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.</li> <li>· Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential</li> </ul> <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C apron.</li> </ul>

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- ▶ Barrier cream.
- ▶ Skin cleansing cream.
- ▶ Eye wash unit.

## Recommended material(s)

## GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
BUTYL	C
NATURAL RUBBER	C
NEOPRENE	C
PE/EVAL/PE	C
PVA	C
VITON	C

\* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

**NOTE:** As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

\* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

## Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 5 x ES	A-AUS / Class 1 P2	-	A-PAPR-AUS / Class 1 P2
up to 25 x ES	Air-line*	A-2 P2	A-PAPR-2 P2
up to 50 x ES	-	A-3 P2	-
50+ x ES	-	Air-line**	-

\* - Continuous-flow; \*\* - Continuous-flow or positive pressure demand

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

## SECTION 9 Physical and chemical properties

## Information on basic physical and chemical properties

Appearance	Clear to slightly yellow solution; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	1.065
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	5.1-5.7	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available

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<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available
<b>Heat of Combustion (kJ/g)</b>	Not Available	<b>Ignition Distance (cm)</b>	Not Available
<b>Flame Height (cm)</b>	Not Available	<b>Flame Duration (s)</b>	Not Available
<b>Enclosed Space Ignition Time Equivalent (s/m3)</b>	Not Available	<b>Enclosed Space Ignition Deflagration Density (g/m3)</b>	Not Available

## SECTION 10 Stability and reactivity

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

## SECTION 11 Toxicological information

## Information on toxicological effects

<b>a) Acute Toxicity</b>	Based on available data, the classification criteria are not met.
<b>b) Skin Irritation/Corrosion</b>	There is sufficient evidence to classify this material as skin corrosive or irritating.
<b>c) Serious Eye Damage/Irritation</b>	There is sufficient evidence to classify this material as eye damaging or irritating
<b>d) Respiratory or Skin sensitisation</b>	There is sufficient evidence to classify this material as sensitising to skin or the respiratory system
<b>e) Mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>f) Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>g) Reproductivity</b>	Based on available data, the classification criteria are not met.
<b>h) STOT - Single Exposure</b>	Based on available data, the classification criteria are not met.
<b>i) STOT - Repeated Exposure</b>	Based on available data, the classification criteria are not met.
<b>j) Aspiration Hazard</b>	Based on available data, the classification criteria are not met.

<b>Inhaled</b>	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p>Exposure to aliphatic alcohols with more than 3 carbons may produce central nervous system effects such as headache, dizziness, drowsiness, muscle weakness, delirium, CNS depression, coma, seizure, and neurobehavioural changes. Symptoms are more acute with higher alcohols. Respiratory tract involvement may produce irritation of the mucosa, respiratory insufficiency, respiratory depression secondary to CNS depression, pulmonary oedema, chemical pneumonitis and bronchitis. Cardiovascular involvement may result in arrhythmias and hypotension. Gastrointestinal effects may include nausea and vomiting. Kidney and liver damage may result following massive exposures. The alcohols are potential irritants being, generally, stronger irritants than similar organic structures that lack functional groups (e.g. alkanes) but are much less irritating than the corresponding amines, aldehydes or ketones. Alcohols and glycols (diols) rarely represent serious hazards in the workplace, because their vapour concentrations are usually less than the levels which produce significant irritation which, in turn, produce significant central nervous system effects as well.</p> <p>Inhalation hazard is increased at higher temperatures.</p>
<b>Ingestion</b>	<p>Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>If swallowed, the toxic effects of glycols (dihydric alcohols) are similar to those of alcohol, with depression of the central nervous system, nausea, vomiting, and degenerative changes in the liver and kidney.</p> <p>Ingestion of propylene glycol produced reversible central nervous system depression in humans following ingestion of 60 ml. Symptoms included increased heart-rate (tachycardia), excessive sweating (diaphoresis) and grand mal seizures in a 15 month child who ingested large doses (7.5 ml/day for 8 days) as an ingredient of vitamin preparation.</p> <p>Excessive repeated ingestions may cause hypoglycaemia (low levels of glucose in the blood stream) among susceptible individuals; this may result in muscular weakness, incoordination and mental confusion.</p> <p>Very high doses given during feeding studies to rats and dogs produce central nervous system depression (although one-third of that produced by ethanol), haemolysis and insignificant kidney changes.</p> <p>In humans propylene glycol is partly excreted unchanged in the urine and partly metabolised as lactic and pyruvic acid. Lactic acidosis may result.</p> <p>Overexposure to non-ring alcohols causes nervous system symptoms. These include headache, muscle weakness and incoordination, giddiness, confusion, delirium and coma.</p>



