Dechra

SAFETY DATA SHEET

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

1.1 Product identifier

Product name **CALESULPHA-T ORAL PASTE FOR HORSES (AUSTRALIA)**

Synonyms

1.2 Uses and uses advised against

Uses ANTIBIOTIC ● HORSE TREATMENT ● VETERINARY APPLICATIONS

This product is for the treatment of bacterial infections in horses caused by organisms sensitive to the combination of Sulfadimidine and Trimethoprim.

1.3 Details of the supplier of the product

Supplier name **DECHRA VETERINARY PRODUCTS (AUSTRALIA) PTY LTD**

Address 2 Cal Close, Somersby, NSW, 2250, AUSTRALIA

Telephone 1300 015 825; (02) 4372 1661

Fax (02) 4372 1668

Email info.au@dechra.com

Website http://www.dechra.com.au/

1.4 Emergency telephone numbers

Emergency 13 11 26 (Poisons Information Centre)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

CLASSIFIED AS HAZARDOUS ACCORDING TO SAFE WORK AUSTRALIA CRITERIA

Physical Hazards

Not classified as a Physical Hazard

Health Hazards

Toxic to Reproduction: Category 2
Specific Target Organ Toxicity (Repeated Exposure): Category 2

Environmental Hazards

Not classified as an Environmental Hazard

2.2 GHS Label elements

Signal word **WARNING**

Pictograms

Hazard statements

H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Prevention statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P281	Use personal protective equipment as required.

Response statements

P308 + P313	IF exposed or concerned: Get medical advice/ attention.

Storage statements

P405	Store locked up.

Disposal statements

P501	Dispose of contents/container in accordance with relevant regulations.

2.3 Other hazards

No information provided.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
TRIMETHOPRIM	738-70-5	212-006-2	8.33%
NON HAZARDOUS INGREDIENTS	Not Available	Not Available	Remainder
SULPHAMETHAZINE	57-68-1	200-346-4	41.67%

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.

Inhalation If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.

Skin If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.

Ingestion For advice, contact a Poisons Information Centre on 13 11 26 (Australia Wide) or a doctor (at once). Rinse mouth out with water and give plenty of water to drink.

First aid facilities Eye wash facilities and safety shower are recommended.

4.2 Most important symptoms and effects, both acute and delayed

Suspected of damaging fertility or the unborn child.

4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

5.2 Special hazards arising from the substance or mixture

Non flammable. May evolve carbon oxides and hydrocarbons when heated to decomposition. May evolve sulphur oxides when heated to decomposition.

5.3 Advice for firefighters

Treat as per requirements for surrounding fires. Evacuate area and contact emergency services. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

5.4 Hazchem code

None allocated.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Wear Personal Protective Equipment (PPE) as detailed in section 8 of the SDS.

6.2 Environmental precautions
Prevent product from entering drains and waterways.

6.3 Methods of cleaning up
Contain spillage, then cover / absorb spill with non-combustible absorbent material (vermiculite, sand, or similar), collect and place in suitable containers for disposal.

6.4 Reference to other sections
See Sections 8 and 13 for exposure controls and disposal.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

7.2 Conditions for safe storage, including any incompatibilities
Store in a cool, dry, well marked area, removed from incompatible substances, foodstuffs and other drugs. Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use. Keep out of reach of children. Store between 2°C and 30°C.

7.3 Specific end uses
No information provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters
Exposure standards The acceptable daily intake (ADI) for Sulfadimidine is set at 0.02mg/kg/day. The corresponding No-observable-effect-level (NOEL) is set at 2mg/kg/day.
The ADI for Trimethoprim is set at 0.02mg/kg/day. The corresponding NOEL is set at 33mg/kg/day.

Biological limits
No biological limit values have been entered for this product.

8.2 Exposure controls
Engineering controls Avoid inhalation. Use in well ventilated areas.

PPE

Eye / Face	Wear splash-proof goggles.
Hands	Wear PVC or rubber gloves.
Body	Wear coveralls.
Respiratory	Where an inhalation risk exists, wear a Type A (Organic vapour) respirator.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	WHITE PASTE
Odour	SLIGHT ODOUR
Flammability	NON FLAMMABLE
Flash point	NOT RELEVANT
Boiling point	NOT AVAILABLE

9.1 Information on basic physical and chemical properties

Melting point	NOT AVAILABLE
Evaporation rate	NOT RELEVANT
pH	NOT AVAILABLE
Vapour density	NOT RELEVANT
Specific gravity	NOT AVAILABLE
Solubility (water)	NOT AVAILABLE
Vapour pressure	NOT AVAILABLE
Upper explosion limit	NOT RELEVANT
Lower explosion limit	NOT RELEVANT
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT RELEVANT
Explosive properties	NOT AVAILABLE
Oxidising properties	NOT AVAILABLE
Odour threshold	NOT AVAILABLE

10. STABILITY AND REACTIVITY

10.1 Reactivity

Carefully review all information provided in sections 10.2 to 10.6.

