

SAFETY DATA SHEET

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

1.1 Product identifier

Product name VETORYL (10MG, 30MG, 60MG AND 120MG) CAPSULES

Synonyms VETORYL

1.2 Uses and uses advised against

Uses DOG TREATMENT ● VETERINARY APPLICATIONS ● VETERINARY USE

For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease

and syndrome) in Dogs.

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

Skin Corrosion/Irritation: Category 2

Serious Eye Damage / Eye Irritation: Category 2A

Specific Target Organ Toxicity (Single Exposure): Category 3 (Respiratory Irritation)

Toxic to Reproduction: Category 2

Environmental Hazards

Aquatic Toxicity (Acute): Category 2 Aquatic Toxicity (Chronic): Category 2

2.2 GHS Label elements

Signal word WARNING

Pictograms









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Hazard statements

H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H401 Toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Prevention statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

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

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response statements

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

P304 + P340 IF INHALED: Remove to fresh air and keep at rest in a position 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.
P321 Specific treatment is advised - see first aid instructions.
P362 Take off contaminated clothing and wash before re-use.

P391 Collect spillage.

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.

2.3 Other hazards

No information provided.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
TRILOSTANE	13647-35-3	237-133-0	12.1 to 36%
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. Also rest and keep

warm.

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. Rinse mouth out with water and give plenty of water to drink.

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.



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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, nitrogen oxides and hydrocarbons 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 25°C

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7.3 Specific end uses

No information provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Exposure standards

No exposure standards have been entered for this product.

Biological limits

No biological limit values have been entered for this product.

8.2 Exposure controls

Avoid inhalation. Use in well ventilated areas. **Engineering controls**

PPE

Eye / Face Not required under normal conditions of use.

Hands Individuals with sensitive skin should consider wearing latex gloves.

Body Not required under normal conditions of use. Respiratory Not required under normal conditions of use.



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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

BLACK AND IVORY COLOURED SOLID **Appearance**

Odour SLIGHT ODOUR **Flammability** NON FLAMMABLE Flash point **NOT RELEVANT Boiling point NOT AVAILABLE**

260°C

Melting point Evaporation rate NOT AVAILABLE NOT AVAILABLE Hq Vapour density **NOT AVAILABLE** Relative density **NOT AVAILABLE** Solubility (water) **INSOLUBLE NOT AVAILABLE** Vapour pressure **NOT RELEVANT** Upper explosion limit Lower explosion limit NOT RELEVANT 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

This product is used in veterinary applications. Use safe work practices to avoid eye contact, prolonged skin Acute toxicity

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contact and ingestion. Refer to medical doctor/specialist for advice regarding adverse side effects.

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

Causes serious eye irritation. Contact may result in irritation, lacrimation, pain, redness and conjunctivitis. Eve

Sensitisation Not classified as causing skin or respiratory sensitisation.

Mutagenicity Not classified as a mutagen. Carcinogenicity Not classified as a carcinogen.

Reproductive Suspected of damaging fertility or the unborn child.

STOT - single Over exposure may result in irritation of the nose and throat, with coughing.

exposure

STOT - repeated

exposure

Not classified as causing organ damage from repeated exposure.

Not classified as causing aspiration. **Aspiration**



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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

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 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

Marine Pollutant.

14.6 Special precautions for user

Hazchem code None allocated.

subject to this Code when transported by road or rail in;

(a) packagings that do not incorporate a receptacle exceeding 500 kg(L); or

(b) IBCs.

Special Provision AU01 - ADG Code 7th Ed.

Label: Miscellaneous

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 60618 (120mg) • 60619 (60mg) • 60620 (30mg) • 64707 (10mg)

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

Labelling of Chemicals.



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Inventory listings AUSTRALIA: AIIC (Australian Inventory of Industrial Chemicals)

All components are listed on AIIC, 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/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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Prepared by

Risk Management Technologies 5 Ventnor Ave, West Perth Western Australia 6005 Phone: +61 8 9322 1711 Fax: +61 8 9322 1794 Email: info@rmt.com.au Web: www.rmtglobal.com

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