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<b>Skin Contact</b>	<p>The material produces moderate skin irritation; evidence exists, or practical experience predicts, that the material either</p> <ul style="list-style-type: none"> <li>▶ produces moderate inflammation of the skin in a substantial number of individuals following direct contact, and/or</li> <li>▶ produces significant, but moderate, inflammation when applied to the healthy intact skin of animals (for up to four hours), such inflammation being present twenty-four hours or more after the end of the exposure period.</li> </ul> <p>Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</p> <p>A single prolonged exposure is not likely to result in the material being absorbed in harmful amounts. However the material may be absorbed in potentially harmful amounts when applied in large quantities to severe burns (second or third degree) over large areas of the body as part of a cream, other topical application or by prolonged contact with clothing accidentally wetted by the material. Absorption under such circumstances can elevated serum osmolality and may result in osmotic shock.</p> <p>Most liquid alcohols appear to act as primary skin irritants in humans. Significant percutaneous absorption occurs in rabbits but not apparently in man.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
<b>Eye</b>	<p>When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.</p> <p>Irritation of the eyes may produce a heavy secretion of tears (lachrymation).</p>
<b>Chronic</b>	<p>Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.</p> <p>Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.</p> <p>Substances than can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers</p> <p>Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.</p> <p>Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.</p> <p>Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.</p> <p>Propylene glycol is though, by some, to be a sensitising principal following the regular use of topical creams by eczema patients. A study of 866 persons using a formulation containing propylene glycol in a patch test indicated that propylene glycol caused primary irritation in 16% of exposed individuals probably caused by dehydration. Undiluted propylene glycol was tested on 1556 persons in a 24 hour patch test. 12.5% showed reactions which were largely toxic (70%) or allergic in nature (30%). Reaction responses reached their maximum on the second day or later. Reactions were seasonal in nature ranging from 17.8% in winter to 9.2% in other seasons. In a patch-test using 25 standard allergens conducted on 500 individuals, propylene glycol ranked fourth in sensitising response. 84 subjects were patch tested using 100% propylene glycol. as well as 2% and 5% in water. With undiluted material, 15% demonstrated a reaction, with 40% of the reactions being allergic in nature and 60% being irritant. In dilute solutions 5 of 248 subjects exhibited a reaction.</p> <p>Undiluted propylene glycol tested on the skin of man produced no irritation under open conditions but when applied under occlusive conditions, for 2 weeks, it produced severe erythema, oedema and vesicles, probably due to sweat retention and weak primary irritation.</p> <p>Predictive contact skin sensitisation tests indicate that propylene glycol is an intermediate grade sensitiser with an index of 1% of tested subjects.</p> <p>Groups of cats fed 5 gm/kg/day of propylene glycol for 14 weeks showed a significant dose-related increase in red blood cell Heinz body formation without any marked signs of haemolytic anaemia. The no-effect-level for cats without formation of Heinz bodies is 100-500 ml/kg. There is no evidence of anaemia or degenerative change. Groups of rats dosed orally with 0.5 or 10 mg/kg/day for 12 weeks had lowered food intake but no adverse effects on body weights. Erythrocytes were more fragile. Heinz bodies were not apparent.</p>

<b>Ilium Tula Injection</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>propylene glycol</b>	<b>TOXICITY</b> Dermal (rabbit) LD50: 11890 mg/kg <sup>[2]</sup> Inhalation (Rat) LC50: >44.9 mg/4h <sup>[1]</sup> Oral (Rat) LD50: 20000 mg/kg <sup>[2]</sup>	<b>IRRITATION</b> Eye (Rodent - rabbit): 100mg - Mild Eye (Rodent - rabbit): 500mg/24H - Mild Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin (Human - child): 30%/96H(continuous) - Moderate Skin (Human - man): 10%/2D Skin (Human - woman): 30%/96H - Mild Skin (Human): 104mg/3D (intermittent) - Moderate Skin (Human): 20%



