

SAFETY DATA SHEET



1. Identification

Product identifier Tulathromycin-Ketoprofen Solution for Injection

Other means of identification

Synonyms DRAXXIN KP * Draxxin KP Injectable Solution for Cattle * Draxxin KP (tulathromycin and ketoprofen injection) * DRAXXIN KP plus Ketoprofen Injectable Solution for Cattle

Recommended use of the chemical and restrictions on use

Recommended use Veterinary antibiotic agent; Non-steroidal, anti-inflammatory drug (NSAID)

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (AU) Zoetis Australia Pty Ltd
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Rhodes NSW 2138 AUSTRALIA

Tel 1800 814 883

Fax (02) 8876 0444

Email productsupport.au@zoetis.com

Emergency Phone 1800 814 883 (all hours)

Police and Fire Brigade Dial 000

If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards Not classified.

Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
	Specific target organ toxicity following repeated exposure	Category 2 (digestive organs, kidney)

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)



Exclamation
mark

Health
hazard

Signal word Warning

Hazard statement(s) Harmful if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs (digestive organs, kidney) through prolonged or repeated exposure.

Precautionary statement(s)

Prevention

Do not breathe mist or vapour. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves.

Response	Get medical advice/attention if you feel unwell. IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. Rinse mouth. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Propylene glycol	57-55-6	30-60
Ketoprofen	22071-15-4	12
Tulathromycin	217500-96-4	10
2-Pyrrolidone	616-45-5	5-10
Citric acid	77-92-9	1-5

Composition comments % = w/v

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing. Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

Symptoms caused by exposure Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Oedema. Prolonged exposure may cause chronic effects.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Alcohol resistant foam. Powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed. Combustible.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Hazchem code	None.
General fire hazards	Combustible.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Do not handle until all safety precautions have been read and understood. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. Wear personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store locked up. Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a well-ventilated place. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis			
Components	Type	Value	
Ketoprofen (CAS 22071-15-4)	TWA	75 µg/m3	
Tulathromycin (CAS 217500-96-4)	TWA	1 mg/m3	
Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)			
Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	Total vapour and particulates.
UK. EH40 Workplace Exposure Limits (WELs)			
Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
		150 ppm	Total vapour and particulates.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Citric acid (CAS 77-92-9)	TWA	2 mg/m ³	Inhalable fraction.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate. Eye wash fountain and emergency showers are recommended.

Individual protection measures, for example personal protective equipment (PPE)**Eye/face protection**

Do not get in eyes. Professional use: If contact is likely, safety glasses with side shields are recommended. Additionally, face shield recommended if splashing is possible. Industrial use: Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Thermal hazards

Not applicable.

Hygiene measures

Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties**Appearance**

Sterile solution.

Physical state

Liquid.

Form

Liquid.

Colour

Colorless - Yellow.

Odour

Not available.

Odour threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits**Flammability limit - lower (%)**

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Keep away from heat, sparks and open flame.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Causes skin irritation. May cause an allergic skin reaction.
Ketoprofen Severity: Irritant

Propylene glycol Species: Rabbit
Severity: Mild

Citric acid Species: Rabbit
Severity: Non-irritating

Tulathromycin Species: Rabbit
Severity: Non-irritating

Eye contact Causes serious eye irritation.
Ketoprofen Severity: Irritant

Citric acid Species: Rabbit
Severity: Irritant

Propylene glycol Species: Rabbit
Severity: Mild

Tulathromycin Species: Rabbit
Severity: positive

Ingestion Harmful if swallowed.

Symptoms related to exposure Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Oedema.

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
2-Pyrrolidone (CAS 616-45-5)		
<u>Acute</u>		
Oral		
LD50	Rat	6500 mg/kg
Citric acid (CAS 77-92-9)		
<u>Acute</u>		
Oral		
LD50	Rat	6730 mg/kg
Ketoprofen (CAS 22071-15-4)		
<u>Acute</u>		
Oral		
LD50	Rat	62.4 mg/kg
<u>Chronic</u>		
Oral		
LOAEL	Dog	3 mg/kg/day, 3 months Gastrointestinal system
	Rat	6 mg/kg/day, 3 months Gastrointestinal System Kidney Blood
Propylene glycol (CAS 57-55-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	20800 mg/kg
Oral		
LD50	Mouse	24900 mg/kg
	Rat	22000 mg/kg
Tulathromycin (CAS 217500-96-4)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD	Rat	> 2000 mg/kg (Minimum Lethal Dose)
<u>Chronic</u>		
Oral		
NOAEL	Dog	5 mg/kg/day, 1 years (Target organs: Liver, Male reproductive system)
<u>Subacute</u>		
Oral		
NOAEL	Dog	15 mg/kg/day, 1 months (Target organs: Liver)
	Rat	50 mg/kg/day, 1 months (Target organs: Liver, Blood)
<u>Subchronic</u>		
Oral		
NOAEL	Rat	15 mg/kg/day, 3 months (Target organs: Liver)
NOEL	Dog	5 mg/kg/day, 3 months (Target organs: Liver)
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/irritation	Causes serious eye irritation.	
Eye contact		
Ketoprofen	Severity: Irritant	

