NOVARTIS

MATERIAL SAFETY DATA SHEET

Version: 4
Revision Date: June 22, 2009

PERCORTEN® - V

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name/Identifier	:	Percorten®-V
Supplier's Name/Address in U.S.	:	Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro, NC 27408 (336) 387-1000
Supplier's Name/Address in Canada	:	Novartis Animal Health Canada, Inc. Suite 400, Plaza 3 2000 Argentia Road Mississauga, ON L5N 1V9 (800) 387-6325
Medical Emergency Assistance (Human or Animal)	:	**(800) 637-0281 (24 hours / 7 days a week)**
CHEMTREC Emergency Telephone Number	:	**(800) 424-9300 (24 hours / 7 days a week) U.S. and Canada** [International: (703) 527-3887 (collect)]
Preparer Information	:	Health, Safety & Environmental Dept. Novartis Animal Health US, Inc. (712) 477-2811 [8:00 am – 5:00 pm M – F (CST)]

2. COMPOSITION/INFORMATION ON INGREDIENTS

Product Information

Product Use	:	Veterinary product for use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.
Active Ingredient	:	Desoxycorticosterone pivalate (DOCP)
Other Information	:	U.S. federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. Read product instructions before use.

Composition Information

Component[1]	CAS Registry Number	Concentration Range	Exposure Limits[2]
Water	7732-18-5	60% - 100%	Not available
Desoxycorticosterone pivalate	808-48-0	2.5%	0.01 mg/m^3 TWA See Note-3
Methylcellulose	9004-67-5	0.5% - 1.5%	Not available

Notes on *Composition Information*

[1] Hazardous/non-hazardous components present at or greater than 1% (0.1%)
[2] OSHA, ACGIH, and WHMIS have not established air contaminant limits for this product.
[3] OSHA, ACGIH, and WHMIS have not established air contaminant limits for this compound. Novartis Animal Health's recommended occupational exposure limit (OEL) is 0.01 mg/m^3 TWA.

3. HAZARDS IDENTIFICATION

Emergency Overview

White aqueous suspension. Repeated skin contact may cause delayed skin sensitization – avoid skin contact. Not expected to present a flammability or reactivity hazard. Do not release to the environment. For use in animals only.

Potential Health Effects

Eyes	:	This product is generally not expected to cause eye irritation.
Skin Irritation/Sensitization/ Absorption	:	This product is generally not expected to be irritating to the skin. This product may cause delayed skin sensitization in a very limited number of persons. This product is not expected to be absorbed through the skin.
Ingestion	:	Ingestion is generally not expected to occur or present a hazard during normal conditions of use. Over ingestion of this product may result in adverse effects.
Inhalation	:	Inhalation is generally not expected to occur or present a hazard during normal conditions of use. Exposure to large amounts or prolonged exposure may cause adverse effects.
Subchronic Toxicity	:	There are no subchronic toxicity data on this product. Based on the data of the individual components, the subchronic toxicity of this product is expected to be low.
Reproductive Toxicity	:	There are no reproductive toxicity data on this product. Based on the data of the individual components, this product is not expected to present a reproductive toxicity hazard.
Teratogenicity (birth defects)	:	There are no teratogenicity data on this product. Based on the data of the individual components, this product is not expected to present a teratogenicity hazard.
Mutagenicity	:	There are no mutagenicity data on this product. Based on the data of the individual components, this product is not expected to present a mutagenicity hazard.

Chronic Effects/Carcinogenicity	:	There are no chronic effects or carcinogenicity data on this product. Based on the data of the individual components, this product is not expected to present a chronic or carcinogenicity hazard. · NTP: Not listed · IARC: Not listed · OSHA: Not listed
Medical Conditions Aggravated by Exposure	:	Hypertension, cardiac disease, or hypersensitivity to DOCP.
Incompatibility	:	Do not use this drug in pregnant dogs. Do not use in dogs suffering from congestive heart disease, severe renal disease, or edema.
Signs & Symptoms of Exposure	:	Exposure may cause skin sensitization in a very limited number of individuals. Some patients may show signs of hypernatremia or hypokalemia.