## Ilium Tula Injection

		Skin (Human): 500mg/7D - Mild
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
tulathromycin	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
citric acid	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (Rodent - rabbit): 750ug/24H - Severe
	Oral (Rat) LD50: 3000 mg/kg <sup>[2]</sup>	Eye: adverse effect observed (irritating) <sup>[1]</sup>
		Skin (Rodent - rabbit): 0.5mL - Moderate
		Skin (Rodent - rabbit): 500mg/24H - Mild
		Skin: adverse effect observed (irritating) <sup>[1]</sup>
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
water	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50: >90000 mg/kg <sup>[2]</sup>	Not Available

**Legend:**

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

<b>PROPYLENE GLYCOL</b>	<p>The acute oral toxicity of propylene glycol is very low, and large quantities are required to cause perceptible health damage in humans. Serious toxicity generally occurs only at plasma concentrations over 1 g/L, which requires extremely high intake over a relatively short period of time. It would be nearly impossible to reach toxic levels by consuming foods or supplements, which contain at most 1 g/kg of PG. Cases of propylene glycol poisoning are usually related to either inappropriate intravenous administration or accidental ingestion of large quantities by children. The potential for long-term oral toxicity is also low. Because of its low chronic oral toxicity, propylene glycol was classified by the U. S. Food and Drug Administration as "generally recognized as safe" (GRAS) for use as a direct food additive.</p> <p>Prolonged contact with propylene glycol is essentially non-irritating to the skin. Undiluted propylene glycol is minimally irritating to the eye, and can produce slight transient conjunctivitis (the eye recovers after the exposure is removed). Exposure to mists may cause eye irritation, as well as upper respiratory tract irritation. Inhalation of the propylene glycol vapours appears to present no significant hazard in ordinary applications. However, limited human experience indicates that inhalation of propylene glycol mists could be irritating to some individuals. It is therefore recommended that propylene glycol not be used in applications where inhalation exposure or human eye contact with the spray mists of these materials is likely, such as fogs for theatrical productions or antifreeze solutions for emergency eye wash stations.</p> <p>Propylene glycol is metabolised in the human body into pyruvic acid (a normal part of the glucose-metabolism process, readily converted to energy), acetic acid (handled by ethanol-metabolism), lactic acid (a normal acid generally abundant during digestion), and propionaldehyde (a potentially hazardous substance).</p> <p>Propylene glycol shows no evidence of being a carcinogen or of being genotoxic.</p> <p>Research has suggested that individuals who cannot tolerate propylene glycol probably experience a special form of irritation, but that they only rarely develop allergic contact dermatitis. Other investigators believe that the incidence of allergic contact dermatitis to propylene glycol may be greater than 2% in patients with eczema.</p> <p>One study strongly suggests a connection between airborne concentrations of propylene glycol in houses and development of asthma and allergic reactions, such as rhinitis or hives in children.</p> <p>Another study suggested that the concentrations of PGEs (counted as the sum of propylene glycol and glycol ethers) in indoor air, particularly bedroom air, is linked to increased risk of developing numerous respiratory and immune disorders in children, including asthma, hay fever, eczema, and allergies, with increased risk ranging from 50% to 180%. This concentration has been linked to use of water-based paints and water-based system cleansers.</p> <p>Patients with vulvodynia and interstitial cystitis may be especially sensitive to propylene glycol. Women suffering with yeast infections may also notice that some over the counter creams can cause intense burning. Post menopausal women who require the use of an oestrogen cream may notice that brand name creams made with propylene glycol often create extreme, uncomfortable burning along the vulva and perianal area. Additionally, some electronic cigarette users who inhale propylene glycol vapor may experience dryness of the throat or shortness of breath. As an alternative, some suppliers will put Vegetable Glycerin in the "e-liquid" for those who are allergic (or have bad reactions) to propylene glycol.</p> <p>Adverse responses to intravenous administration of drugs which use PG as an excipient have been seen in a number of people, particularly with large dosages thereof. Responses may include "hypotension, bradycardia... QRS and T abnormalities on the ECG, arrhythmia, cardiac arrest, serum hyperosmolality, lactic acidosis, and haemolysis". A high percentage (12% to 42%) of directly-injected propylene glycol is eliminated/secreted in urine unaltered depending on dosage, with the remainder appearing in its glucuronide-form. The speed of renal filtration decreases as dosage increases, which may be due to propylene glycol's mild anesthetic / CNS-depressant -properties as an alcohol. In one case, intravenous administration of propylene glycol-suspended nitroglycerin to an elderly man may have induced coma and acidosis.</p> <p>Propylene glycol is an approved food additive for dog food under the category of animal feed and is generally recognized as safe for dogs with an LD50 of 9 mL/kg. The LD50 is higher for most laboratory animals (20 mL/kg)</p> <p>Similarly, propylene glycol is an approved food additive for human food as well. The exception is that it is prohibited for use in food for cats due to links to Heinz body anemia.</p>
<b>TULATHROMYCIN</b>	Tulathromycin was evaluated for skin and ocular irritation in albino rabbits. The compound proved to be neither a corrosive material nor a skin irritant. Tulathromycin produced severe eye irritation characterised by iritis and substantial but reversible conjunctivitis and corneal opacity. The results indicated that tulathromycin is an ocular irritant in rabbits. The potential of tulathromycin to produce sensitisation following topical exposure was evaluated in guinea pigs given a combination of

