SAFETY DATA SHEETS

This SDS packet was issued with item: 078674865

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078674873 078706212 078877839 078944706 078951003



SECTION 1: IDENTIFICATION		
1.1 Product identifier		
Product name:	Vetoryl [®] (Capsules 5mg, 10mg, 30mg, 60mg and 120mg)	
Synonyms:	Adrestan [JP]	
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		
Registered company name (UK):	Dechra Ltd	
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK	
Telephone:	+44 (0) 1756 791311	
Fax:	+44 (0) 1756 798604	
Website:	www.dechra.com	
Email:	Not available	
Registered company name (US):	Dechra Veterinary Products	
Address:	Dechra Pharmaceutical Products 7015 College Blvd Suite 525 Overland Park KS 66211 USA	
Telephone:	866-933-2472	
Fax:	Not available	



	www.dechra.com
Email:	Not available
1.4 Emergency Telephone	Numbers
Dechra (US):	866-933-2472
SECTION 2: HAZARDS IDEN	ITIFICATION
	ostance or mixture re according to Reg. (EC) No 1272/2008 and their amendments. oods for transport purposes (EU).
	tance by the 2012 OSHA Hazard Communication Standard (29 as Dangerous Goods for transport purposes (US).
Legend:	1. Classified by Chemwatch
regulation (EC) No	 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	•
	,



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. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. Precautionary Statement(s) Store locked up. P405 Store locked up. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. Precautionary Statement(s) Dispose of contents/container in accordance with local regulations. 2.3 Other Hazard Information Ispose of contents/container in accordance with local regulations. Ingestion may produce health damage* Cumulative effects may result following exposure* Exposure can cause irreversible effects *. PEDACH (FLI) Article F3 F0: The minipute damage to the parts in Substance of Var. High Canada		
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 a POISON CENTER or doctor/physician if you feel unwell. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. Precautionary Statement(s) 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 *.	P261	Avoid breathing dust/fumes.
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Ingestion may produce health damage* Cumulative effects may result following exposure* Exposure can cause irreversible effects *.	P501	
	Ingestion may produce health Cumulative effects may result Exposure can cause irreversit	damage* following exposure* ble 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.Index Number 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 I	by Chemwatch	

SECTION 4: FIRST AID MEASURES		
4.1 Description of first a	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		
1.2 Indication of immed	4.3 Indication of immediate modical attention and special treatment needed	

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 arisir	ng 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 act	ions 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 (CO₂) 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 h	andling	
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

•	
	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: TOXIC	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: TOXIC	OLOGICAL INFORMAT	ION		
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:				
	Not Available	Not Available		
Trilostane:	Acute toxicity Irritation			
	Oral (rat) LD ₅₀ : >15000 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/irrita	ation:			
May case skin irritatio	n.			
Serious eye damage	e/ irritation:			
May case eye irritation	n.			
Respiratory or skin	sensitization:			
May cause respiratory	y irritation. Not a skin sens	sitizer.		
Germ cell mutageni	city:			
Two studies were conducted, one in mice and one in rats, in accordance with internationally agreed guidelines. Both these studies produced negative results.				
Reproductive toxici	ty:			
reduces fertility. Base result in toxic effects of bones, at levels wh healthy young men s hormone testosteron	ed on experience with an to the development of th hich do not cause signific howed that trilostane car e.	there is a suspicion this material directly imal studies, exposure to the material may e foetus, including changes in the development cant toxic effects to the mother. Studies in also decrease the production of the male		
STOT - single even	CUROL			

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 treatm	ent methods		
packaging	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 (Disposal) Regulations 2001.		
Waste Treatment Options:			
	In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.		
SECTION 14: TRAN	NSPORT INFORMATION	I	
Labels required:			
Marine pollutan	t:		
Hazchen	n: Not Applicable		
Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS			
14.1 UN Numbe	er N/a		
14.2 UN Prope Shipping Nam			
14.3 Transpo	-)	N/a	
hazard class(es) Sub risk N/a		N/a	



14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for	Special provisions	N/a
user	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-I DANGEROUS GOOD		ULATED FOR TRANSPORT OF
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport	ICAO/IATA Class	N/a
hazard class(es)	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
	Special provisions	N/a
precautions for user	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- DANGEROUS GOOD		OT REGULATI	ED FOR TRANSPORT OF	
14.1 UN Number	N/a			
14.2 UN Proper Shipping Name	N/a	N/a		
14.3 Transport	IMDG Class	N/a		
hazard class(es)	IMDG Sub risk	N/a		
14.4 Packing group	N/a			
14.5 Environmental hazards	N/a			
	EMS Number	N/a		
precautions for user	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			
Inland waterways tra DANGEROUS GOOD		REGULATED	FOR TRANSPORT OF	
14.1 UN Number	N/a			
14.2 UN Proper Shipping Name				
14.3 Transport hazard class(es)				
14.4 Packing group	N/a			
14.5 Environmental hazard	N/a			
14.6 Special			N/a	
precautions for user	Special provisions N/a		N/a	
	Limited quantity		N/a	
	Equipment required		N/a	
	Fire cones number		N/a	



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

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

Reactivity hazard

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	CAS number	Index Number	ECHA Dossier
Trilostane	13647-35-3	Not Available	Not Available

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

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

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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