
1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

1.1 Product identifier

Product name MITOTANE 500 TABLETS
Synonyms APEX MITOTANE 500 TABLETS • MITOTANE 500

1.2 Uses and uses advised against

Uses VETERINARY APPLICATIONS
Treatment of pituitary-dependent hyper-adrenocorticism in dogs and in the palliative treatment of adrenal carcinoma.

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

Specific Target Organ Toxicity (Single Exposure): Category 3
Carcinogenicity: Category 2
Specific Target Organ Toxicity (Repeated Exposure): Category 1

Environmental Hazards

Not classified as an Environmental Hazard

2.2 GHS Label elements

Signal word DANGER

Pictograms**Hazard statements**

H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
H372 Causes damage to organs through prolonged or repeated exposure.

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Prevention statements

P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P281	Use personal protective equipment as required.

Response statements

P304 + P340	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.

Storage statements

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Disposal statements

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

No information provided.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
MITOTANE	53-19-0	200-166-6	58 to 62%
CELLULOSE	9004-34-6	232-674-9	20 to 30%
NON HAZARDOUS INGREDIENTS	Not Available	Not Available	Remainder

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). If swallowed, do not induce vomiting.
First aid facilities	A safety shower should be available.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

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 silicon 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

If spilt, collect and reuse where possible.

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 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 below 30°C.

7.3 Specific end uses

No information provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Exposure standards

Ingredient	Reference	TWA		STEL	
		ppm	mg/m ³	ppm	mg/m ³
Cellulose (paper fibre) (a)	SWA [AUS]	--	10	--	--

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. Maintain dust levels below the recommended exposure standard.

PPE

- Eye / Face** At high dust levels, wear dust-proof goggles.
- Hands** Individuals with sensitive skin should consider wearing latex gloves.
- Body** Not required under normal conditions of use.
- Respiratory** Where an inhalation risk exists, wear a Class P2 (Particulate) respirator.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	WHITE TO OFF-WHITE TABLET
Odour	SLIGHT ODOUR
Flammability	NON FLAMMABLE
Flash point	NOT RELEVANT
Boiling point	NOT AVAILABLE

PRODUCT NAME MITOTANE 500 TABLETS**9.1 Information on basic physical and chemical properties**

Melting point	NOT AVAILABLE
Evaporation rate	NOT AVAILABLE
pH	NOT AVAILABLE
Vapour density	NOT AVAILABLE
Specific gravity	NOT AVAILABLE
Solubility (water)	NOT AVAILABLE
Vapour pressure	NOT AVAILABLE
Upper explosion limit	NOT AVAILABLE
Lower explosion limit	NOT AVAILABLE
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
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 will not occur.

10.4 Conditions to avoid

Avoid contact with incompatible substances.

10.5 Incompatible materials

Compatible with most commonly used materials.

10.6 Hazardous decomposition products

May evolve carbon oxides and 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
MITOTANE	> 5000 mg/kg (rat)	--	--
CELLULOSE	> 5000 mg/kg (rat)	> 2000 mg/kg (rabbit)	> 5800 mg/m ³ /4 hours (rat)

Skin	Contact may result in irritation, redness and rash.
Eye	Contact may result in irritation, lacrimation, pain, redness and conjunctivitis.
Sensitisation	Not classified as causing skin or respiratory sensitisation.
Mutagenicity	Not classified as a mutagen.
Carcinogenicity	Suspected of causing cancer. Mitotane is classified as possibly carcinogenic to humans (IARC Group 2B).
Reproductive	Not classified as a reproductive toxin.
STOT - single exposure	Irritating to the respiratory system. Over exposure may result in irritation of the nose and throat, with coughing.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration	Not classified as causing aspiration.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Acute Toxicity to Fish:

Mitotane: LC 50 (Oncorhynchus mykiss (rainbow trout), 96H): 70 mcg/L; LC 50 (fathead minnows, 96H): 4400 mcg/L.

Acute Toxicity to Aquatic Invertebrates:

EC50 (Daphnia) : 3.2 – 4.5mcg/L.

12.2 Persistence and degradability

This product is not readily biodegradable.

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 For small quantities, collect and place in sealable containers. Dispose of, as with other clinical waste, by high temperature incineration (recommended > 1100°C). Burial to landfill may be acceptable, but only at an approved and licensed waste disposal site.

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

No information provided.

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).

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.
EUROPE: EINECS (European Inventory of Existing Chemical Substances)
All components are listed on EINECS, 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.

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/m ³	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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