SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Vetoryl® (Capsules 5mg, 10mg, 30mg, 60mg and 120mg)
Synonyms:	Vetoryl Capsules
Proper Shipping name:	Not applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	In dogs: For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome).
Uses advised against:	Not for human use. Advised to women who are pregnant or intending to become pregnant to avoid handling the capsules.
1.3 Details of the supplier of the substance or mixture	
Supplier Name:	Dechra Veterinary Products NZ Limited
Address:	PO Box 1604 Paraparaumu Beach, 5252 New Zealand
Telephone:	0800 479 838
Website:	www.dechra.co.nz
Email:	info.nz@dechra.com

1.4 Emergency Telephone Numbers	
The National Poisons Centre:	0800 764 766

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).

Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).

Legend:	*1. Classified by Chemwatch*
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	**H315 -** Skin corrosion / irritation Category 2 **H319 -** Eye irritation Category 2 **H361 -** Reproductive toxicity 2 **H335 -** STOT - SE (resp. Irr) Category 3 **H411 -** Chronic aquatic hazard Category 2
Legend:	*1. Classified by Chemwatch*
Classification (US):	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Reproductive Toxicity Category 2, Specific target organ toxicity – single exposure Category 3 (respiratory tract irritation), Acute Aquatic Hazard Category 2, Chronic Aquatic Hazard Category 2

2.2 Label Elements

GHS Label Elements:	
Signal Word:	WARNING

Hazard statement(s):

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H361	Suspected of damaging fertility or the unborn child.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary Statement(s) Prevention:

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.

P261	Avoid breathing dust/fumes.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement(s) Response:	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call The National Poison Centre or doctor/physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
Precautionary Statement(s) Storage:	
P405	Store locked up.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.

2.3 Other Hazard Information
Ingestion may produce health damage*
Cumulative effects may result following exposure*
Exposure can cause irreversible effects *.

REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures			
1. CAS No 2. EC Number 3. 3.Index Number 4. 4.REACH Number	**% Weight**	**Name**	**Classification according to regulations (EC) No 1272/2008 [CLP] (EU)**
1. 13647-35-3 2. Not Available 3. Not Available 4. Not Available	12.1-36	Trilostane	Skin corrosion / irritation Category 2, Eye irritation Category 2, Reproductive toxicity 2, STOT - SE (Resp. Irr) Category 3, Chronic aquatic hazard Category 2; H315, H319, H361, H335, H411[1]
	Balance	Ingredients determined not to be hazardous	
Legend:	*1. Classified by Chemwatch*		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	If swallowed, do not induce vomiting. Seek medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.

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:	Select extinguishing media suitable for surrounding area
Unsuitable:	There is no restriction on the type of extinguisher which may be used
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	Avoid contamination with oxidizing agents, i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine, etc. as ignition may result.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Solid which exhibits difficult combustion or is difficult to ignite. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. An accumulation of fine dust can burn quickly and violently after ignition. Combustion products contain: - Carbon dioxide (CO_2) - Nitrogen oxides (NO_x) - Carbon monoxide (CO) - Other pyrolysis products that are characteristic of organic matter combustion. May emit toxic smoke. May emit corrosive vapours.

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	
See section 12	
6.3 Methods and material for containment and cleaning up Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately.

	Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal.
Major Spills:	Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. **IF DRY:** Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. **IF WET:** Vacuum/shovel up and place in labelled containers for disposal. **ALWAYS:** Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Wear suitable clothing when risk of exposure occurs. When handling, **DO NOT** eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Store in original containers in a cool, dry area. Keep containers securely sealed. Empty containers can contain residues that may be retrieved. This substance may explode in the presence of a suitable source of ignition; store away from incompatible materials and foodstuff containers. Do not use this veterinary medicinal product after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month. Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Polyethylene or polypropylene container. Do not store above 25°C. Keep the blister pack in the outer carton. Check all containers are clearly labelled and free from leaks. Product is in the form of a hard capsule: ivory body and black cap with the capsule strength printed on the body of the capsule. Shelf life of the veterinary medicinal product as packaged for

	sale: 3 years.
Storage incompatibility:	Avoid reaction with oxidising agents.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
DERIVED NO EFFECT LEVEL - DNEL (EU)
Not Available
PREDICTED NO EFFECT LEVEL - PNEC (EU)
Not Available
OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA (EU):	
Not Available	
INGREDIENT DATA (US):	
Not Available	
EMERGENCY LIMITS (EU/US):	
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:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	Wear appropriate clothing

Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not available
Respiratory protection:	Not applicable

8.3 Environmental exposure controls
See Section 12

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Active: Solid brown crystals
Capsule: ivory body and black cap
Container: Capsules are stored in a blister pack, inside a carton.
Physical state: Solid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not applicable
Melting point / freezing point (degrees C): 260°C (with decomposition)
Initial boiling point and boiling range: Decomposes
Flash Point: Not applicable
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
Solubility in water and solvents (mg/l): Immiscible
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: 329.44
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

10: REACTIVITY AND STABILITY	
10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Will not polymerize.
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	If the capsules are split, the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
Ingestion:	Accidental ingestion of the material may be damaging to the health of the individual. Chronic ingestion may cause latent testosterone deficiency in males. Suspected of damaging fertility or the unborn child. Trilostane may interfere with other drugs such as oral contraceptives and certain diuretics.
Skin contact:	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition. Open cuts, abraded or irritated skin should not be exposed to this material.
Eye contact:	This material can cause eye irritation and damage in some persons.

