

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Doxycycline 50mg/100mg Tablets
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	For treatment of bacterial infections in dogs.
Uses advised against:	None
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Apex Laboratories Pty Ltd
Address:	Apex Laboratories Pty Ltd ACN 614 716 700 2 Cal Close Somersby NSW 2250
Telephone:	1300 015 825 (Business hours: 08:30 – 17:30)
Fax:	+61 2 4372 1668
Email:	thetvet@apexlabs.com.au
Website:	www.apexlabs.com.au
1.4 Emergency Telephone Numbers	
	13 11 26 (Poisons Information Centre)
SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
GHS classification(s):	Toxic to reproduction – Category 1 Skin sensitizer – Sub-category 1B
2.2 Label Elements	
Signal Word:	DANGER
Hazard Statement(s)	
H360D	May damage the unborn child
H317	May cause an allergic skin reaction
Additional Statement(s)	

None	
Precautionary Statement(s) Prevention:	
P280	Wear protective gloves
P272	Contaminated work clothing should not be allowed out of the workplace
Precautionary Statement(s) Response:	
P202	Do not handle until all safety precautions have been read and understood
P281	Use personal protective equipment as required
P308 + P313	If exposure or concerned: get medical advice
P302 + P352	If on skin: wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: get medical advice
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/packaging according to local regulations
2.3 Other Hazard Information	
N/a	

SECTION 3: INFORMATION ON THE INGREDIENTS			
3.1 Substances			
See section below for composition of mixtures			
3.2 Mixtures			
Ingredient	CAS No	EC Number	Content
Doxycycline monohydrate	17086-28-1	Not listed	30-35%
Other non-hazardous ingredients	N/a	N/a	To 100%
SECTION 4: FIRST AID MEASURES			
4.1 Description of first aid measures			
Eye contact:	In case of accidental contact of the product with the eyes rinse abundantly with fresh water, removing any contact lenses. Seek		

	medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water and non-abrasive soap. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Inhalation:	Generally not required due to the nature and packaging of the product. If concerned, remove to fresh air and seek medical advice if irritation occurs.
Ingestion:	Rinse mouth with water and give water to drink. Seek medical advice immediately.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
Not Available	
SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Dry agent, water fog, mist or spray, carbon dioxide. As appropriate for surrounding area.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	No known toxic hazards.
Hazchem code:	None allocated.
SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.	

6.3 Methods and material for containment and cleaning up	
Minor Spills:	Spillage of the product is unlikely to be serious. However, avoid contact with skin and eyes.
Major Spills:	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Control personal contact with the substance, by using protective equipment. Avoid contact with skin and eyes. Collect spillage into clean, dry, labelled containers and dispose after consulting appropriate authorities.
SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protective gloves and clothing when handling the product, keeping exposure to the product to a minimum. Wash hands after handling the product. Prohibit eating, drinking and smoking in storage and handling areas. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Store below 30°C (room temperature). Storage areas and containers should be protected from light, freezing or physical damage and tightly sealed when not in use.
Storage incompatibility:	Not available.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA:	
Not Available	
EMERGENCY LIMITS:	
Not Available	
8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	Not required when product used as directed.
Eye and face protection:	No special equipment needed when handling small quantities. OTHERWISE: Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	Not required when product used as directed. Sensitive individuals should wear gloves.
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not required under normal conditions of use.
8.3 Environmental exposure controls	
See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellow, round, scored tablets
Physical state: Tablet
Odour: None
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Specific gravity/density: Not available
Solubility in water and solvents (mg/l): Not available
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

SECTION 10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	No conditions to avoid other than extreme heat.
10.5 Incompatible materials:	No data available.

10.6 Hazardous decomposition:	No known decomposition products.	
SECTION 11: TOXICOLOGICAL INFORMATION		
If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126		
Inhalation:	Not normally a hazard due to non-volatile nature of the product.	
Ingestion:	Ingestion may result in irritation of the gastrointestinal tract, nausea, vomiting and diarrhea. May cause permanent discolouration of teeth if used during tooth development. Photosensitivity has been reported.	
Skin contact:	May irritate the skin in some persons. Hypersensitivities can produce red rashes, dermatitis with sloughing, hives and swollen cracked lips. Loosening and pigmentation of the nails can also occur.	
Eye contact:	May irritate the eyes.	
Chronic:	Repeated exposure may cause allergic reactions.	
Doxycycline:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : >5000 mg/kg	Skin (rabbit): non-irritating
		Eye (rabbit): non-irritating
Skin corrosion/irritation:		
The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.		
Serious eye damage/irritation:		
Unlikely to cause eye irritation.		
Respiratory or skin sensitization:		
The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.		
Germ cell mutagenicity:		
Not expected to be mutagenic.		
Carcinogenicity:		
Not expected to be carcinogenic.		

Reproductive toxicity:
Reproductive & fertility: Oral (rat) 250 mg/kg/day; NOAEL no effect at max dose Embryo/fetal development: Oral (monkey) 50 mg/kg/day; NOAEL not teratogenic
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
No data available
12.2 Persistence and degradability
No data available
12.3 Bioaccumulative potential
No data available
12.4 Mobility in Soil
No data available
12.5 Other adverse effects
Not Available

SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	<p>Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill; however, contact the relevant local Waste Disposal Authority.</p> <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p>

Waste Treatment Options:	Do not dispose into sewers or waterways	
Sewage Disposal Options:	Do not dispose into sewers or waterways	
SECTION 14: TRANSPORT INFORMATION		
Labels required:	None	
Marine pollutant:	NO	
Hazchem:	N/a	
Land transport (ADG):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

Air transport (IATA / ICAO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
Sea transport (IMDG / IMO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a

SECTION 15: REGULATORY INFORMATION

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

Australian Pesticides & Veterinary Medicines Authority (APVMA) Approval No.: 56206 (100mg); 58341 (50mg)

Poison Schedule	Classified as Schedule 4 according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
Classifications	Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. The classifications and phrases listed below are based on the Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)].
Hazard codes	H317: May cause an allergic skin reaction H360D: May damage the unborn child
Risk phrases	R43: May cause sensitisation by skin contact R61: May cause harm to the unborn child
Safety phrases	Not Applicable
Inventory listing(s)	AUSTRALIA: AICS (Australian Inventory of Chemical Substances) All components are listed on AICS, or are exempt.

SECTION 16: OTHER 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.

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

This SDS summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user must review this SDS in the context of how the product will be handled and used in the workplace. Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product.

The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.