



TULAXX INJECTION

Abbey Animal Health Pty Ltd SAFETY DATA SHEET

Section 1- Identification of Product and Supplier

Supplier Company Details: Abbey Animal Health Pty Ltd

Address: Unit 27/ 1 Maitland place, Norwest NSW, 2153

Telephone Number: 02 8088 0720

Facsimile Number: 02 8088 0721

Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour Service).

PRODUCT NAME

TULAXX INJECTION

PRODUCT USE

For the treatment of respiratory infections in cattle and pigs and early stages of foot rot in sheep.

Section 2- Hazards Identification

Statement of Hazardous Nature this product is classified as: Hazardous according to the criteria of SWA.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code criteria when transported by road or rail. Refer to Section 14.

GHS Signal word: **WARNING.**

GHS Classification

Serious eye damage/Eye irritation- Category 1

Skin sensitization- Category 1

Hazard pictogram



HAZARD STATEMENTS

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

PREVENTION

P261: Avoid breathing dust/fume/ gas/mist/ vapours/spray.

P264: Wash hands thoroughly after handling.

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

P280: Wear protective gloves.

RESPONSE

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

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

P362: Take off the contaminated clothing and wash it before reuse.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 3- Composition / Information on Ingredients

Ingredients	CAS No	Conc mg/mL	TWA (mg/m ³)	STEL (mg/m ³)
Tulathromycin	217500-96-4	100	Not set	Not set
Other non-hazardous ingredients		100%	Not set	Not set

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

Section 4- First Aid Measures

Call Poisons Information Centre Phone Australia 131 126, if you feel that you may have been poisoned or irritated by this product.

Swallowed: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Eye: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Inhaled: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Section 5- Fire Fighting Measures

Fire/Explosion Hazard: Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous Combustion Products: May emit toxic fumes of oxides of carbon and nitrogen.

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Section 6 - Accidental Release Measures

Methods and materials for containment and cleaning

Contain the source of spill if it is safe to do so. Collect spill with non-combustible absorbent material. Clean spill area thoroughly.

Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Section 7 - Handling and Storage

Handling: When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store below 30°C (Room Temperature).

Section 8 - Exposure Controls / Personal Protection

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

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

SWA Exposure Limits

TWA (mg/m3)

STEL (mg/m3)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

The ADI for Tulathromycin is set at 0.005 mg/kg/day and NOEL is set at (M). ADI means Acceptable Daily Intake; NOEL means No-observable-effect-level. Data from Australian ADI List, June 2022.

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

Ventilation: This product should only be used in a well-ventilated area. If natural ventilation is inadequate, use of a fan is suggested.

Eye Protection: Protective glasses or goggles should be worn when this product is being used. Failure to protect your eyes may cause them harm. Emergency eye wash facilities are also recommended in an area close to where this product is being used.

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

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

Respirator: As this product is classed as a respiratory sensitiser, special care should be taken with respiratory selection if you are sensitised to this product or any of its declared ingredients. If there is a significant chance that dust is likely to build up in the area where this product is being used, we recommend that you use a suitable dust mask. Otherwise, not normally necessary.

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

Section 9 - Physical and Chemical Properties

Physical State:	Colourless to slightly yellow solution.
Boiling Point:	No data available.
Vapour Pressure:	No data available.
Odor:	No data available.
Specific Gravity:	No data available.
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

Section 10 - Stability and Reactivity

Stability: Product is stable under normal conditions of storage.

Conditions to avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible materials: As a precautionary measure, keep away from strong oxidizers.

Section 11 - Toxicological Information

No adverse health effects expected if the product is handled in accordance with this Safety Data Sheet and product label.

ACUTE TOXICITY

Tulathromycin:

Rat	Oral	LD50	> 2000 mg/kg
Rat	Dermal	LD50	>2000 mg/kg

REPEATED DOSE TOXICITY

Tulathromycin

1 Month	Rat	Oral	50 mg/kg/day	NOAEL	Liver, Blood
3 Month(s)	Rat	Oral	15 mg/kg/day	NOAEL	Liver
1 Month	Dog	Oral	15 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral	5 mg/kg/day	NOEL	Liver
1 year(s)	Dog	Oral	5 mg/kg/day	NOAEL	Liver, male reproductive system

Reproduction & Developmental Toxicity

Tulathromycin

2 Generation Reproductive Toxicity: Rat-Oral 50 mg/kg/day NOAEL Paternal toxicity

2 Generation Reproductive Toxicity: Rat-Oral 100 mg/kg/day NOAEL neonatal toxicity, Fertility

Embryo / Fetal Development: Rat-Oral 200 mg/kg/day NOAEL No effects

Embryo / Fetal Development: Rabbit-Oral 50 mg/kg/day NOAEL No effects

GENETIC TOXICITY

Tulathromycin

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
In Vivo Micronucleus Chromosome Aberration	Rat	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative

Section 12 - Ecological Information

Potential Environmental Considerations: No environmental data exists for this product. However, avoid contamination of waterways.

AQUATIC TOXICITY

Tulathromycin

<i>Daphnia magna</i>	(Water Flea)	OECD EC50	64mg/L; 48hrs
<i>Mysidopsis bahia</i>	(Mysid Shrimp)	OECD LC50	20mg/L; 48hrs

<i>Cyprinodon variegatus</i>	(Sheepshead Minnow)	OECD LC50	20mg/L; 48hrs
<i>Oncorhynchus mykiss</i>	(Rainbow Trout)	OECD LC50	>982mg/L; 96hrs
<i>Selenastrum capricornutum</i>	(Green Alga)	OECD EC-50	70µg/L; 72hrs

Section 13 - Disposal Considerations

Dispose of container by wrapping with paper and putting in garbage.

Section 14 - Transport Information

No specific transport considerations apply since *TULAXX INJECTION* is NOT classified as a dangerous good according to Australian Dangerous Goods (ADG) Code.

Section 15 - Regulatory Information

Poisons Schedule: S4

APVMA Approval Number: 85687

Approved pack size: 50mL, 100mL, 250mL, 500mL

For more information please refer to the APVMA approved product label

Section 16 – Other Information

Abbey Animal Health Pty Ltd

Telephone Number: 02 8088 0720

Facsimile Number: 02 8088 0721

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This Safety Data Sheet (SDS) summarizes our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace.

Each user must review this SDS in the context of how the product will be handled and used in the workplace.

If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

***Note: This SDS is valid for 5 years from the effective date.**