10.2 Chemical stability

Stable under recommended conditions of storage.

10.3 Possibility of hazardous reactions

Polymerization is not expected to occur.

10.4 Conditions to avoid

Avoid heat, sparks, open flames and other ignition sources.

10.5 Incompatible materials

Incompatible with oxidising agents (e.g. hypochlorites), acids (e.g. nitric acid) and alkalis (e.g. sodium hydroxide).

10.6 Hazardous decomposition products

May evolve toxic gases (carbon/ sulphur oxides, hydrocarbons) when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity This product is used in veterinary applications. Use safe work practices to avoid eye contact, prolonged skin contact and ingestion. Refer to medical doctor/specialist for advice regarding adverse side effects.

Information available for the ingredients:

Ingredient	Oral LD50	Dermal LD50	Inhalation LC50
TRIMETHOPRIM	2764 mg/kg (mouse)	--	--
SULPHAMETHAZINE	50 g/kg (mouse)	--	--

Skin Contact may result in irritation, redness, pain and rash.

Eye Contact may result in irritation, lacrimation, pain and redness.

Sensitisation Not classified as causing skin or respiratory sensitisation. Individuals with a history of allergies to this class of substances should avoid contact as it may cause sensitisation.

Mutagenicity Not classified as a mutagen.

Carcinogenicity Not classified as a carcinogen.

Reproductive Suspected of damaging fertility or the unborn child. Sulfadimidine may possibly affect development and/or reproduction.

STOT - single exposure Not classified as causing organ damage from single exposure. However, high level exposure may result in headache, nausea and respiratory tract irritation.

STOT - repeated exposure Causes damage to organs (Bone) through prolonged or repeated exposure.

Aspiration Not classified as causing aspiration.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
No information provided.

12.2 Persistence and degradability
No information provided.

12.3 Bioaccumulative potential
No information provided.

12.4 Mobility in soil
No information provided.

12.5 Other adverse effects
No information provided.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal Return to manufacturer/supplier where possible. For small amounts, bury in approved landfill site. Contact the manufacturer/supplier for additional information (if required).

Legislation Dispose of in accordance with relevant local legislation.

14. TRANSPORT INFORMATION

NOT CLASSIFIED AS A DANGEROUS GOOD BY THE CRITERIA OF THE ADG CODE, IMDG OR IATA

	LAND TRANSPORT (ADG)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	None allocated.	None allocated.	None allocated.
14.2 Proper Shipping Name	None allocated.	None allocated.	None allocated.
14.3 Transport hazard class	None allocated.	None allocated.	None allocated.
14.4 Packing Group	None allocated.	None allocated.	None allocated.

14.5 Environmental hazards
Not a Marine Pollutant

14.6 Special precautions for user

Hazchem code None allocated.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Poison schedule Classified as a Schedule 4 (S4) Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

APVMA Numbers 62149

Classifications Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals.

Inventory listings **AUSTRALIA: AICS (Australian Inventory of Chemical Substances)**
All components are listed on AICS, or are exempt.

16. OTHER INFORMATION

Additional information

WORKPLACE CONTROLS AND PRACTICES: Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

RESPIRATORS: In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:
The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

HEALTH EFFECTS FROM EXPOSURE:
It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
CAS #	Chemical Abstract Service number - used to uniquely identify chemical compounds
CNS	Central Nervous System
EC No.	EC No - European Community Number
EMS	Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
GHS	Globally Harmonized System
GTEPG	Group Text Emergency Procedure Guide
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration, 50% / Median Lethal Concentration
LD50	Lethal Dose, 50% / Median Lethal Dose
mg/m³	Milligrams per Cubic Metre
OEL	Occupational Exposure Limit
pH	relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm	Parts Per Million
STEL	Short-Term Exposure Limit
STOT-RE	Specific target organ toxicity (repeated exposure)
STOT-SE	Specific target organ toxicity (single exposure)
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SWA	Safe Work Australia
TLV	Threshold Limit Value
TWA	Time Weighted Average

Report status

This document has been compiled by RMT on behalf of the manufacturer, importer or supplier of the product and serves as their Safety Data Sheet ('SDS').

It is based on information concerning the product which has been provided to RMT by the manufacturer, importer or supplier or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer, importer or supplier.

While RMT has taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, RMT accepts no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS.

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