
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

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|---|--|
| Product Name: | Tribrisсен 20 Tablets |
| Product Code: | 60420 (100 tablets) |
| Recommended Use: | An oral antibiotic tablet for the treatment of infections in dogs and cats by organisms sensitive to trimethoprim - sulfadiazine combinations. |
| 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 |
| Reproductive Toxicity Category 2 | H361 | Suspected of damaging fertility or the unborn child |

Signal word: Warning

GHS Pictograms:



Exclamation
mark



Health
hazard

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 dust.
P264 Wash hands 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.
P281 Use personal protective equipment as required.
P280 Wear protective gloves and eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response

- P308 + P313 IF exposed or concerned: Get medical advice/attention.
P301 + P312 IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P330 Rinse mouth.
P304 + P341 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/physician.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P362 Take off contaminated clothing and wash before reuse.
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.

Storage

- P405 Store locked up.

Disposal

- Dispose of empty container and unused product by wrapping with paper and putting in garbage.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

| INGREDIENT | CAS No. | CONTENT |
|---|----------|---------|
| Sulfadiazine | 68-35-9 | 30% |
| Trimethoprim | 738-70-5 | 6% |
| Ingredients not contributing to the hazards | | > 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: None known.

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 do NOT induce vomiting. 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.

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. If eye irritation persists, get 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: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. When cleaning up spills, wear gloves and appropriate protective clothing. For small spills, clean 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: This is a Schedule 4 (Prescription Animal Remedy) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of dusts. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

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 or its ingredients. For trimethoprim the ADI is set at 0.02 mg/kg/day and the NOEL is 33 mg/kg/day.

Engineering Controls: Make sure that the work environment remains clean.

Personal Protective Equipment (PPE):

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

Skin protection: When handling bulk product, 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: | White, sugar coated tablets | Lower flammability limits: | Not available |
| Odour: | Not available | Vapour Pressure: | Not available |
| Odour threshold: | Not available | Vapour density: | Not available |
| pH: | Not applicable | Relative density: | Not applicable |
| Melting Point: | Not available | Specific Gravity: | Not applicable |
| Boiling Point: | Not available | Solubility in Water: | Disintegrates in water |
| 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 applicable |

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: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Acute Toxicity (Oral) Category 4**.

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

Trimethoprim: Oral 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 Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Corrosion/Irritation Category 2**.

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**.

Respiratory or 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 **Skin Sensitizer Category 1**. Sulfadiazine is a known respiratory sensitizer and known skin sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

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 similar formulations, the mixture is classified as **Reproductive Toxicity Category 2**.

In a surveillance study of Michigan Medicaid recipients involving 229,101 completed pregnancies conducted between 1985 & 1992, 2296 newborns had been exposed to the combination of trimethoprim-sulfamethoxazole during the 1st trimester. A total of 126 (5.5%) major birth defects were observed (98 expected). This incidence is suggestive of an association between the drug combination & congenital defects. In another human study, a higher rate of cardiovascular malformations was found after treatment with trimethoprim-sulfamethazine in the second-third months of pregnancy.

Sulfonamide/trimethoprim combinations have been shown to cause a drop in the sperm count after 1 month of continuous treatment in males.

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.

Aspiration hazard: No data available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

Fish

Sulfadiazine: LC₅₀ (96h): 4033 mg/L;

Trimethoprim: LC₅₀ (96h) 795.6 mg/L.

Crustacea

Sulfadiazine: EC₅₀ (48h): 88 mg/L;

Trimethoprim: No data.

Algae and other aquatic plants

Sulfadiazine: EC₅₀ (7 day): 0.135 mg/L;

Trimethoprim: EC₅₀ (96h) 2.6 mg/L, EC₅₀ (7 day) 112 mg/L; NOEC (72h) 16 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) |

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Crush or puncture and bury in an approved landfill if an approved recycling system is not available.

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.: 36122

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:

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|------------------------|--|
| ADI | Acceptable daily intake. The amount of a specific substance that can be ingested (orally) on a daily basis over a lifetime without an appreciable health risk. |
| 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. |
| 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: 31 May 2016 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 1 July 2011.**Revision History:**

| Date of Revision | Reason |
|------------------|--|
| 31 May 2016 | Reclassification of substance to GHS classification and update of SDS to comply with SWA Code of Practice. |
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END OF SDS