Ilium Tula Injection
Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: **3**

Chemwatch: **5436-74**
Version No: **2.1.1.1**
Safety Data Sheet according to WHS and ADG requirements

Issue Date: **18/11/2020**
Print Date: **23/11/2020**
S.GHS.AUS.EN

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

Product Identifier

Product name	Ilium Tula Injection
Synonyms	Ilium Tulathromycin Injection; APVMA number 88512
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.

Details of the 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	www.Troylab.com.au
Email	admin@troylab.com.au

Emergency telephone number

Association / Organisation	**Troy Laboratories Pty Ltd**
Emergency telephone numbers	02 8808 3600 (Office hours (8am – 4pm, Monday to Friday))
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

Poisons Schedule	S4
Classification [1]	Skin Corrosion/Irritation Category 2, Serious Eye Damage Category 1, Skin Sensitizer 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**

Hazard statement(s)

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

Precautionary statement(s) Prevention

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing mist/vapours/spray.
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.

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P310	Immediately call a POISON CENTER or doctor/physician.
P321	Specific treatment (see advice on this label).
P362	Take off contaminated clothing and wash before reuse.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

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.

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

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

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Immediately hold eyelids apart and flush the eye continuously with running water. ▸ 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. ▸ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▸ Transport to hospital or doctor without delay. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: ▸ Immediately remove all contaminated clothing, including footwear. ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Inhalation	▸ If fumes or combustion products are inhaled remove from contaminated area. ▸ Lay patient down. Keep warm and rested. ▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▸ 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. ▸ Transport to hospital, or doctor.
Ingestion	▸ If swallowed do **NOT** induce vomiting. ▸ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▸ Observe the patient carefully. ▸ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▸ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▸ Seek medical advice.

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.

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Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Use fire fighting procedures suitable for surrounding area. ▸ **DO NOT** approach containers suspected to be hot. ▸ Cool fire exposed containers with water spray from a protected location. ▸ If safe to do so, remove containers from path of fire. ▸ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	▸ The material is not readily combustible under normal conditions. ▸ However, it will break down under fire conditions and the organic component may burn. ▸ Not considered to be a significant fire risk. ▸ Heat may cause expansion or decomposition with violent rupture of containers. ▸ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). ▸ May emit acrid smoke. Decomposes on heating and produces toxic fumes of: carbon dioxide (CO_2) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.
HAZCHEM	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

Minor Spills	▸ Clean up all spills immediately. ▸ Avoid breathing vapours and contact with skin and eyes. ▸ Control personal contact with the substance, by using protective equipment. ▸ Contain and absorb spill with sand, earth, inert material or vermiculite. ▸ Wipe up. ▸ Place in a suitable, labelled container for waste disposal.
Major Spills	Moderate hazard. ▸ Clear area of personnel and move upwind. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves. ▸ Prevent, by any means available, spillage from entering drains or water course. ▸ Stop leak if safe to do so. ▸ Contain spill with sand, earth or vermiculite. ▸ Collect recoverable product into labelled containers for recycling. ▸ Neutralise/decontaminate residue (see Section 13 for specific agent). ▸ Collect solid residues and seal in labelled drums for disposal. ▸ Wash area and prevent runoff into drains. ▸ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▸ If contamination of drains or waterways occurs, advise emergency services.

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	▸ **DO NOT** allow clothing wet with material to stay in contact with skin ▸ Avoid all personal contact, including inhalation. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Prevent concentration in hollows and sumps. ▸ **DO NOT** enter confined spaces until atmosphere has been checked. ▸ **DO NOT** allow material to contact humans, exposed food or food utensils. ▸ Avoid contact with incompatible materials. ▸ When handling, **DO NOT** eat, drink or smoke. ▸ Keep containers securely sealed when not in use. ▸ Avoid physical damage to containers. ▸ Always wash hands with soap and water after handling. ▸ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▸ Use good occupational work practice. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS. ▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Other information	Consider storage under inert gas. ▸ Store in original containers. ▸ Keep containers securely sealed.

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	▸ No smoking, naked lights or ignition sources. ▸ Store in a cool, dry, well-ventilated area. ▸ Store away from incompatible materials and foodstuff containers. ▸ Protect containers against physical damage and check regularly for leaks. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

Suitable container	100mL clear glass vial with a rubber stopper and aluminium seal.
Storage incompatibility	▸ Avoid reaction with oxidising agents, bases and strong reducing agents. ▸ Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.