## Ilium Tula Injection

intradermal injections and topical applications (maximation study design). A positive reaction was produced in nearly all test animals (9 of 10) at the 24 and 48-hour scoring intervals, indicating that tulathromycin can be considered a contact sensitizer in guinea pigs. Cardiotoxicity with degenerative multifocal damage of the myocardium was observed in individual 6-months old calves at a single subcutaneous dose of 12.5 mg/kg bw and 15 mg/kg bw. No signs of myocardial damage were observed in other studies at 7.5 mg/kg bw in 4 to 6 weeks old calves and at 12.5 mg/kg bw in 8 months old calves. A toxicological ADI of 0.05 mg/kg bw/day (3 mg/person) was established for tulathromycin based on the NOEL of 5 mg/kg bw from the 3-month subchronic toxicity study in dogs and rats and a safety factor of 100. In the embryo/foetal development studies and the reproductive 2-generation study, no effect doses were about 300 times higher than this ADI. An ADI of 0.011 mg/kg bw (i.e. 0.66 mg/person) was established for tulathromycin. The results of single dose studies in rats and dogs using oral and intravenous administration indicated low acute toxicity of tulathromycin by the oral route, and intermediate toxicity by the intravenous route. Following oral administration, the lethal doses were estimated to be greater than 1000 mg/kg bw in dogs (100, 300 and 1000 mg tulathromycin/kg bw, 2 animals per sex and dose level) and greater than 2000 mg/kg bw in rats (100, 300, 1000, 2000 mg/kg bw, 3 animals per sex and dose), i.e. higher than the maximum doses tested. However, vomiting occurred in dogs and no information on the amount of oral dose possibly lost was provided. Effects at 100 mg/kg bw were limited to mild gastrointestinal disturbances such as emesis. No drug-related effects on respiration rate, body temperature, blood pressure, heart rate, or electrocardiographic parameters were noted up to and including 1000 mg/kg bw. The highest asymptomatic dose in rats was 300 mg/kg bw based on findings such as loose stools, elevated leukocytic and erythrocytic parameters and elevated hepatic enzymes (alanine aminotransferase (ALT), aspartate aminotransferase (AST), sorbitol dehydrogenase (SHD)) at 1000 mg/kg bw and/or 2000 mg/kg bw. The maximum non-lethal dose by intravenous administration was 10 mg/kg bw for both dogs (1 and 10 mg/kg bw; 2 animals per sex and dose level and 30 mg/kg bw; 1 male) and male rats (0.1, 1.0, 10, 30 and 100 mg tulathromycin/kg bw, 3 males per dose). In male rats (females not tested) doses of 10 mg/kg bw were shown to be asymptomatic. The maximum asymptomatic dose in dogs was less than 1.0 mg/kg bw based on findings at 1.0 and 10 mg/kg bw which were indicative of gastrointestinal disturbances (loose stools). Higher intravenous doses led to deaths in the case of male rats and collapse with apnoea in the single male dog tested. In an acute dermal toxicity study in 3 male and 3 female rabbits no mortality occurred following a 24 hour exposure to 2000 mg tulathromycin/kg bw. Slight oedema and slight skin desquamation together with decreased food consumption and decreased defecation were the only observations in these animals. Oral gavage repeated dose toxicity studies were carried out in rats. In the 1-month rat study (10, 50 and 200 mg tulathromycin/kg bw/day, 10 animals per sex and dose), effects included elevations in hepatic transaminase enzymes, decrease in relative liver weights, and elevations in monocyte and eosinophil counts at 200 mg/kg. Further observations were significantly decreased serum bile acids in males at all dose levels and significantly increased alanine aminotransferase (ALT) values in females at the two higher doses. All findings were without histological correlates and the dose of 10 mg/kg bw may be established as a NOEL based on the minor serum chemistry changes recorded in males at this dose. In a preliminary oral gavage embryo/foetal and early postnatal development study, rats were dosed with 50, 100, 200 and 500 mg tulathromycin/kg bw from gestation day 6 to 17 (8 females per group) or from gestation day 6 through to lactation day 11 (8 females per group). Adverse findings noted in both the foetal development and postnatal phases at 500 mg/kg bw included high maternal mortality (25 and 63 percent in the two parts of the study, respectively), decreased maternal body weight and body weight gain and decreased food consumption. There were no adverse effects on foetal survival, foetal malformations, postnatal survival or gross examination of surviving dams at termination at any dose level. Mean pup weights were reduced throughout the postnatal phase at 500 mg/kg bw. Oral gavage doses of 15, 100 and 200 mg tulathromycin/kg bw were administered in the definitive rat embryo/foetal development study (22 animals per dose; gestation day 6 through to 17). Mean daily food consumption at days 6 to 18 and net body weight change of dams were reduced at the higher doses. Compared to concurrent controls, percent of viable foetuses was lower and post-implantation loss was increased at the two higher doses. Mean foetal weights were very slightly but significantly reduced in all treated groups. No doserelationship was apparent for this observation and it was not considered of biological relevance. There were no adverse effects on maternal reproductive parameters and foetal malformations at any dose level investigated. The NOEL for maternal toxicity and the NOEL for foetal effects in this study was 15 mg/kg bw. Tulathromycin was tested in a comprehensive series of mutagenicity test systems: in vitro with the microbial gene mutation assay, the mammalian cell (CHO/HGPRT) gene mutation assay, the chromosome aberration assay with human lymphocytes and in vivo with the rat micronucleus assay. Tulathromycin did not induce gene mutations, with or without metabolic activation, in either the bacterial or mammalian cell mutation assays. Tulathromycin did not demonstrate clastogenic activity, with or without metabolic activation in human lymphocytes and was negative in the rat micronucleus assay. The results of the genetic toxicology assays indicated that tulathromycin is not genotoxic. Due to the absence of a chemical structural relationship to known carcinogens, the negative results of the genotoxicity assays, and the lack of a carcinogenic potential of other macrolide antibiotics it was assumed that tulathromycin is devoid of a carcinogenic potential.

