

Safety Data Sheet

According to Hazardous Substances (Safety Data Sheets) Notice 2017 and Amendments under New Zealand, Hazardous Substances and New Organisms Act 1996 and Amendments.

Initial preparation date: 31.08.2022

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Revision Date: 22.06.2026

Vetoryl (5mg, 10mg, 20mg, 30mg, 60mg, 120mg) Capsules

SECTION 1: Identification

Product identifier

Product name: Vetoryl (5mg, 10mg, 20mg, 30mg, 60mg, 120mg) Capsules

Synonyms: Vetoryl

Recommended use and restriction on use:

Recommended use: VETERINARY USE: For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs.

Restrictions on use: Not for human use.

Manufacturer or supplier details

Supplier

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

New Zealand

National Poisons Centre

0800 764 766

SECTION 2: Hazard identification

Not classified as a Dangerous Good according to NZS 5433:2020 Transport of Dangerous Goods on Land.

Classification in accordance with the Hazardous Substances (Hazard Classification) Notice 2020 and GHS Revision 7:

Hazard classification:

Skin irritation, category 2

Eye irritation, category 2

Reproductive toxicity, category 2

Label elements

Hazard pictogram(s):



Signal word: Warning.

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Hazard statements:

H315 Causes skin irritation

H319 Causes serious eye irritation

H361 Suspected of damaging fertility or the unborn child

Precautionary statements:

P264 Wash hands thoroughly for 15 minutes after handling

P280 Wear protective gloves

P201 Obtain special instructions before use

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

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

P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).

P332+P313 If skin irritation occurs: Get medical advice P362 Take off contaminated clothing and wash before reuse

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 attention

P308+P313 If exposed or concerned: Get medical attention

P405 Store locked up

P501 Dispose of contents and container in accordance with local regulations

Hazards not otherwise classified:

None.

SECTION 3: Composition/information on ingredients

Substance: Not applicable.

Mixture:

Identification	Name	Weight %
CAS number: 13647-35-3	Trilostane	1-30
CAS number: 557-04-0	Magnesium distearate	1

Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of section 55 (7) of the HSNO Act.

SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

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After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Rinse eyes with plenty of gently flowing lukewarm water for 15 minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed:

Acute symptoms and effects:

Skin contact may result in redness, pain, burning and inflammation.
Eye contact may result in irritation, redness, pain, inflammation, itching, burning and tearing.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).
Long term exposure may affect fertility. Symptoms include, but are not limited to: menstrual problems, altered sexual behavior/fertility/ and pregnancy outcome. Long term exposure may also affect development of the unborn child. Symptoms include, but are not limited to: intrauterine growth retardation, pre-term birth, birth defects and postnatal death.

Immediate medical attention and special treatment:

Immediate medical attention:

Not determined or not available.

Special treatment:

Not determined or not available.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards arising from the chemical:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment and precautions for firefighters

Protective equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

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Precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Advice on how to contain and clean up a spill or release:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

SECTION 7: Handling and storage

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

Storage container: Blister pack in cartons

Store below 25°C. Keep the blister strips in the carton.

SECTION 8: Exposure controls/personal protection

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
New Zealand	Magnesium distearate	557-04-0	8-Hour TWA: 10 mg/m ³

Biological limit values:

No biological limit values limits noted for the ingredient(s).

Engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent)

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Personal protective equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Capsule: ivory body and black cap solid
Odour	Slight odour
Odour threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	260 °C
Initial boiling point/range	Not determined or not available.
Flash point	Not determined or not available.
Flammability (solid, gas)	Non flammable
Upper flammability/explosive limit	Not relevant
Lower flammability/explosive limit	Not relevant
Vapour pressure	Not determined or not available.
Vapour density	Not determined or not available.
Relative density	Not determined or not available.
Solubility(ies)	Immiscible in water
Partition coefficient: n-octanol/water	Not determined or not available.
Auto-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

Other information: None.

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SECTION 10: Stability and reactivity

Chemical reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible materials:

None known.

Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity:

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Trilostane	oral	LD50 Rat: > 15000 mg/kg
Magnesium distearate	dermal	LD50 Rat: >10000 mg/kg
	oral	LD50 Rat: >10000 mg/kg

Skin corrosion/irritation

Assessment:

Causes skin irritation.

Product data: No data available.

Substance data:

Name	Result
Trilostane	Causes skin irritation.

Serious eye damage/irritation

Assessment:

Causes serious eye irritation.

Product data: No data available.

Substance data:

Name	Result
Trilostane	Causes serious eye irritation.

Respiratory or skin sensitization:

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

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Carcinogenicity

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

Germ cell mutagenicity

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive toxicity

Assessment:

Suspected of damaging fertility or the unborn child.

Product data: No data available.

Substance data:

Name	Result
Trilostane	Suspected of damaging fertility or the unborn child.

Specific target organ toxicity (single exposure)

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Aspiration toxicity

Assessment:

Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Inhalation; Ingestion; Skin contact; Eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No additional information.

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SECTION 12: Ecological information

Ecotoxicity

Aquatic

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Terrestrial

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data: No data available.

Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

Mobility in soil

Product data: No data available.

Substance data: No data available.

Other adverse effects: No additional information.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Special precautions to be taken during disposal:

No additional information.

Disposal methods that should not be used:

No additional information.

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SECTION 14: Transportation information

Road/Rail transport: (NZS 5433)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-ICAO)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC):

Substance	CAS	Status
Trilostane	13647-35-3	Not Listed

HSNO approval number: HSR100757

Group Standard Title: Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020.

HSNO Controls: Not determined

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

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Agricultural Compounds and Veterinary Medicines Act 1997:

ACVM number	ACVM Nos: A011808 (5mg), A010903 (10mg), A012124 (20mg), A010935 (30mg), A010936 (60mg), A010937 (120mg)
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Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms:

ATE	Acute Toxicity Estimate
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
EC50	Effective Concentration of 50%
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MARPOL	International Convention for the Prevention of Pollution from Ships
NZIoC	New Zealand Inventory of Chemicals
TWA	Time Weighted Average
UN	United Nations
VOC	Volatile Organic Compounds

Disclaimer:

The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

Revision Date	Notes
22-06-2026	Version 2 (Supersedes Version 1:31 August 2022)

End of Safety Data Sheet