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

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
propylene glycol	Polypropylene glycols	30 mg/m3	330 mg/m3	2,000 mg/m3
propylene glycol	Propylene glycol; (1,2-Propanediol)	30 mg/m3	1,300 mg/m3	7,900 mg/m3

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

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
tulathromycin	D	> 0.01 to ≤ 0.1 mg/m³
citric acid	E	≤ 0.01 mg/m³
Notes:	*Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.*	

Exposure controls

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	▸ Safety glasses with side shields. ▸ Chemical goggles. ▸ 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], [AS/NZS 1336 or national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	▸ Wear chemical protective gloves, e.g. PVC. ▸ Wear safety footwear or safety gumboots, e.g. Rubber **NOTE:** ▸ 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. ▸ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. 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. 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. 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. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

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	· frequency and duration of contact, · chemical resistance of glove material, · glove thickness and · dexterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). · 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. · 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. · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. · Contaminated gloves should be replaced. As defined in ASTM F-739-96 in any application, gloves are rated as: · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended. 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. 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. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example: · 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. · 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 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.
Body protection	See Other protection below
Other protection	▸ Overalls. ▸ P.V.C apron. ▸ 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:
Ilium Tula Injection

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(SO2), G = Agricultural chemicals, K = Ammonia(NH3), 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

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Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	5.1-5.7	**Decomposition temperature**	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 Available	**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
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo. 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. Aliphatic alcohols with more than 3-carbons cause headache, dizziness, drowsiness, muscle weakness and delirium, central depression, coma, seizures and behavioural changes. Secondary respiratory depression and failure, as well as low blood pressure and irregular heart rhythms, may follow. Inhalation hazard is increased at higher temperatures.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. 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. 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. 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. 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. In humans propylene glycol is partly excreted unchanged in the urine and partly metabolised as lactic and pyruvic acid. Lactic acidosis may result. Overexposure to non-ring alcohols causes nervous system symptoms. These include headache, muscle weakness and inco-ordination, giddiness, confusion, delirium and coma.
Skin Contact	The material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. A single prolonged exposure is not likely to result in the material causing harm. However, when applied in large quantities to damaged skin as a topical preparation or by contact with clothing accidentally contaminated by the material, there may be the potential to absorb the material in harmful amounts. Most liquid alcohols appear to act as primary skin irritants in humans. Significant percutaneous absorption occurs in rabbits but not apparently in man. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions 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.
Eye	If applied to the eyes, this material causes severe eye damage. Irritation of the eyes may produce a heavy secretion of tears (lachrymation).
Chronic	Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Propylene glycol is thought to be sensitizing following the regular use of topical creams by eczema patients. Testing in humans showed that 16% of exposed individuals, irritation occurred, with 12.5% showing toxic or allergic reactions. The reaction responses reached their maximum on the second day or later. Reactions were seasonal in nature, with a maximum in winter. Undiluted propylene glycol tested on human skin produced no irritation under open conditions, but when applied under occlusive conditions for 2 weeks, it produced severe redness, swelling and blistering, probably due to both sweat retention and irritation. Animal testing shows propylene glycol may lead to fragility in red blood cells.

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Ilium Tula Injection	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
propylene glycol	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: 20800 mg/kg[2]	Eye (rabbit): 100 mg - mild
	Inhalation (rat) LC50: >44.9 mg/l/4H[2]	Eye (rabbit): 500 mg/24h - mild
	Oral (dog) LD50: =20000 mg/kg[2]	Eye: no adverse effect observed (not irritating)[1]
	Oral (mouse) LD50: =22000 mg/kg[2]	Skin(human):104 mg/3d Intermit Mod
	Oral (mouse) LD50: =23900 mg/kg[2]	Skin(human):500 mg/7days mild
	Oral (rabbit) LD50: =18000-19000 mg/kg[2]	Skin: no adverse effect observed (not irritating)[1]
	Oral (rabbit) LD50: =18500 mg/kg[2]	
	Oral (rat) LD50: 20000 mg/kg[2]	
tulathromycin	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
citric acid	**TOXICITY**	**IRRITATION**
	5500 mg/kg[2]	Eye (rabbit): 0.75 mg/24h-SEVERE
	Oral (rat) LD50: ~11700 mg/kg[2]	Skin (rabbit): 500 mg/24h - mild
	Oral (rat) LD50: 3000 mg/kg[2]	
water	**TOXICITY**	**IRRITATION**
	Oral (rat) LD50: >90000 mg/kg[2]	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*	

