SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Apex Clindamycin 75mg/150mg 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 dental infections wounds, abscesses and osteomyelitis caused by bacteria susceptible to Clindamycin in dogs and cats.
Uses advised against:	None
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Veterinary Products (Australia) Pty Ltd
Address:	2 Cal Close Somersby NSW 2250
Telephone:	1300 015 825 (Business hours: 08:30 – 17:30)
Fax:	+61 2 4372 1668
Email:	info.au@dechra.com
Website:	www.dechra.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):	Serious eye damage/eye irritation – Category 2A Sensitisation, skin – Category 1
2.2 Label Elements	
Signal Word:	WARNING
Hazard Statement(s)	
H319	Causes serious eye irritation
H317	May cause an allergic skin reaction

Additional Statement(s)	
None	
Precautionary Statement(s) Prevention:	
P261	Avoid breathing dust
P264	Wash hands thoroughly after handling
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves/protective clothing/eye protection/face protection
Precautionary Statement(s) Response:	
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
P302 + P352	If on skin: wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: get medical advice/attention
P363	Wash contaminated clothing before reuse
Precautionary Statement(s) Storage:	
N/A	
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
Clindamycin hydrochloride	21462-39-5	N/a	15-20%
Other non-hazardous ingredients	N/a	N/a	To 100%

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact:	Remove contaminated clothing. Flush area with large amounts of soap and water. Seek medical attention.
Inhalation:	Generally not required due to the nature and packaging of the product. If concerned, remove to fresh air and seek medical advice if concerned.
Ingestion:	If swallowed, wash out mouth with water. Contact a Poisons Information Centre or doctor. Do not induce vomiting without medical advice.
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 Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Dry agent, water, foam, 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:	Not applicable.
Hazchem code:	Not applicable.

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. Contain spillage, then sweep up spillage, collect and place in suitable containers for disposal. 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:	Combustible materials.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA:	
None established.	
EMERGENCY LIMITS:	
None established.	
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. Otherwise, wear PVC or rubber 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: Oblong tablet
Physical state: Solid
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 relevant
Evaporation rate: Not relevant
Flammability: Not flammable
Upper/lower flammability or explosive limits: Not relevant
Vapour pressure: Not available
Relative Density (at degrees C): Not relevant
Specific gravity/density: Not relevant
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 STABILITITY

10.1 Reactivity:	Product is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
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:	No dangerous reactions are anticipated under conditions of normal use.
10.4 Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5 Incompatible materials:	Strong oxidizing agents.

10.6 Hazardous decomposition:	May evolve toxic gases when heated to decomposition.

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 of large quantities may result in nausea, vomiting, abdominal pain and diarrhoea. Pseudomembranous colitis may also occur.
Skin contact:	Repeated exposure may cause skin sensitisation.
Eye contact:	May cause serious eye irritation.
Chronic toxicity:	
Clindamycin hydrochloride:	Oral (rat), 6 months, 600 mg/kg/day; NOAEL – No effects at max dose
	Oral (dog), 6 months, 600 mg/kg/day; LOAEL – Gastrointestinal system
	Rat (oral), 12 months, 300 mg/kg/day; NOAEL – No effects at max dose
	Oral (dog), 12 months, 300 mg/kg/day; NOAEL – No effects at max dose
Acute toxicity:	
Clindamycin hydrochloride:	Oral (rat) LD_{50}: 2618 mg/kg
	Oral (mouse) LD_{50}: 1479 mg/kg
	Subcutaneous (rat) LD_{50}: 891 mg/kg
	Intravenous (mouse) LD_{50}: 143 mg/kg
Irritation:	
Clindamycin hydrochloride:	Eye (rabbit): Moderate
	Eye (rat): Not irritating
	Skin (rat): Not irritating
Respiratory or skin sensitization:	
May cause skin sensitisation.	
Mutagenicity:	
Clindamycin hydrochloride:	Bacterial Mutagenicity (Ames) *Salmonella* – Negative *In vitro* Micronucleus - Negative
Carcinogenicity:	

Not expected to be carcinogenic.	
Reproductive toxicity:	
Clindamycin hydrochloride:	Reproductive & Fertility: Oral (rat): 300 mg/kg/day - NOAEL – fertility affected
	Embryo/Foetal Development: Oral (rat): 600 mg/kg/day – NOAEL – not teratogenic
	Embryo/Foetal Development: Oral (mouse): 600 mg/kg/day – NOAEL – not teratogenic
	Embryo/Foetal Development: Subcutaneous (rat): 250 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:	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. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.
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:	Not relevant		
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		
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		
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		

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.: 70247

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	H319: Causes serious eye irritation H317: May cause an allergic skin reaction
Risk phrases	R36: Irritating to eyes R43: May cause sensitisation by skin contact
Safety phrases	None
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.