

SAFETY DATA SHEET



Title: TRIBRISSEN TABLETS

Document: SDS-AU109

Rev: 2.3

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Status: Current

Issue Date: 26-Jun-2024

Effective Date: 26-Jun-2024

Review Date: 03-Sep-2025

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:

Tribrisen 20 Tablets
Tribrisen 80 Tablets

Product Identifier:

Trimethoprim / Sulfadiazine antibiotic tablets.

Recommended Use:

For the oral treatment of infections in dogs and cats caused by organisms sensitive to trimethoprim-sulfadiazine combinations.

Company Identification:

Zoetis Australia Pty Ltd
ABN: 94 156 476 425

Address:

Level 6, 5 Rider Boulevard
Rhodes NSW 2138
Australia

Telephone:

1800 814 883

Fax:

(02) 8876 0444

Email:

productsupport.au@zoetis.com

National Poisons Information Centre:

13 11 26 (all hours)

Police, Fire Brigade, Ambulance:

Dial 000

Emergency Telephone Number:

1800 814 883 (all hours)

Section 2: HAZARDS IDENTIFICATION

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

GHS Category	Hazard code	Hazard Statement
Skin 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.

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Signal Word: DANGER

GHS Pictograms:



**Exclamation
Mark**



**Health
Hazard**

Precautionary Statements:

General

- P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

Prevention

- P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust.
P264 Wash hands thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves and eye protection.
P284 In case of inadequate ventilation wear respiratory protection.

Response

- P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P332+P313 If skin irritation or rash occurs: Get medical advice / attention.
P304+ P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTRE or doctor.
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.
P308+P313 IF exposed or concerned: Get medical advice / attention.
P312 Call a POISON CENTRE or doctor if you feel unwell.
P362+P364 Take off contaminated clothing and wash it before reuse.

Storage

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

Disposal

- P501 Dispose of contents and / or container in accordance with local regulations.

* 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.

Other hazards: Individuals sensitive to sulfadiazine and trimethoprim may exhibit an allergic reaction, possibly severe.

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Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Sulfadiazine	68-35-9	45 – 55 %
Cellulose	9004-34-6	20 – 50 %
Trimethoprim	738-70-5	9 – 11 %
Other non-hazardous ingredients	N/A	< 10 %

Section 4: FIRST AID MEASURES

General information: Consult the National Poisons Centre on 13 11 26 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 this SDS, product container or label at hand.

Symptoms and Effects of Exposure: May cause an allergic reaction in persons sensitive to sulfadiazine and / or trimethoprim. Accidental ingestion of trimethoprim can cause nausea, vomiting, headache, pruritis (itchiness) and skin rash.

Inhalation: If fumes or combustion products are inhaled remove patient from contaminated area. 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. Transport patient to hospital, or a doctor as soon as possible.

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, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his / her care and a copy of this SDS should be provided. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of this SDS. **Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:** INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Wear a protective glove when inducing vomiting by mechanical means.

Skin: 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: 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. If eye irritation persists, get medical advice / attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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

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Advice to Doctor: Contains sulfadiazine and trimethoprim which present sensitisation potential. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable. Not combustible. Not considered to be a significant fire risk.

Hazardous Combustion Products: If involved in a fire, may emit noxious and corrosive 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 boots and breathing apparatus.

HAZCHEM: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear appropriate protective clothing. Clean up all spills immediately. Exclude non-essential people from the area. Use dry clean up procedures and avoid generating dust. Ventilate area after pick-up is 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: Handle this product with care to avoid exposure, taking all recommended precautions. Avoid all personal contact, including inhalation. Use in a well-ventilated area. Use personal protective equipment as required. DO NOT allow material to contact humans, exposed food or food utensils. Do not drink, eat or smoke when handling this product. Wash hands thoroughly after use.

Storage: Store in in securely sealed original containers, away from foodstuffs. Store below 25°C. (air conditioning) in a cool, dry, well-ventilated area. Protect from light. Protect containers against physical damage.

Other Information: Avoid contact with incompatible substances as listed in Section 10. 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: An exposure limit for the mixture has not been established. Available exposure limits for the ingredients are as follows:

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OCCUPATIONAL EXPOSURE LIMITS (OEL)

AUSTRALIAN EXPOSURE STANDARDS

Source	Ingredient	TWA	STEL
Australia Exposure Standards	Cellulose	10 mg/m ³	Not Available

Engineering Controls: Handle in a well-ventilated area. Ensure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye protection: Safety glasses with eye side shields or chemical goggles are recommended when handling bulk quantities of this product and an eye wash unit should be at hand.

Skin protection: When handling bulk quantities, prevent skin contact by wearing chemical protective gloves, e.g. PVC and safety footwear or safety gumboots, e.g. rubber.