Eye contact

Citric acid

Species: Rabbit
Severity: Irritant

Propylene glycol

Species: Rabbit
Severity: Mild

Tulathromycin

Species: Rabbit
Severity: positive**Respiratory or skin sensitisation****Respiratory sensitisation** Not a respiratory sensitizer.**Skin sensitisation** May cause an allergic skin reaction.**Skin sensitisation**

Tulathromycin

GPMT
Species: Guinea Pig
Severity: Severe**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Ketoprofen

Bacterial Mutagenicity (Ames)
Result: Negative with activation , without activation
Species: Salmonella

Tulathromycin

Bacterial Mutagenicity (Ames)
Result: negative
Species: SalmonellaIn Vitro Chromosome Aberration
Result: negative
Species: Chinese Hamster Ovary (CHO) cellsIn Vitro Chromosome Aberration
Result: negative
Species: Human lymphocytesIn Vitro Mammalian Cell Mutagenicity
Result: negative
Species: Chinese Hamster Ovary (CHO) cellsIn Vivo Micronucleus Chromosome Aberration
Result: negative
Species: Rat

Ketoprofen

Sister Chromatid Exchange
Result: negative
Species: Human lymphocytes**Carcinogenicity**

Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Developmental effects

Tulathromycin

200 mg/kg/day Embryo / Fetal Development, No effects at maximum dose
Result: NOAEL
Species: Rat
Organ: Oral50 mg/kg/day Embryo / Fetal Development, No effects at maximum dose
Result: NOAEL
Species: Rabbit
Organ: Oral

Reproductivity
Tulathromycin

50 mg/kg/day 2 Generation Reproductive Toxicity, Paternal toxicity; No effects on reproductive parameters or neonatal development at any dose level.
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure May cause damage to organs (digestive organs, kidney) through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Other information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Based on available data, the classification criteria are not met for hazardous to the aquatic environment. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components		Species	Test Results
2-Pyrrolidone (CAS 616-45-5)			
Aquatic			
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>)	13.21 mg/l, 48 hours
	LC50	<i>Daphnia magna</i> (Water Flea)	13.21 mg/l, 48 Hours
Propylene glycol (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>)	710 mg/l, 96 hours
Tulathromycin (CAS 217500-96-4)			
	EC50	<i>Selenastrum capricornutum</i> (Green Alga)	70 µg/l, 72 Hours (ErC50)
	IC50	Polytox	19 mg/l
Aquatic			
Crustacea	EC50	<i>Daphnia magna</i> (Water Flea)	64 mg/l, 48 Hours
	LC50	<i>Mysidopsis bahia</i> (Mysid Shrimp)	20 mg/l, 48 Hours
Fish	LC50	<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	20 mg/l, 48 Hours
		<i>Oncorhynchus mykiss</i> (rainbow trout)	> 982 mg/l, 96 Hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available for this product. Not expected to bioaccumulate.

Partition coefficient n-octanol / water (log Kow)
Tulathromycin

-1.41, (Measured Log P @ pH 7.0)

Mobility in soil No data available for this product.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

- Australia Medicines & Poisons Appendix A**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix B**
Propylene glycol (CAS 57-55-6)
- Australia Medicines & Poisons Appendix D**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix E**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix F**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix G**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix H**
Ketoprofen (CAS 22071-15-4)
- Australia Medicines & Poisons Appendix I**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix J**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Appendix K**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Schedule 10**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Schedule 2**
Poisons schedule number not allocated.
- Australia Medicines & Poisons Schedule 3**
Ketoprofen (CAS 22071-15-4)

Australia Medicines & Poisons Schedule 4

Ketoprofen (CAS 22071-15-4)
 Tulathromycin (CAS 217500-96-4)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Citric acid (CAS 77-92-9)	1000 - 9999 TONNES See the regulation for additional information.
Propylene glycol (CAS 57-55-6)	10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date	07-January-2020
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties