

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078558848

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

078599810



**Product Name:** Percorten-V® Injection for Dogs

**Page No:** 1 of 4

**Date of issue:** November 2008

## MATERIAL SAFETY DATA SHEET

### Section 1 - Identification of Chemical Product and Company

#### COMPANY DETAILS:

**Novartis Animal Health Australasia Pty Limited**  
**A.C.N. 076 745 198**  
**54 Waterloo Road**  
**North Ryde NSW 2113**

**Phone: (02) 9805 3555**

**Fax: (02) 9888 8387**

**Product Name:** Percorten-V® Injection for Dogs  
**Active Ingredients:** Deoxycortone Pivalate  
**Product Use:** For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency  
**Revision Date:** November 2008

### Section 2 Hazards Identification

**Hazard classification:** Hazardous Substance  
Non-Dangerous Goods  
**Risk Phrases:** None  
**Safety Phrases:** None  
**SUSDP Classification:** 4  
**UN Number:** None Allocated

### Section 3 Composition / Information on Ingredients

Ingredients	CAS No.	Content (%w/v)
Deoxycortone Pivalate	[808-48-0]	2.5
Thimerosal	[54-64-8]	0.002
Other ingredients determined not to be hazardous		<2
Water	[7732-18-5]	to volume

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

### Section 4 First Aid Measures

**Label regulated First Aid Statement:** If poisoning occurs contact a Doctor or Poisons Information Centre (Phone 131126).  
**Scheduled poisons :** Product is an S<sub>4</sub> scheduled poison. Poisons Information Centres in each State capital city can provide additional assistance for scheduled poisons (Phone 131126).  
**Inhalation:** Move affected person to fresh air and keep rested until recovered.  
**Skin Contact:** Remove contaminated clothing and wash affected areas thoroughly with soap and water.  
**Eye contact:** If product gets in eyes, flush with large quantities of clean tap water for several minutes.  
**Swallowed:** If poisoning occurs contact a Doctor or Poisons Information Centre (Phone 131126).  
**Advice to doctor:** Note the nature of the product (mineralocorticoid hormone). Product was previously approved in the USA for use in humans for treatment of

Novartis Animal Health Australasia Pty Ltd

**MATERIAL SAFETY DATA SHEET**

Addison's disease. Ingestion of small amounts should not present a problem. However, if a large amount has been ingested (several vials) and emesis is inadequate, lavage stomach. Activated carbon can be given to absorb remaining product. Treat symptomatically together with measures to correct fluid and electrolyte imbalance. In case of hypokalemia, digitalis should be used only with caution

**Section 5 Fire Fighting Measures**

- Extinguishing Media:** This product is non-flammable and non-explosive. Use extinguishing media suited to the materials that are burning such as powder, foam, carbon dioxide or water-spray.
- Fire Fighting:** Fight fire in the early stages if safe to do so. Wear respiratory protection with a full mask and combination filter in ventilated areas. In enclosed premises wear respirator with independent air supply. When fighting fires involving significant quantities of this product, wear safety boots, non-flammable overalls, gloves, hat and goggles.

**Section 6 Accidental Release Measures**

- Accidental Release:** In case of spillage it is important to take all steps necessary to:  
Avoid eye and skin contact. Avoid contamination of surface and ground water, drainage systems and other waterways.  
*Procedure for spill:*  
Keep all bystanders away. Wear goggles, full length clothing and PVC gloves. Reposition any leaking packages so as to minimise leakage. Cover spilled liquid with an absorbent material such as pet litter. Sweep up and place in an approved chemical waste container. Flush the area with water to remove any residue. Avoid contamination of sewers and waterways.

**Section 7 Handling and Storage**

- Safe Handling:** Avoid contact with skin, eyes and clothing.
- Storage:** Keep out of reach of children. Store below 25°C (Air Conditioning) in original container tightly closed. Store away from direct sunlight and humidity. Do not freeze.

**Section 8 Exposure Controls / Personal Protection**

- Exposure Limits:** No specific exposure standards have been set for this material. The nuisance particulate exposure standard of 10 mg/m<sup>3</sup> of inspirable dust (8 hr time weighted average) should not be exceeded for airborne dust generated from this material.
- Eye Protection:** No special protective equipment required.
- Skin protection:** No special protective equipment required. If contact is possible when opening containers and using this material, wear PVC gloves.
- Respirator:** No special protective equipment required.
- Protective material types:** No special protective equipment required.
- General advice:** After use and before eating, drinking or smoking, wash hands with soap and water.

**MATERIAL SAFETY DATA SHEET****Section 9 - Physical and Chemical Properties**

<b>Physical State:</b>	Homogenous suspension
<b>Colour:</b>	White/ off-white
<b>Odour:</b>	No particular odour
<b>Corrosiveness:</b>	Non-corrosive
<b>Flammability</b>	Non-flammable
<b>pH</b>	5-7

**Section 10 - Stability and Reactivity**

<b>Chemical Stability:</b>	Product is stable under normal conditions.
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**Section 11 - Toxicological Information**

<b>Acute Toxicity :</b>	Moderately toxic.
Oral:	Based on the acute oral LD <sub>50</sub> in mice = 1000 mg/kg body weight, ingestion of 60 ml or more may be fatal to an adult human. However, given that the product is supplied in 4 ml vials, this would require the ingestion of the contents of 15 or more vials. No hazard is therefore expected from normal clinical use.
Dermal:	No hazard is expected from normal clinical use
Inhalation:	No hazard is expected from normal clinical use
<b>Local Effects:</b>	<u>Irritation</u>
Skin:	No hazard is expected from normal clinical use
Eyes:	No hazard is expected from normal clinical use
<u>Sensitisation</u> -	<b>Potential Skin Sensitiser</b> - repeated skin contact may cause a sensitisation (allergic) reaction in sensitive individuals

**Section 12 - Ecological Information**

No ecological data is available.

**Section 13 - Disposal Considerations**

<b>After intended use:</b>	Dispose of empty vial by wrapping with paper and putting in garbage.
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**Section 14 - Transport Information**

<b>UN Number:</b>	None allocated
<b>UN proper shipping name:</b>	None allocated
<b>Class &amp; Subsidiary Risk :</b>	None allocated
<b>Packaging Group:</b>	None allocated
<b>HAZCHEM Code:</b>	None allocated

**Section 15 - Regulatory Information**

<b>Australia:</b>	Product first registered for use in Australia on the 25 <sup>th</sup> September 2005 by the Australian Pesticides and Veterinary Medicines Authority
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**MATERIAL SAFETY DATA SHEET****Section 16 - Other Information**

This MSDS contains only safety-related information. For other data see product literature.

**Acronyms**

<b>ADG Code:</b>	Australian Code for the Transport of Dangerous Goods by Road and Rail
<b>AICS:</b>	Australian Inventory of Chemical Substances
<b>CAS Number:</b>	Chemical Abstracts Service Registry Number
<b>Hazchem Number:</b>	Emergency action code of numbers and letters that provide information to emergency services especially fire-fighters
<b>IARC</b>	International Agency for Research on Cancer
<b>NOHSC</b>	National Occupational Health and Safety Commission
<b>NOS</b>	Not otherwise specified
<b>NTP</b>	National Toxicology Program (USA)
<b>R-Phrase</b>	Risk Phrase
<b>STEL</b>	Short-term Exposure Limit
<b>SUSDP</b>	Standard for the Uniform Scheduling of Drugs & Poisons
<b>TWA</b>	Time Weighted Average
<b>UN Number</b>	United Nations Number

**Note:**

This product is a registered veterinary chemical and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Federal health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

This Material Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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## 1. Identification

<b>Product identifier</b>	<b>Percorten-V Injection for Dogs</b>
<b>Other means of identification</b>	
<b>Item Code</b>	CA5320
<b>Recommended use</b>	Veterinary Product
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	
<b>Company Name</b>	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
<b>Phone:</b>	1-877-Elanco1 (1-877-352-6261)
<b>Email:</b>	lilly_msds@lilly.com
<b>Emergency Telephone Numbers:</b>	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973 Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 2
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Warning
<b>Hazard statement</b>	
H361	Suspected of damaging fertility or the unborn child.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P281	Use personal protective equipment as required.
<b>Response</b>	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Not available.
<b>Disposal</b>	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Deoxycorticosterone Pivalate	PREGN-4-ENE-3,20-DIONE, 21-(2,2-DIMETHYL-1-OXOPROPOXY)-		2.5
THIMEROSAL		54-64-8	0.002

