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	Veterinary antibiotic agent; Non-steroidal, anti-inflammatory drug (NSAID)
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917 All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx
Supplier	Not available.

2. Hazard identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 1
	Sensitization, skin	Category 1
	Specific target organ toxicity following repeated exposure	Category 2 (digestive organs, kidney)
Environmental hazards	Not classified.	

Label elements

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

Precautionary statement

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	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell. Rinse mouth. IF ON SKIN: Wash with plenty of 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. Immediately call a POISON CENTRE/doctor. Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
1,2-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
The exact percentage composition of this mixture has been withheld as a trade secret.

4. 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.

Most important symptoms/effects, acute and delayed 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.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information 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.

5. Fire-fighting measures

Suitable extinguishing media Alcohol resistant foam. Powder. Carbon dioxide (CO2).

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 firefighters 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.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Combustible.

6. Accidental release measures

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

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.

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

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/personal protection

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

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
1,2-Propylene Glycol (CAS 57-55-6)	TWA	155 mg/m3	Vapour and aerosol.
		10 mg/m3	Aerosol
		50 ppm	Vapour and aerosol.

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

Control banding approach Not available.

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, such as personal protective equipment

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.
General hygiene considerations	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 information	
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 likely 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
1,2-Propylene glycol	Species: Rabbit Severity: Mild
Citric acid	Species: Rabbit Severity: Non-irritating
Tulathromycin	Species: Rabbit Severity: Non-irritating

Eye contact Causes serious eye damage.

Ketoprofen	Severity: Irritant
Citric acid	Species: Rabbit Severity: Irritant
1,2-Propylene glycol	Species: Rabbit Severity: Mild
Tulathromycin	Species: Rabbit Severity: positive

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics 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.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
1,2-Propylene glycol (CAS 57-55-6)		
Acute		
Dermal		
LD50	Rabbit	20800 mg/kg
Oral		
LD50	Mouse	24900 mg/kg
	Rat	22000 mg/kg
2-Pyrrolidone (CAS 616-45-5)		
Acute		
Oral		
LD50	Rat	6500 mg/kg
Citric acid (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	6730 mg/kg
Ketoprofen (CAS 22071-15-4)		
Acute		
Oral		
LD50	Rat	62.4 mg/kg

Components	Species	Test Results
Chronic		
Oral		
LOAEL	Dog	3 mg/kg/day, 3 months Gastrointestinal system
	Rat	6 mg/kg/day, 3 months Gastrointestinal System Kidney Blood
Tulathromycin (CAS 217500-96-4)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD	Rat	> 2000 mg/kg (Minimum Lethal Dose)
Chronic		
Oral		
NOAEL	Dog	5 mg/kg/day, 1 years (Target organs: Liver, Male reproductive system)
Subacute		
Oral		
NOAEL	Dog	15 mg/kg/day, 1 months (Target organs: Liver)
	Rat	50 mg/kg/day, 1 months (Target organs: Liver, Blood)
Subchronic		
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/eye irritation Causes serious eye damage.

Eye contact

Ketoprofen	Severity: Irritant
Citric acid	Species: Rabbit Severity: Irritant
1,2-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: Salmonella
	In Vitro Chromosome Aberration Result: Negative Species: Chinese Hamster Ovary (CHO) cells
	In Vitro Chromosome Aberration Result: Negative Species: Human lymphocytes
	In Vitro Mammalian Cell Mutagenicity Result: Negative Species: Chinese Hamster Ovary (CHO) cells
	In Vivo Micronucleus Chromosome Aberration Result: Negative Species: Rat
Ketoprofen	Sister Chromatid Exchange Result: Negative Species: Human lymphocytes

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

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: Oral
	50 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.

Further 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
1,2-Propylene glycol (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	710 mg/l, 96 hours
2-Pyrrolidone (CAS 616-45-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia pulex)	13.21 mg/l, 48 hours
	LC50	Daphnia magna (Water Flea)	13.21 mg/l, 48 Hours
Tulathromycin (CAS 217500-96-4)			
	EC50	Selenastrum capricornutum (Green Alga)	70 µg/l, 72 Hours (ErC50)
	IC50	Polytox	19 mg/l
Aquatic			
Crustacea	EC50	Daphnia magna (Water Flea)	64 mg/l, 48 Hours
	LC50	Mysidopsis bahia (Mysid Shrimp)	20 mg/l, 48 Hours
Fish	LC50	Cyprinodon variegatus (Sheepshead Minnow)	20 mg/l, 48 Hours
		Oncorhynchus mykiss (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 instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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

TDG

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

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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
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

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Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties