

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Tribrisсен 80 Tablets
Product Code:	60430 (500 tablets)
Recommended Use:	For the oral treatment of infection in dogs caused by organisms sensitive to trimethoprim-sulfadiazine.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications: Considered a Hazardous Substance according to the criteria of GHS.

Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

GHS Hazard Classification:*

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.
Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)	H335	May cause respiratory irritation.

GHS Pictograms:

Exclamation mark



Health hazard

Signal Word: DANGER

Precautionary Statements:

Prevention	
P201	Obtain special instructions before use.
P261	Avoid breathing dust
P271	Use only outdoors or in a well-ventilated area
P280	Wear protective gloves e.g. PVC or vinyl
P281	Use personal protective equipment as required
P285	In case of inadequate ventilation wear respiratory protection.

Response

P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+ P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P305+P351 +P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTRE or doctor / physician.
P362	Take off contaminated clothing and wash before reuse.

Storage

P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Disposal

P501	Dispose of contents / container in accordance with local / national regulations.
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* N.B.: These statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Sulfadiazine	68-35-9	52%
Cellulose	9004-34-6	30-60 %
Trimethoprim	738-70-5	10%
Other non-hazardous ingredients	-	< 10%

Section 4: FIRST AID MEASURES

General information:	Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. 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 product container or label at hand.
Inhalation:	If fumes or combustion products are inhaled remove from contaminated area. Sensitive individuals might exhibit allergic reactions, possibly life threatening. Seek medical advice. Show this SDS to a medical practitioner.
Ingestion:	Sensitive individuals might exhibit allergic reactions, possibly life threatening. If swallowed, rinse mouth with water. Seek medical advice. Show this SDS to a medical practitioner.
Skin:	Mild irritant. May cause skin rashes in sensitised persons. If skin contact occurs, immediately remove all contaminated clothing, including footwear. Wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.
Eye:	Mild to moderate irritant. If eye contact occurs, rinse cautiously with water for at least 20 minutes. If eye irritation persists, get medical advice/attention.
Chronic:	Due to the presence of sulfadiazine, prolonged or repeated exposure may lead to sensitisation reactions. Due to the presence of trimethoprim, prolonged or repeated contact may lead to nausea, vomiting, skin rash and pruritus.
Advice to Doctor:	Contains sulfadiazine and trimethoprim which present sensitisation potential. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point:	Not flammable.
Hazardous Combustion Products:	If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.

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 boots and breathing apparatus.
Special hazards:	Fire Incompatibility: Avoid contamination with oxidising agents.
HAZCHEM:	None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal:	Wear appropriate protective clothing. Exclude non-essential people from the area. Use dry clean up procedures and avoid generating dust. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely.
Protective Clothing:	For appropriate personal protective equipment see section 8.
Environmental Precautions:	If contamination of drains and waterways occurs, advise Emergency Services.

Section 7: HANDLING AND STORAGE

Handling:	Avoid all personal contact, including inhalation. Use personal protective equipment as required.
Storage:	Store in original container, away from foodstuffs. Store below 25°C. (air conditioning).
Other Information:	Always read the label before use. See label for further information on handling and storage.

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. Do not handle until all safety precautions have been read and understood.
Protective Equipment:	Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.
Engineering Controls:	Handle in a well ventilated area.
Hygiene Precautions:	Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White, bi-convex, half-scored tablets.	Lower flammability limits:	Not applicable.
Odour:	Not available.	Vapour Pressure:	Not available.
Odour threshold:	Not available.	Vapour density:	Not available.
pH:	Not available.	Relative density:	Not available.
Melting Point:	Not available.	Specific Gravity:	Not available.
Boiling Point:	Not available.	Solubility in Water:	Partly soluble, disintegrates.
Flash Point:	Not flammable.	Partition coefficient:	Not available.
Evaporation Rate:	Not available.	Auto-ignition temperature:	Not available.
Flammability:	Not applicable.	Decomposition temperature:	Not available.
Upper flammability Limits:	Not applicable.	Viscosity:	Not applicable.

Section 10: STABILITY AND REACTIVITY

Stability:	When stored appropriately this product should show no significant degradation within the expiry period shown on the labelling.
Hazardous Polymerisation:	Not known to occur.
Materials to Avoid:	Avoid oxidising agents.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:	<p>Inhalation: Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual. Cellulose, given via the windpipe, caused fibrosis in the alveoli and airways, with injuries of the lung cells. Some health effects associated with wood, cotton, flax, jute and hemp particles or fibres are not attributable to cellulose content but to other substances and/or impurities.</p> <p>Ingestion: Based on available data for the ingredients, the mixture is classified as harmful if swallowed - Acute Toxicity (Oral) Category 4. Accidental ingestion of the material may be harmful; Trimethoprim may produce nausea and vomiting. Trimethoprim may cause disturbance in the production of blood cells. Trimethoprim may cause hyperkalaemia (high blood potassium concentration). Sulfadiazine is a possible kidney and renal system toxicant. Large doses of cellulose may be administered orally as non-nutritive bulk, with doses of up to 30 g/day tolerated as bulk laxative while extremely large oral doses may produce disturbances to the gut.</p> <p>Sulfadiazine: LD₅₀ (oral): 1500 mg / kg (mouse)</p> <p>Trimethoprim: LD₅₀ (oral): 4850 mg / kg (F4 mouse) LD₅₀ (oral): 1500 - 1850 mg / kg (rat)</p> <p>Cellulose: LD₅₀ (oral): 5000 mg / kg (rat)</p>
Skin Irritation/ Corrosion:	Based on available data for the ingredients, the mixture is classified as Skin Corrosion/ Irritation Category 2 - Causes skin irritation. May cause hypersensitivity.
Serious Eye Damage/ Irritation:	Based on available data for the ingredients, the mixture is classified as Eye Irritation Category 2A – Causes serious eye irritation. May cause hypersensitivity.
Respiratory or Skin sensitisation:	Based on available data for the ingredients, the mixture is classified as Respiratory Sensitizer Category 1 & Skin Sensitizer Category 1- May cause allergy or asthma symptoms or breathing difficulties if inhaled & May cause an allergic skin reaction. Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.
Mutagenicity:	Based on available data for the ingredients, the mixture is classified as Germ cell mutagenicity Category 2 – Suspected of causing genetic defects.
Carcinogenicity:	There has been some concern that this material can cause cancer but there is not enough data to make an assessment.
Reproductive Toxicity:	Based on available data for the ingredients, the mixture is classified as Reproductive Toxicity Category 1B - May damage fertility or the unborn child. Sulfonamides may cause reproductive toxicity (e.g. reduced sperm counts) with prolonged use.
STOT – Single Exposure:	Based on available data for the ingredients, the mixture is classified as Specific target organ toxicant after single exposure - single exposure Category 3 . May cause respiratory tract irritation.
STOT – Repeated Exposure:	No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as single target organ toxicant after repeated exposure but prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas. Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention.

Aspiration hazard: May cause hypersensitivity.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Based on available data for the ingredients, the mixture is not classified as harmful to environment. However, DO NOT discharge the mixture into sewer or waterways.

<u>Sulfadiazine:</u>	Fish: LC50 (96 h): 4033.48 mg/L; Crustacea: EC50 (48 h): 88 mg/L.
<u>Cellulose:</u>	Fish: LC50 (96 h): 7.45 mg/L; Algae or other aquatic plants: EC50 (96 h): 17857.93 mg/L.
<u>Trimethoprim:</u>	Fish: LC50 (96 h): 795.57 mg/L; Algae or other aquatic plants: EC50 (96 h): 2.629mg/L;

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Sulfadiazine	High	High	Low	Low
Cellulose	Low	Low	Low	Low
Trimethoprim	High	Low	Low	Low

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to APVMA approved label or by approved waste collection.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 36119

ACIS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredients: Sulfadiazine and Trimethoprim are mentioned in SUSMP.

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	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7 th Edition.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
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.
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.
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.

References

ChemID Plus, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Sulfadiazine and Trimethoprim.

New Zealand Environmental Protection Authority, HSNO Chemical Classification and Information Database (CCID), entries for Sulphadiazine (CAS Number: 68-35-9) and Trimethoprim (CAS Number: 738-70-5).

VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>), entries for sulfadiazine and trimethoprim.

This version issued: 20 July 2017 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 20 July 2012.

Revision History:

Date of Revision	Reason
20 July 2017	Updates to section 1, 2, 3, 4, 5, 10, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.

END OF SDS