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

Other: When handling bulk quantities of this product, overalls, PVC apron, barrier cream, skin cleansing cream and eye wash unit may be required.

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.

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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 and direct sunlight.

Incompatible Materials: Avoid contact with strong acids, bases and oxidising agents.

Hazardous Decomposition Products: May produce toxic fumes of carbon dioxide (CO₂), nitrogen oxides (NO_x), sulfur oxides (SO_x) and other pyrolysis products typical of burning organic material on decomposition.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. However, accidental ingestion of the mixture may be harmful. Sulfonamides and their derivatives can cause extensive kidney damage, and destroy red blood cells. An overdose may cause an accumulation of acid in the blood or a diminished blood sugar level. Side effects of Trimethoprim ingestion can include; nausea, vomiting, headache, pruritis (itchiness) and skin rash. Disturbance of liver and kidney function may also occur.

Sulfadiazine: LD₅₀: 1500 mg/kg (mouse)

Cellulose: LD₅₀: >5000 mg/kg (rat)

Trimethoprim: LD₅₀: 2764 mg/kg (mouse)

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Skin Irritation / Corrosion: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Irritation Category 2**. Sulfadiazine can cause inflammation of the skin on contact in some persons and it may accentuate pre-existing dermatitis conditions.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Eye Irritation Category 2A**. Sulfadiazine can cause eye irritation and damage in some persons. Eye drops with sulfonamides can cause local irritation, sensations of burning and stinging, blurred vision and loss of depth perception. The conjunctiva and cornea may become inflamed, and the cornea and lens may become clouded.

Respiratory and Skin sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Respiratory Sensitizer Category 1** and a **Skin Sensitizer Category 1**. 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.

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Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Germ Cell Mutagenicity Category 2**. Trimethoprim is suspected of causing genetic mutations and developmental disorders.

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: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Reproductive Toxicity Category 1B**. There is some evidence that Sulfadiazine may reduce fertility and result in toxic effects to the unborn baby. Trimethoprim is suspected of reducing fertility and long-term exposure may cause physical defects in the developing embryo (teratogenesis).

STOT – Single Exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Specific Target Organ Toxicant - Single Exposure Category 3 (Respiratory Tract Irritation)**. Sulfadiazine and Cellulose can both cause respiratory irritation in some persons. Inhalation of cellulose vapours may be damaging to the health of the individual.

STOT – Repeated Exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a single target organ toxicant after repeated exposure. However, long-term exposure to respiratory irritants may result in airways disease and 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.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

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.

Fish

Sulfadiazine: LC₅₀ (96 h): 4033.48 mg/L;
Cellulose: LC₅₀ (96 h): 9160000 mg/L;
Trimethoprim: LC₅₀ (96 h): 795.58 mg/L.

Crustacea

Sulfadiazine: EC₅₀ (48 h): 88 mg/L;
Cellulose: No Data;
Trimethoprim: No Data.

Algae or other aquatic plants

Sulfadiazine: No Data;
Cellulose: EC₅₀ (96 h): 340000000 mg/L;
Trimethoprim: EC₅₀ (96 h): 2.629mg/L.

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Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Sulfadiazine	High	High	Low (LogKOW = -0.09)	Low (KOC = 188.9)
Cellulose	Low	Low	Low (LogKOW = -5.1249)	Low (KOC = 10)
Trimethoprim	High	High	Low (LogKOW = 0.91)	Low (KOC = 905)

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 putting in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classed as a Dangerous Good for transport purposes by road, sea or air.

Section 15: REGULATORY INFORMATION

Poisons Schedule (SUSMP): Schedule 4

APVMA Registration No: 36119 (Tribrisen 80 Tablets), 36122 (Tribrisen 20 Tablets)

Section 16: OTHER INFORMATION

This information is based on data believed by Zoetis Australia 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 Zoetis Australia 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:

APVMA	Australian Pesticides and Veterinary Medicines Authority.
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.
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.
OEL	Occupational Exposure Limits
PPE	Personal Protective Equipment.

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PVC	Polyvinyl Chloride.
SDS	Safety Data Sheet.
STEL	Short Term Exposure Limit
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
TWA	Time-Weighted Average. The average amount of a substance a person can be exposed to over an eight-hour day.

References

ChemID Plus
Chemwatch
EPA New Zealand Chemical Classification and Information Database (CCID)
HSDB (Hazardous Substances Data Bank)
VSDB (Veterinary Substances Database)

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.
31 August 2020	Combined Tribriszen 80 and Tribriszen 20 SDSs. GHS update: Removed Acute Toxicity (Oral): Category 4 classification as LD ₅₀ data does not support this. Wording and formatting updates to all sections to bring in line with other Jurox SDSs.
1 March 2023	Update of Customer Service and emergency telephone numbers to Zoetis numbers.
26 June 2024	Update to Zoetis SDS.

END OF SDS