SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Zycortal® (Suspension for Injection)
Synonyms:	Desoxycortone Pivalate
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:	For use as replacement therapy for the mineralocorticoid deficit in dogs with primary hypoadrenocorticism (Addison's disease).
Uses advised against:	Not for human use. Do not use in case of hypersensitivity to the active substance or to any of the excipients. Pregnant and breastfeeding women should avoid administration of the product.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	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
New Zealand Supplier:	RxVet Ltd
Address:	Unit 15 2-4 Northpoint Street Plimmerton Porirua 5026
Telephone:	0800 479 838
Fax:	04 974 7793
Website:	www.rxvet.co.nz

Email:	info@rxvet.co.nz
1.4 Emergency Telephone Numbers	
Dechra (US):	866-933-2472
New Zealand National Poisons Center:	0800 764 766 [0800 POISON], 24 hour service
SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Classification[1]:	Acute Toxicity (Oral) Category 5, Acute Toxicity (Dermal) Category 5, Acute Toxicity (Inhalation) Category 5, Eye Irritation Category 2B, Reproductive Toxicity Category 2
Legend:	*1. Classified by Chemwatch*
Determined by Chemwatch using GHS/HSNO criteria:	6.1E (dermal), 6.1E (inhalation), 6.1E (oral), 6.4A (mild), 6.7B
2.2 Label Elements	
GHS Label Elements:	
Signal Word:	WARNING
Hazard statement(s):	
H303	Toxic if swallowed.
H313	Toxic in contact with skin.
H333	Causes skin irritation.
H320	Causes serious eye irritation.
H351	May cause an allergic skin reaction.
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use.
P281	Use personal protective equipment as required.
P264	Wash all exposed external body areas thoroughly after handling.
Precautionary Statement(s) Response:	
P304 + P312	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
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.
Precautionary Statement(s) Storage:	
P405	Store locked up.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.
2.3 Other Hazard Information	
Not available	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

CAS No	% Weight	Name	Indication
808-48-0	2.5	Desoxycortone Pivalate	May cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. May cause irritation to skin and eyes.
Not available	Proprietary	Other ingredients determined not to be hazardous	Not applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In case of accidental spillage onto eyes, immediately wash the affected area with water. If irritation occurs, seek immediate medical attention and show the package leaflet or the label to the medical practitioner.
Skin contact:	If skin contact occurs, immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). If irritation occurs, seek immediate medical attention 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

SECTION 3: INFORMATION ON THE INGREDIENTS	
	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:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, seek immediate medical attention and show the package leaflet or the label to the medical practitioner. Remove material and flush mouth with water, then provide liquid slowly and as much as casualty can comfortably drink.
Self-injection:	In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the medical practitioner.
4.2 Most important symptoms and effects, both acute and delayed	
Eye contact:	The material may be irritating to the eye, with prolonged contact causing inflammation.
Skin contact:	Hypersensitivity to the active substance or excipients may occur after prolonger or repeated exposure. Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Ingestion:	Overdose of Desoxycortone Pivalate may produce excessive sodium and water retention leading to hypertension, edema, pulmonary congestion and signs and symptoms of congestive heart-failure. Other symptoms of overdose include polyuria, polydipsia, increased blood volume and cardiac enlargement.
Self-injection:	Product may cause pain and swelling at the injection site if accidentally self-administered.
See Section 11 for more detailed information	
4.3 Indication of immediate medical attention and special treatment needed Treat symptomatically. This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose.[1]	
Legend:	*1. MARTINDALE, The Extra Pharmacopoeia, 29th Ed.*

SECTION 3: INFORMATION ON THE INGREDIENTS	
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:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. **Do not** approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn.
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 breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite.

SECTION 3: INFORMATION ON THE INGREDIENTS	
	Prevent, by any means available, spillage from entering drains or water course.
SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe handling:	Wear suitable protection gloves and clothing when handling the product. When handling do **NOT** eat, drink or smoke. Always wash hands with water after handling. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Observe manufacturer's storage and handling recommendations.
7.2 Conditions for safe storage, including any incompatibilities	
Safe Storage:	Store at a temperature of 25°C. Excursions permitted between 15°C and 30°C. Do not store above 30°C. Protect from light. Do not freeze. Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after first opening the immediate packaging: 120 days. Keep out of the reach and sight of children. Product is stored in cardboard box containing one Type I clear glass vial (containing 4 ml) with a coated chlorobutyl rubber stopper and aluminium seal with a plastic flip off cap. Check that containers are clearly labelled.
Storage incompatibility:	None known.
7.3 Specific end uses	
Not available	
SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
Occupational Exposure Limits (OEL)	
Ingredient data: Not available	
Emergency limits: Not available	
8.2 Exposure controls	
Appropriate engineering	General exhaust is adequate under normal operating

SECTION 3: INFORMATION ON THE INGREDIENTS	
controls:	conditions. 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:	No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: Safety glasses with side shields.
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves, e.g. PVC
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities.
Thermal hazards:	Not applicable
Respiratory protection:	Not applicable

Recommended Material(s)

Glove Selection Index
Glove selection is based on a modified presentation of the:
***"*Forsberg Clothing Performance Index".**
The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection;

Zycortal

Material	CPI
BUTYL	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NITRILE	C
PVA	C
VITON	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion

SECTION 3: INFORMATION ON THE INGREDIENTS

C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise
be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

8.3 Environmental exposure controls

See Section 12

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Opaque white suspension
Desoxycortone Pivalate:
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Desoxycortone Pivalate: 5 to 7
Melting point / freezing point (degrees C): Desoxycortone Pivalate: 200-206°C
Initial boiling point and boiling range: Not available
Flash Point: In water – no flash point
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): 1. Not soluble
2. Methanol: Sparingly soluble
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: Desoxycortone Pivalate: 414.58
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

SECTION 3: INFORMATION ON THE INGREDIENTS	
SECTION 10: STABILITY AND REACTIVITY	
10.1 Reactivity:	See Section 7
10.2 Chemical stability:	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. Hazardous polymerisation will not occur.
10.4 Conditions to avoid:	Protect from light.
10.5 Incompatible materials:	See Section 7.
10.6 Hazardous decomposition:	See Section 5
SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	Not normally a hazard due to non-volatile nature of product.
Ingestion:	Overdose of Desoxycortone Pivalate may produce excessive sodium and water retention leading to hypertension, edema, pulmonary congestion and signs and symptoms of congestive heart-failure. Other symptoms of overdose include polyuria, polydipsia, increased blood volume and cardiac enlargement.
Skin contact:	The material may cause skin irritation after prolonged or repeated exposure. Hypersensitivity to the active substance or excipients may occur. Skin contact with the material may damage the health of the individual; systemic effects may result following absorption. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye contact:	The material may be irritating to the eye, with prolonged contact causing inflammation./ Repeated or prolonged exposure to irritants may produce conjunctivitis.
Self-injection:	Product may cause pain and swelling at the injection site if accidentally self-administered. This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. Pregnant and breast-feeding women should avoid administration of the product.

SECTION 3: INFORMATION ON THE INGREDIENTS		
Chronic:	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Chronic exposure to glucocorticoids can lead to changes in hormone production, a change in fat distribution (central obesity with wasting of limbs), susceptibility to infections, osteoporosis, cataracts, glaucoma, mental disturbance, high blood sugar and sugar in the urine. There may be muscular weakness and fatigue, acne, period disturbances in women and peptic ulcers. This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates.	
Zycortal:	**Toxicity**	**Irritation**
	This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates.	User safety studies conducted with the final formulation of Zycortal in acute dermal and eye irritation studies in the rabbit showed that Zycortal was a minimal irritant to the rabbit eye and a mild irritant to rabbit skin. Zycortal is considered to be a non-sensitiser in a local lymph node assay in the mouse.

