



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: 16 Voyager Circuit, Glendenning NSW 2761

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 respiratory infections in cattle and pigs.

Section 2- Hazards Identification

Statement of Hazardous Nature

This product is classified as: Classified as hazardous according to the criteria of SWA.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

GHS Signal word: WARNING.

GHS Classification

Serious eye damage/Eye irritation- Category 1

Skin sensitization- Category 1

PICTOGRAM



HAZARD STATEMENT

H317: May cause an allergic skin reaction.

First Effective Date: 19th March 2020

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:

Chemical Name	CAS Number	Conc, %w/v
Tulathromycin	217500-96-4	10
Non-hazardous ingredients	secret	to 100

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.

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.

Personal Protective Equipment:

Eye/face protection: Eye protection is not normally required under normal product. However, if in doubt, wear suitable protective glasses or goggles.

Skin protection: This product is not harmful and normal skin protection is not typically required. However, in general, we suggest that you avoid skin contact with all chemical products and wear suitable gloves (preferably elbow length gloves) when skin contact is likely. Wash hands or other exposed areas after handling and use.

Respiratory protection: Respiratory protection equipment is recommended under conditions where dusts are likely to build up in an area where this product is being used.

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/da NOAEL Paternal toxicity

2 Generation Reproductive Toxicity: Rat-Oral 100 mg/kg/da 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

Disposal

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

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

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

This Safety Data Sheet (SDS) summarizes our best knowledge of the health and safety hazard information of the product according to the GHS requirements 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.