PROPYLENE GLYCOL	The acute oral toxicity of propylene glycol is very low; large amounts are needed to cause perceptible health damage in humans. Serious toxicity generally occurs only at blood concentrations over 1 g/L, which requires extremely high intake over a relatively short period of time; this is nearly impossible with consuming foods or supplements which contain 1g/kg of PG at most. Poisonings are usually due to injection through a vein or accidental swallowing of large amounts by children. The potential for long-term oral toxicity is also low. Prolonged contact with propylene glycol is essentially non-irritating to the skin. Undiluted propylene glycol is minimally irritating to the eye, and can produce a slight, temporary inflammation of the conjunctiva. Exposure to mists may cause irritation of both the eye and the upper airway. Inhalation of propylene glycol vapours may 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. Propylene glycol is metabolized in humans to pyruvic acid, acetic acid, lactic acid and propionaldehyde; the last of which is potentially hazardous. Propylene glycol show s no evidence of causing cancer or genetic toxicity. Research has suggested that individuals who cannot tolerate propylene glycol probably experience a special form of irritation, but they only rarely develop allergic contact dermatitis. Other investigators believe that the incidence of allergic contact dermatitis in people exposed to propylene glycol may be greater than 2% in patients with eczema. One study strongly suggests a connection between airborne concentrations of propylene glycol in houses and development of asthma and allergic reactions, such as inflammation of the nose and hives, in children. Another study suggested that the concentration of PGEs (propylene glycol and glycol ethers) in indoor 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. Patients with bladder inflammation and vulvodynia (chronic pain of the vulva) may be especially sensitive to propylene glycol. Women suffering with yeast infections may notice that some over the counter creams cause intense burning. Post-menopausal women who require the use of an oestrogen cream may notice that creams made with propylene glycol often cause extremely uncomfortable burning along the vulva and around the anus. Some electronic cigarette users who inhale propylene glycol vapour may experience dryness of the throat or shortness of breath. Adverse responses to administration of drugs which use propylene glycol as an incipient have been seen in a number of people especially at high doses. These include low blood pressure, slow heart rate, ECG abnormalities, heartbeat irregularities, lactic acidosis, breakdown of red cells and cardiac arrest.
TULATHROMYCIN	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. 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 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

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	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 aminotrasferase (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 eosinoph
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 mutations. 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.
PROPYLENE GLYCOL & CITRIC ACID	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.
TULATHROMYCIN & WATER	No significant acute toxicological data identified in literature search.

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

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

SECTION 12 Ecological information

Toxicity

Ilium Tula Injection

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

propylene glycol

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96	Fish	>10-mg/L	2
EC50	48	Crustacea	43-500mg/L	2
EC50	96	Algae or other aquatic plants	19-100mg/L	2
NOEC	168	Fish	11-530mg/L	2

tulathromycin

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

citric acid

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96	Fish	1-516mg/L	2
EC50	48	Crustacea	>50mg/L	2
EC50	72	Algae or other aquatic plants	990mg/L	2
EC0	72	Crustacea	<80mg/L	1

water

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

Legend: *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 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.

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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 m3 /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

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 (KOC = 1)
citric acid	LOW (KOC = 10)
water	LOW (KOC = 14.3)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	▸ Containers may still present a chemical hazard/ danger when empty. ▸ Return to supplier for reuse/ recycling if possible. Otherwise: ▸ 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. ▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product. 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. A Hierarchy of Controls seems to be common - the user should investigate: ▸ Reduction ▸ Reuse ▸ Recycling ▸ Disposal (if all else fails) 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. ▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains. ▸ It may be necessary to collect all wash water for treatment before disposal. ▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▸ Where in doubt contact the responsible authority. ▸ Recycle wherever possible. ▸ 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. ▸ 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). ▸ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	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

Continued...

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

Not Applicable

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

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5
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)

National Inventory Status

National Inventory	Status
Australia - AIIC	No (tulathromycin)
Australia - Non-Industrial Use	No (propylene glycol; tulathromycin; citric acid; water)
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	No (tulathromycin)
Taiwan - TCSI	No (tulathromycin)
Mexico - INSQ	No (tulathromycin)
Vietnam - NCI	No (tulathromycin)
Russia - ARIPS	No (tulathromycin)
Legend:	*Yes = All CAS declared ingredients are on the inventory* *No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

SECTION 16 Other information

Revision Date	18/11/2020
Initial Date	18/11/2020

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
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

Continued...

end of SDS