SAFETY DATA SHEET



 Title: TRIVETRIN INJECTION
 Document: SDS-AU114

 Rev: 2.2
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 Status: Current
 Issue Date: 21-Jun-2024
 Effective Date: 21-Jun-2024
 Review Date: 07-Jun-2027

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: Trivetrin Injection

Product Identifier: Solution for injection containing 40 mg/mL Trimethoprim and

200 mg/mL Sulfadoxine.

Recommended Use: For the treatment of infections caused by organisms sensitive to

trimethoprim and sulfadoxine in cattle, sheep, pigs, horses, cats

and dogs.

Restrictions on Use: For animal treatment only.

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@zoetis.com

National Poisons Information Centre: 13 11 26 (24 hours)

Police, Fire Brigade, Ambulance: Dial 000

Emergency Telephone Number: 1800 814 883 (all hours)

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
Skin Irritation Category 2	H315	Causes skin irritation.
Eye Irritation Category 2A	H319	Causes serious eye irritation.
Reproductive Toxicity Category 1B	H360	May damage fertility or the unborn child.
Specific Target Organ Toxicity – SE (Respiratory Tract Irritation) Category 3	H335	May cause respiratory irritation.
Germ Cell Mutagenicity	H341	Suspected of Causing Genetic Defects

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Signal word: DANGER GHS Pictograms:





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 vapours.

P264 Wash hands thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves, eye protection / face protection.

Response

P302+P352 IF ON SKIN: wash with plenty of soap and water.

P304+P340 IF INHALED: Remove person to fresh air and keep 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.
P312 Call a POISON CENTER/doctor if you feel unwell.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

<u>Storage</u>

P403+P233 Store in well-ventilated place. Keep container tightly closed.

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.

N.B.: The above 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: None known.

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Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Sulfadoxine	2447-57-6	20%
Trimethoprim	738-70-5	4%
Sodium Hydroxide	1310-73-2	< 5%
Glycerol Formal	5464-28-8	>50%
Ingredients not contributing to the hazards	-	10 – 30%

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: Accidental ingestion of the material may be harmful. Overdose may cause an accumulation of acid in the blood or a diminished blood sugar level with confusion and coma resulting. Sensitisation reactions may occur in susceptible individuals.

Inhalation: If fumes or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary. 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. Call a POISON CENTER/doctor if you feel unwell.

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. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Injection: Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleaner or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately.

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

Advice to Doctor: Treat symptomatically.

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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 poisonous 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 Code: Not specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. Avoid breathing vapours and contact with skin and eyes. Clean up all spills immediately. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential personnel from the area. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or water courses and call emergency services. Stop leak if safe to do so.

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 product is a Scheduled Poison (S4) 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 accidental self-injection. Avoid contact with skin, eyes and inhalation of vapours. Use in a well-ventilated area. Do not allow clothing wet with material to stay in contact with skin. Use personal protective equipment as required. 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. Store in a cool, dry, well-ventilated area. Store in original containers, securely sealed, away from foodstuffs. Store locked up and protect containers against physical damage. DO NOT re-use the container.

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.

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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. No exposure standards for the ingredients are available.

The ADI for trimethoprim is 0.02 mg/kg/day. The NOEL for trimethoprim is 33 mg/kg/day.

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

Personal Protective Equipment (PPE):

<u>Eye protection</u>: Safety glasses with side shields or chemical goggles are recommended when handling bulk quantities of this product.

<u>Skin protection</u>: When handling bulk quantities, prevent skin contact by wearing chemical protective gloves e.g. PVC. Wear 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:	Pale yellow liquid	Lower flammability limits:	Not available
Odour:	Not available	Vapour Pressure:	Not available
Odour threshold:	Not available	Vapour density:	Not available
pH:	9 – 10.5	Relative density:	Not applicable
Melting Point:	Not applicable	Specific Gravity:	1.23 – 1.25
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 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.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Decomposes on heating and may produce toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other pyrolysis products typical of burning organic material.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

<u>Ingestion:</u> 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, ingestion of this material may be harmful to the health of the individual.

Sulfadoxine: Oral LD₅₀: 5200 mg/kg (mouse). Trimethoprim: Oral LD₅₀: 2764 mg/kg (mouse). Sodium Hydroxide: Oral LD₅₀: 325 mg/kg (rabbit).

Glycerol Formal: No data.

