
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	TRIBACTRAL ANTIBACTERIAL SUSPENSION FOR INJECTION
Product Code:	60210 (100 mL)
Recommended Use:	A sterile antibiotic injection for the treatment of infections caused by organisms sensitive to trimethoprim and sulfadiazine in cattle, sheep, pigs and horses.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street, Rutherford, NSW 2320, Australia
Email:	jenq@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Acute Toxicity (Oral) Category 4	H302	Harmful if swallowed
Skin Corrosion/Irritation Category 2	H315	Causes skin irritation
Eye Irritation Category 2A	H319	Causes serious eye irritation
Respiratory Sensitizer Category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction
Germ cell mutagenicity Category 2	H341	Suspected of causing genetic defects
Reproductive Toxicity Category 1B	H360	May damage fertility or the unborn child

Signal word: DANGER

GHS Pictograms:



Health hazard Exclamation mark

Precautionary statements:Prevention

- P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing vapours.
P264 Wash hands areas thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, eye protection and face protection.
P281 Use personal protective equipment as required.
P285 In case of inadequate ventilation wear respiratory protection.

Response

- P301+P312 IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P330 Rinse mouth.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
P304+P340 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTRE or doctor.
P363 Wash contaminated clothing before reuse.
P308+P313: If exposed or concerned: Get medical advice.

Storage

- P405 Store locked up.

Disposal

- P501 Dispose of unused product in accordance with local regulations. Dispose of empty container by wrapping with paper and placing in garbage.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Sulfadiazine	68-35-9	40%
Trimethoprim	738-70-5	8%
Sodium hydroxide	1310-73-2	< 10%
Ingredients not contributing to the hazards		30 – 60%

Section 4: FIRST AID MEASURES

General Information: Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Symptoms and Effects of Exposure: Overdose of sulfadiazine may cause an accumulation of acid in the blood or a diminished blood sugar level with confusion and coma resulting. Symptoms of exposure to trimethoprim include nausea, vomiting, headache, pruritis (itchiness) and skin rash. Disturbance of liver and kidney function may also occur.

Inhalation: If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually not necessary. If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Ingestion: IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the meantime, give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. 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.

Injection: Treat as for needlestick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.

Skin: 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.

Eye: If eye contact occurs: Immediately 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 for at least 20 minutes. Seek medical advice/attention.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: No data.

Hazardous Combustion Products: If involved in a fire, may emit noxious and irritant fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and breathing apparatus.

HAZCHEM Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. Avoid breathing and contact with skin and eyes. For small spills, sweep up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Prevent spillage from entering drains or water courses and call emergency services.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: Use in a well-ventilated area. Avoid accidental self-injection. Avoid contact with skin, eyes and inhalation of vapours. Use personal protective equipment as required. DO NOT allow clothing wet with material to stay in contact with skin. Do not eat, drink or smoke while handling product. Wash hands after use.

Storage: Keep out of reach of children. Store below 25°C (air conditioning). Protect from light.

Other Information: Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product nor for any ingredients. The ADI for trimethoprim is 0.02 mg/kg/day. The NOEL for trimethoprim is 33 mg/kg/day.

Engineering Controls: Use in a well-ventilated area and make sure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when handling this product.

Skin protection: Prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory protection: Not required for the normal use of this product.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pale yellow solution with white precipitate which is readily dispersible to form a suspension.	Lower flammability limits:	Not available
Odour:	Not available	Vapour Pressure:	Not available
Odour threshold:	Not available	Vapour density:	Not available
pH:	10.0 – 10.5	Relative density:	Not available
Melting Point:	Not available	Specific Gravity:	Approx. 1.19
Boiling Point:	Not available	Solubility in Water:	Miscible
Flash Point:	Not available	Partition coefficient:	Not available
Evaporation Rate:	Not available	Auto-ignition temperature:	Not available
Flammability:	Not flammable	Decomposition temperature:	Not available
Upper flammability limits:	Not available	Viscosity:	Not available

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: No data available.

Section 11: TOXICOLOGICAL INFORMATION**Acute Toxicity:**

Ingestion: The product is classified as harmful if swallowed. Sulfadiazine is readily absorbed from the gastrointestinal tract. Animal experiments indicate that ingestion of less than 150 g of sulfadiazine or trimethoprim may be fatal or may produce serious damage to the health of the individual.

Sulfadiazine: Oral (mouse) LD₅₀: 1500 mg/kg.

Trimethoprim: Oral (mouse) LD₅₀: 2764 mg/kg.

Sodium hydroxide: Oral (rabbit) LD₅₀: 500 mg/kg.

Inhalation: No data available.

Dermal: No data available.

Injection: If injected perivascularly irritation or tissue death may occur due to the alkaline nature of the product.

Sulfadiazine: Subcutaneous (mouse) LD₅₀: 1600 mg/kg; Intraperitoneal (mouse) LD₅₀: 750 mg/kg; Intravenous (mouse) LD₅₀: 180 mg/kg.

Trimethoprim: Subcutaneous (mouse, rat) LD₅₀: > 5000 mg/kg; Intraperitoneal (mouse) LD₅₀: 400 mg/kg; Intravenous (mouse) LD₅₀: 132 mg/kg.

Sodium hydroxide: Intraperitoneal (mouse) LD₅₀: 40 mg/kg.

Skin Corrosion / Irritation: The product is classified as a skin irritant. Sulfadiazine is considered to be a skin irritant and the alkaline nature of the solution can also cause skin irritation / corrosion.

Serious Eye Damage / Irritation: The product is classified as a serious eye irritant. Sulfadiazine is considered to be an eye irritant and the alkaline nature of the solution can also cause serious eye irritation.

Respiratory or Skin Sensitisation: Due to the presence of sulfadiazine the product is classified as a respiratory sensitiser and a skin sensitiser.

Germ Cell Mutagenicity: The product is classified as a germ cell mutagen. Strong evidence exists that trimethoprim may cause irreversible mutations (though not lethal) even following a single exposure.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: The product is classified as a reproductive toxicant. Ample evidence exists that developmental disorders are directly caused by human exposure to trimethoprim. Trimethoprim is teratogenic and embryotoxic at high doses through folic acid antagonism. In addition, there is a suspicion that trimethoprim directly reduces fertility.

STOT: Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

STOT: Repeat exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure. However, sulfonamides and their derivatives have been known to cause extensive kidney damage, and destroy red blood cells.

Aspiration hazard: No data available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Trimethoprim is harmful in the aquatic environment.

Fish

Sulfadiazine: LC₅₀ (96h): 4033 mg/L.

Trimethoprim: LC₅₀ (96h): 796 mg/L.

Sodium hydroxide: LC₅₀ (96h): 4.2 mg/L; NOEC (96h): 56 mg/L.

Crustacea

Sulfadiazine: LC₅₀ (48h): 88 mg/L.

Sodium hydroxide: EC₅₀ (48h): 40.4 mg/L; EC₅₀ (384h) 27902 mg/L.

Algae and other aquatic plants

Sulfadiazine: EC₅₀ (168h): 0.14 mg/L.

Trimethoprim: EC₅₀ (96h): 2.6 mg/L, NOEC (72h): 16 mg/L.

Sodium hydroxide: EC₅₀ (96h): 1034 mg/L.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Sulfadiazine	HIGH	HIGH	LOW (LogKOW = -0.09)	LOW (KOC = 188.9)
Trimethoprim	HIGH	HIGH	LOW (LogKOW = 0.91)	LOW (KOC = 905)
Sodium hydroxide	LOW	LOW	LOW (LogKOW = -3.8796)	LOW (KOC = 14.3)

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Dispose of container by wrapping with paper and placing in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA No.: 48032

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

ADG Code	Australian Dangerous Goods Code.
ADI	
AICS	Australian Inventory of Chemical Substances.
CAS No.	Chemical Abstracts Service Registry Number.
EC₅₀	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
IATA	International Air Transport Association.
IMDG Code	International Maritime Dangerous Goods Code.
KOC	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
KOW	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
LC₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEC	No-observable-effect-concentration.
NOEL	No-observable-effect-level
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
SWA	Safe Work Australia.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 11 April 2016 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 30 June 2011.**Revision History:**

Date of Revision	Reason
11 April 2016	GHS classification and update of SDS to comply with SWA Code of Practice.

END OF SDS