SECTION 3: INFORMATION ON THE INGREDIENTS			
Desoxycorticosterone Pivalate :	**Toxicity**	**Irritation**	
	May cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. CEL TWA: 0.02 mg/m3 (CEL=Chemwatch Exposure Limit) (compare Merck, Sharp and Dohme recommendation for dexamethasone). All corticosteroids have numerous and varied pharmacological actions. In humans, single dose or short term (several days) use is virtually without harmful effects. However, prolonged therapeutic use of corticosteroids may result in suppression of pituitary function. The daily threshold dose for this effect is approximately 0.5 mg for a 50 kg individual. Therefore typical exposure limits of about 0.02 mg/m3 have been calculated from the threshold dose. This is thought to provide about a two-fold safety factor.	May cause irritation to eye and skin	
a) Acute toxicity:	May cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates.	**f) Carcinogenicity:**	Not expected to be carcinogenic

SECTION 3: INFORMATION ON THE INGREDIENTS			
b) Skin corrosion /irritation:	May cause irritation	**g) Reproductive toxicity:**	May cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates.
c) Serious eye damage/ irritation:	May cause irritation	**h) STOT – single exposure:**	Not available
d) Respiratory or skin sensitization:	Not expected to be a respiratory sensitization. Not a skin sensitizer.	**i) STOT – repeated exposure:**	Not available
e) Germ cell mutagenicity:	Not mutagenic in Ames, in vitro or in vivo tests	**j) Aspiration hazard:**	Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Desoxycortone Pivalate	LC_{50}	96	Fish	0.404mg/L	1
Desoxycortone Pivalate	EC_{50}	96	Algae or other aquatic plants	0.127mg/L	1
Desoxycortone Pivalate	EC_{50}	96	Algae or other aquatic plants	0.354mg/L	1
Legend:	*1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)*				

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air

SECTION 3: INFORMATION ON THE INGREDIENTS		
Desoxycortone Pivalate	HIGH	HIGH
12.3 Bioaccumulative potential		
Ingredient	**Bioaccumulative Potential**	
Desoxycortone Pivalate	HIGH (LogKOW = 5.0693)	
12.4 Mobility in Soil		
Ingredient	**Mobility**	
Desoxycortone Pivalate	LOW (KOC = 17560)	
12.5 Results of PBT and vPvB assessment Not Available		
12.6 Other adverse effects Not Available		
SECTION 13: DISPOSAL CONSIDERATIONS		
13.1 Waste treatment methods		
Product / packaging disposal:	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. Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.	

SECTION 3: INFORMATION ON THE INGREDIENTS		
SECTION 14: TRANSPORT INFORMATION		
Labels required: N/a		
Marine pollutant:	NO	
Hazchem:	N/a	
Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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 / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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

SECTION 3: INFORMATION ON THE INGREDIENTS		
	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-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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 This substance is to be managed using the conditions specified in an applicable Group Standard

SECTION 3: INFORMATION ON THE INGREDIENTS

HSR Number	Group Standard
HSR100757	Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2012

Registered pursuant to the ACVM Act 1997 No A11422
Restricted Veterinary Medicine

DESOXYCORTONE PIVOLATE (808-48-0) IS ON THE FOLLOWING REGULATORY LISTS

New Zealand Inventory of Chemicals (NZIoC)

Location Test Certificate
Subject to Regulation 55 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations, a location test certificate is required when quantity greater than or equal to those indicated below are present.

Hazard Class	Quantity beyond which controls apply for closed containers	Quantity beyond which controls apply when use occurring in open containers
Not Applicable	Not Applicable	Not Applicable

Approved Handler
Subject to Regulation 56 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations and Regulation 9 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations, the substance must be under the personal control of an Approved Handler when present in a quantity greater than or equal to those indicated below.

Class of substance	Quantities
Not Applicable	Not Applicable

Refer group Standards for further information

National Inventory	Status
Australia - AICS	N (Desoxycortone Pivalate)
Canada - DSL	N (Desoxycortone Pivalate)
Canada - NDSL	N (Desoxycortone Pivalate)
China - IECSC	N (Desoxycortone Pivalate)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Desoxycortone Pivalate)
Korea - KECI	N (Desoxycortone Pivalate)
New Zealand - NZIoC	N (Desoxycortone Pivalate)
Philippines - PICCS	N (Desoxycortone Pivalate)
USA - TSCA	N (Desoxycortone Pivalate)

SECTION 3: INFORMATION ON THE INGREDIENTS	
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)*
15.2 Chemical Safety Assessment Not applicable	
SECTION 16: OTHER INFORMATION	
The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Prepared by DECHRA LTD on the basis of the best available data. No representation is given that the information provided is complete in all respects. This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from DECHRA LTD. Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.	