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

**CITRIC ACID**

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

For citric acid (and its inorganic citrate salts)

Based on extensive animal testing data and on human experience, citric acid has low acute toxicity. Citric acid is not suspected of causing cancer, birth defects or reproductive toxicity. Further, it does not cause mutation. Also, the sensitizing potential is considered low. In contrast, irritation, particularly of the eyes but also the airways and the skin, is the main hazard presented by citric acid.

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<b>PROPYLENE GLYCOL &amp; CITRIC ACID</b>	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
<b>TULATHROMYCIN &amp; WATER</b>	No significant acute toxicological data identified in literature search.

<b>Acute Toxicity</b>	✗	<b>Carcinogenicity</b>	✗
<b>Skin Irritation/Corrosion</b>	✓	<b>Reproductivity</b>	✗
<b>Serious Eye Damage/Irritation</b>	✓	<b>STOT - Single Exposure</b>	✗
<b>Respiratory or Skin sensitisation</b>	✓	<b>STOT - Repeated Exposure</b>	✗
<b>Mutagenicity</b>	✗	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## SECTION 12 Ecological information

## Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
<b>Ilium Tula Injection</b>	Not Available	Not Available	Not Available	Not Available	Not Available
<b>propylene glycol</b>	LC50	96h	Fish	710mg/L	4
	EC50	48h	Crustacea	>114.4mg/L	4
	EC50	72h	Algae or other aquatic plants	19300mg/l	2
	NOEC(ECx)	336h	Algae or other aquatic plants	<5300mg/l	1
	EC50	96h	Algae or other aquatic plants	19000mg/l	2
<b>tulathromycin</b>	Not Available	Not Available	Not Available	Not Available	Not Available
<b>citric acid</b>	EC50	48h	Crustacea	>50mg/l	2
	EC50(ECx)	48h	Crustacea	>50mg/l	2
	EC50	72h	Algae or other aquatic plants	990mg/l	2
	LC50	96h	Fish	>100mg/l	2
<b>water</b>	Not Available	Not Available	Not Available	Not Available	Not Available
<b>Legend:</b>	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Propylene glycol is known to exert high levels of biochemical oxygen demand (BOD) during degradation in surface waters. This process can adversely affect aquatic life by consuming oxygen needed by aquatic organisms for survival. Large quantities of dissolved oxygen (DO) in the water column are consumed when microbial populations decompose propylene glycol.