<u>Inhalation:</u> 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. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Sulfadoxine: No data.
Trimethoprim: No data.
Sodium Hydroxide: No data.
Glycerol Formal: No data.

<u>Dermal:</u> 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. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Entry into the bloodstream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Sulfadoxine: No data.

Trimethoprim: No data.

Sodium Hydroxide: Dermal LD₅₀: 1350 mg/kg (rabbit).

Glycerol Formal: No data.

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<u>Injection:</u> No data for the mixture is available. Effects will vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling) to acute allergic reaction.

Sulfadoxine: Subcutaneous LD₅₀: 2900 mg/kg (mouse).

Intraperitoneal LD₅₀: 2900 mg/kg (mouse).

Trimethoprim: Subcutaneous LD₅₀: >5000 mg/kg (mouse).

Intraperitoneal LD₅₀: 400 mg/kg (mouse); Intravenous LD₅₀: 132 mg/kg (mouse) Intraperitoneal LD₅₀: 40 mg/kg (mouse).

Sodium Hydroxide: Intraperitoneal LD₅₀: 40 mg/kg (mouse). Glycerol Formal: Intraperitoneal LD₅₀: 7500 mg/kg (mouse).

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

Serious Eye Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is considered to be an **Eye Irritant Category 2A**. Contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory or skin sensitiser.

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**. 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: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Reproductive Toxicant 1B**. Trimethoprim is teratogenic and embryotoxic at high doses through folic acid antagonism. Ample experimental evidence exists, that developmental disorders are directly caused by human exposure to trimethoprim, due to its effects on folic acid levels, which is important in the early stages of a baby's development.

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 after single exposure Category 3 (Respiratory Irritation).

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.

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.

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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 an ecological toxicant.

Fish

Sulfadoxine: No data.

Trimethoprim: LC_{50} (96h): >100 mg/L. Sodium Hydroxide: LC_{50} (96h): 144 – 267 mg/L.

Glycerol Formal: No data.

Crustacea

Sulfadoxine: No data.

Trimethoprim: EC_{50} (48h): 52.15 - 57.5 mg/L. Sodium Hydroxide: EC_{50} (48h): 34.59 - 47.13 mg/L.

Glycerol Formal: No data.

Algae and other aquatic plants

Sulfadoxine: No data.

Trimethoprim: EC₅₀ (72h): 74.4 - 86.7 mg/L, EC₅₀ (96h): 59.81 – 117.4 mg/L.

Sodium Hydroxide: No data. Glycerol Formal: No data.

Ingredient	Persistence:	Persistence:	Bioaccumulation	Mobility	
	Water/Soil	Air			
Sulfadoxine	HIGH	HIGH	LOW (LogKOW = 1.2889)	LOW (KOC = 920.3)	
Trimethoprim	HIGH	HIGH	LOW (LogKOW = 0.91)	LOW (KOC = 905)	
Sodium Hydroxide	LOW	LOW	LOW (LogKOW = -3.8796)	LOW (KOC = 14.3)	
Glycerol Formal	No data available	No data available	No data available	No data available	

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 the garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous Good for land, sea or air transport.

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Section 15: REGULATORY INFORMATION

Poison Schedule (Product): Schedule 4

APVMA No.: 36308

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 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:

ADI Acceptable Daily Intake.

AICS Australian Inventory of Chemical Substances.

APVMA Australian Pesticides and Veterinary Medicines Authority.

BCF Bioconcentration factor.

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.

Globally Harmonized System of Classification and Labelling of Chemicals.

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.

NOEL No-observable-effect-level PPE Personal Protective Equipment.

PVC Polyvinyl chloride. SDS Safety Data Sheet.

STOT Specific Target Organ Toxicity.

STOT – SE Specific target organ toxicity – single exposure

SUSMP Standard for the Uniform Scheduling of Medicines and Poisons.

SWA Safe Work Australia.

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References:

ChemID Plus

Chemwatch

EPA New Zealand Chemical Classification and Information Database (CCID)

European Chemicals Agency (ECHA)

HSDB (Hazardous Substances Data Bank)

Revision History:

Date of Revision	Reason
04 July 2017	Five year update. New email address.
07 June 2022	Routine 5-year review. Move to GHS 7. Updates to all sections including update to
	GHS classification.
01 March 2023	Update of Customer Service and emergency telephone numbers to Zoetis numbers.
21 June 2024	Minor revision to update the company details to Zoetis Australia. Minor formatting
21 Julie 2024	changes.

END OF SDS