**Composition comments** Other components below reportable levels

### 4. First-aid measures

<b>Inhalation</b>	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
<b>Skin contact</b>	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
<b>Ingestion</b>	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Suspected of damaging fertility or the unborn child. None known.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Prevent entry into waterways, sewer, basements or confined areas.  Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Provide adequate ventilation. Observe good industrial hygiene practices. Wear appropriate personal protective equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values

Components	Type	Value
THIMEROSAL (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

#### US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
THIMEROSAL (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
THIMEROSAL (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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

### Exposure guidelines

#### US - California OELs: Skin designation

THIMEROSAL (CAS 54-64-8) Can be absorbed through the skin.

#### US - Tennessee OELs: Skin designation

THIMEROSAL (CAS 54-64-8) Can be absorbed through the skin.

#### US ACGIH Threshold Limit Values: Skin designation

THIMEROSAL (CAS 54-64-8) Can be absorbed through the skin.

#### US NIOSH Pocket Guide to Chemical Hazards: Skin designation

THIMEROSAL (CAS 54-64-8) Can be absorbed through the skin.

**Appropriate engineering controls** Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles).

#### Skin protection

**Hand protection** Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

**Other** Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

**Respiratory protection** Not available.

**Thermal hazards** Not available.

**General hygiene considerations** Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Observe any medical surveillance requirements.

## 9. Physical and chemical properties

### Appearance

**Physical state** Liquid.

**Form** Suspension.

**Color** White.

**Odor** Not available.

**Odor threshold** Not available.

**pH** 5 - 7

**Melting point/freezing point** Not available.



<b>Initial boiling point and boiling range</b>	212 °F (100 °C) at 100 kPa
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	2.37 kPa at 20 C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Deoxycorticosterone Pivalate		
<u><b>Acute</b></u>		
<b>Oral</b>		
LD50	Mouse	1000 mg/kg
THIMEROSAL (CAS 54-64-8)		
<u><b>Acute</b></u>		
<b>Oral</b>		
LD50	Rat	75 mg/kg
<b>Skin corrosion/irritation</b>	Rabbit: Mild skin irritation. (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Rabbit: Mild eye irritation. (Active ingredient) Based on available data, the classification criteria are not met.	

## Respiratory or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Due to lack of data the classification is not possible.

**Germ cell mutagenicity** No effects identified in animal studies. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Suspected of damaging fertility or the unborn child. (Active ingredient)

**Specific target organ toxicity - single exposure** No significant target organ toxicity reported. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** No significant target organ toxicity reported. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Aspiration hazard** Not applicable.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
THIMEROSAL (CAS 54-64-8)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	LC50 Bullhead, catfish ( <i>Ictalurus</i> sp.)	7.5 mg/l, 24 hours

**Persistence and degradability** No data is available on the degradability of this product.

### Bioaccumulative potential

#### Partition coefficient n-octanol / water (log Kow)

Deoxycorticosterone Pivalate 4.846, (Calculated)

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Not available.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

THIMEROSAL (CAS 54-64-8)

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations**

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

THIMEROSAL (CAS 54-64-8)

**US. New Jersey Worker and Community Right-to-Know Act**

THIMEROSAL (CAS 54-64-8)

**US. Pennsylvania Worker and Community Right-to-Know Law**

THIMEROSAL (CAS 54-64-8)

**US. Rhode Island RTK**

THIMEROSAL (CAS 54-64-8)

**US. California Proposition 65**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

THIMEROSAL (CAS 54-64-8)

Listed: July 1, 1990

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 05-10-2016

**Version #** 01

**Disclaimer**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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**Revision information**

Product and Company Identification: Product Codes  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties: Multiple Properties  
Regulatory Information: Risk Phrases - Class.  
GHS: Classification