Sufficient dissolved oxygen levels in surface waters are critical for the survival of fish, macro-invertebrates, and other aquatic organisms. If oxygen concentrations drop below a minimum level, organisms emigrate, if able and possible, to areas with higher oxygen levels or eventually die. This effect can drastically reduce the amount of usable aquatic habitat. Reductions in DO levels can reduce or eliminate bottom-feeder populations, create conditions that favour a change in a community's species profile, or alter critical food-web interactions.

log Kow : -1.41- -0.3

Half-life (hr) air : 32

Henry's atm m<sup>3</sup>/mol: 1.20E-08

BOD 5: 0.995,2.2%

ThOD : 1.685

BCF : <1

Bioaccumulation : not sig

processes Abiotic: photoxid

**DO NOT discharge into sewer or waterways.**

## Persistence and degradability

Continued...

## Ilium Tula Injection

Ingredient	Persistence: Water/Soil	Persistence: Air
propylene glycol	LOW	LOW
citric acid	LOW	LOW
water	LOW	LOW

## Bioaccumulative potential

Ingredient	Bioaccumulation
propylene glycol	LOW (BCF = 1)
citric acid	LOW (LogKOW = -1.64)
water	LOW (LogKOW = -1.38)

## Mobility in soil

Ingredient	Mobility
propylene glycol	HIGH (Log KOC = 1)
citric acid	LOW (Log KOC = 10)

## SECTION 13 Disposal considerations

## Waste treatment methods

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> </ul> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▶ Reduction</li> <li>▶ Reuse</li> <li>▶ Recycling</li> <li>▶ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> <li>▶ Recycle wherever possible.</li> <li>▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.</li> <li>▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).</li> <li>▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.</li> </ul>
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## SECTION 14 Transport information

## Labels Required

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

## 14.7. Maritime transport in bulk according to IMO instruments

## 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

**14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code**

Product name	Group
propylene glycol	Not Available
tulathromycin	Not Available
citric acid	Not Available
water	Not Available

**14.7.3. Transport in bulk in accordance with the IGC Code**

Product name	Ship Type
propylene glycol	Not Available
tulathromycin	Not Available
citric acid	Not Available
water	Not Available

**SECTION 15 Regulatory information****Safety, health and environmental regulations / legislation specific for the substance or mixture****propylene glycol is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**tulathromycin is found on the following regulatory lists**

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

**citric acid is found on the following regulatory lists**

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

**water is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**Additional Regulatory Information**

Not Applicable

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (tulathromycin)
Canada - DSL	No (tulathromycin)
Canada - NDSL	No (propylene glycol; tulathromycin; citric acid; water)
China - IECSC	No (tulathromycin)
Europe - EINEC / ELINCS / NLP	No (tulathromycin)
Japan - ENCS	No (tulathromycin)
Korea - KECI	No (tulathromycin)
New Zealand - NZIoC	No (tulathromycin)
Philippines - PICCS	No (tulathromycin)
USA - TSCA	TSCA Inventory 'Active' substance(s) (propylene glycol; citric acid; water); No (tulathromycin)
Taiwan - TCSI	No (tulathromycin)
Mexico - INSQ	No (tulathromycin)
Vietnam - NCI	Yes
Russia - FBEPH	No (tulathromycin)
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

**SECTION 16 Other information**

Revision Date	23/12/2022
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Continued...

## Ilium Tula Injection

<b>Initial Date</b>	18/11/2020
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**SDS Version Summary**

Version	Date of Update	Sections Updated
3.1	23/12/2022	Classification review due to GHS Revision change.

**Other information**

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

**Definitions and abbreviations**

- ▶ PC - TWA: Permissible Concentration-Time Weighted Average
- ▶ PC - STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ▶ ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ▶ TEEL: Temporary Emergency Exposure Limit,
- ▶ IDLH: Immediately Dangerous to Life or Health Concentrations
- ▶ ES: Exposure Standard
- ▶ OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ▶ TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- ▶ OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ▶ DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code
  
- ▶ AIIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- ▶ NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ▶ KECI: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory
- ▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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