SECTION 11: TOXICOLOGICAL INFORMATION		
Chronic:	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Chronic ingestion may cause latent testosterone deficiency in males.	
Vetoryl Capsules 10mg, 30mg, 60mg, 120mg:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Trilostane:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: >15000 mg/kg[1]	May cause skin and eye irritation.
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*		
Skin corrosion/irritation:		
May case skin irritation.		
Serious eye damage/ irritation:		
May case eye irritation.		
Respiratory or skin sensitization:		
May cause respiratory irritation. Not a skin sensitizer.		
Germ cell mutagenicity:		
Two studies were conducted, one in mice and one in rats, in accordance with internationally agreed guidelines. Both these studies produced negative results.		
Reproductive toxicity:		
Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, including changes in the development of bones, at levels which do not cause significant toxic effects to the mother. Studies in healthy young men showed that trilostane can also decrease the production of the male hormone testosterone.		
STOT – single exposure:		

SECTION 11: TOXICOLOGICAL INFORMATION
The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Exposure of the environment to trilostane will occur when it is excreted in the urine and faeces of treated dogs. Only a small percentage of the total dog population will need treating for Cushing's disease; dogs are usually kept singly, resulting in small scale exposure in discrete areas. No warnings regarding the use of the product are therefore required. **Do NOT** allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites. **DO NOT** discharge into sewer or waterways.
12.2 Persistence and degradability
Not Available
12.3 Bioaccumulative potential
Not Available
12.4 Mobility in Soil
Not Available
12.5 Results of PBT and vPvB assessment Not Applicable
12.6 Other adverse effects Not Available

SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	DO NOT **allow wash water from cleaning or process equipment to enter drains.** 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. A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse Recycling Disposal (if all else fails) Ensure that the disposal of material is carried out in accordance with Hazardous Substances Regulations.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.

SECTION 14: TRANSPORT INFORMATION		
Labels required:		
Marine pollutant:		
Hazchem:	Not Applicable	
Land transport (NZS 5433): NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE:DANGEROUS GOODS 2005; NZS 5433: 2012, IMDG OR IATA		
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
	Limited quantity	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA):		
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

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	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
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

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

TRILOSTANE (13647-35-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs of Chemicals ECICS (English)
- European Union - European inventory of existing chemical commodities (EINECS)

- US - California Proposition 65 - Reproductive Toxicity
- US Priority List for the Development of Proposition 65 Safe Harbour Levels – No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC	
FEDERAL REGULATIONS:	
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Section 311/312 Hazard Categories	
Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	Yes
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No
US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)	
None Reported	
STATE REGULATIONS	
US. CALIFORNIA PROPOSITION 65	
N/a	
US - CALIFORNIA PREPOSITION 65 - CARCINOGENS & REPRODUCTIVE TOXICITY (CRT): LISTED SUBSTANCE	
Trilostane listed	

15.2 Chemical Safety Assessment
ECHA SUMMARY

Ingredient	**ACVM numbers**	**ACVM Numbers**	**ACVM Numbers**
Trilostane	A010903, A010935	A010936, A010937	A011808

Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
1	Skin Irrit. 2, Eye Irrit. 2, Repr. 2	GHS07, GHS08, Wng	H315, H319, H361
2	Skin Irrit. 2, Eye Irrit. 2, Repr. 2	GHS08, Wng	H315, H319, H361, H335, H302, H312, H332
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

National Inventory	**Status**
Australia - AICS	N (trilostane)
Canada - DSL	N (trilostane)
Canada - NDSL	N (trilostane)
China - IECSC	N (trilostane)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (trilostane)
Korea - KECI	N (trilostane)
New Zealand - NZIoC	N (trilostane)
Philippines - PICCS	N (trilostane)
USA - TSCA	N (trilostane)
Legend:	*Y = All ingredients are on the inventory* *N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

SECTION 16: OTHER INFORMATION

Full text Risk and Hazard codes:

H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled

Relevant risk statements are found in section 2.1

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 - Personal eye protection
EN 340 - Protective clothing
EN 374 - Protective gloves against chemicals and microorganisms
EN 13832 - Protective footwear against chemicals
EN 133 - Respiratory protection

NFPA 704 diamond (US):

Blue = Health, Red = Fire, Yellow = Reactivity, White = Special (Oxidizer or water reactive substances)

Definitions and abbreviations
PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations

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The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.