4. FIRST AID MEASURES

Skin Contact	:	Wash skin with soap and water. If irritation develops, seek medical attention.
Eye Contact	:	Flush eyes with water for several minutes. If irritation develops, seek medical attention.
Inhalation	:	If small amounts of this product are inhaled, specific treatment is generally not expected to be necessary. If exposed to excessive levels, if contact is prolonged, or if exposure causes adverse symptoms, move person to fresh air and get immediate medical attention.
Ingestion	:	In case of accidental overdose/over-ingestion, seek medical attention or contact a poison control center immediately.
Note to Physicians	:	This product is a veterinary product for use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency. This product contains the active ingredient desoxycorticosterone pivalate (DOCP). See Section 2 for the individual components in this product.

5. FIRE FIGHTING MEASURES

Flash Point	:	Not applicable.
Flammable Limits	:	Not applicable.

Autoignition Temperature	:	Not applicable.
Hazardous Combustion Products	:	Thermal decomposition may generate toxic vapors.
Extinguishing Media	:	Use water spray, carbon dioxide, dry chemical, or alcohol foam when fighting fires involving this material.
Fire Fighting Instructions	:	This material is not flammable. Wear a self-contained breathing apparatus pressure demand (MSHA/NIOSH approved or equivalent) and full protective gear.
Explosion Data	:	Not applicable.
Other	:	If water is used to fight fire, dike and collect runoff if possible.

6. ACCIDENTAL RELEASE MEASURES

Spill and Cleanup Procedures	:	Vacuum or collect material and place in a disposal container.
Other Instructions	:	Do not reuse recovered material. Do not release this product to the environment.

7. HANDLING AND STORAGE

Handling	:	Avoid contact with skin and eyes. Handle in well ventilated locations.
Storage	:	Store at room temperature preferably between 15 °C - 30 °C (59 °F - 86 °F). Protect from light. Protect from freezing. Keep away from food and drinking water.
Use Information	:	U.S. federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. Read product instructions before use.
Other	:	Do not release this product to the environment.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Eye/Face Protection	:	Eye protection should be worn during use and handling operations. Face protection should be worn when there is a potential for exposure to the face.
Skin Protection	:	Skin protection, including gloves, should be worn when there is a potential for dermal exposure to this product during use and handling operations.

Respiratory Protection	:	Respiratory protection is not expected to be necessary during use and handling operations unless the product (or its vapors) becomes airborne above low levels.
Engineering Controls	:	Good general ventilation should be sufficient to control low airborne levels of the product. If the product is present above low levels, local exhaust may be necessary to control worker exposure.
Exposure Guidelines	:	There are no established exposure guidelines or limits for this product. See Section 2 for additional information.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State	:	White aqueous suspension
Odor	:	No odor
pH	:	5 - 7
Vapor Pressure	:	Not available
Vapor Density	:	Not available
Boiling Point	:	Not available
Freezing/Melting Point	:	0 °C (32 °F)
Specific Gravity	:	~1.0 g/ml
Evaporation Rate	:	Not available
Octanol/Water Partition Coefficient	:	Not available
Odor Threshold	:	Not available
Solubility in Water	:	Soluble
Volatility	:	Not available

10. STABILITY AND REACTIVITY

Stability	:	Stable.
Conditions to Avoid	:	None.
Incompatibility/Materials to Avoid	:	None.
Hazardous Decomposition or Byproducts	:	None.
Hazardous Polymerization	:	Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicological Data on the Components

Component	Acute Oral LD_{50}	Acute Dermal LD_{50}	Acute Inhalation LC_{50}
Water	NA	NA	NA
Desoxycorticosterone pivalate	1,000 mg/kg (mouse)	NA	NA
Methylcellulose	NA	NA	NA

Notes on acute toxicological data

NA = Not available

Toxicological Data on the Product

Acute Toxicological Data : There are no acute toxicological data on this product. The available acute data on the components is shown in the above table. Based on the data of the individual components, the acute toxicity of this product is expected to be low.

Eye Irritation Data : This product is generally not expected to cause eye irritation.

Skin Irritation/Sensitization/ Absorption Data : This product is generally not expected to be irritating to the skin. This product may cause delayed skin sensitization in a very limited number of persons. This product is not expected to be absorbed through the skin.

Subchronic Toxicity Data : There are no subchronic data on this product. Based on the data of the individual components, including the active ingredient (DOCP), the subchronic toxicity of this product is expected to be low.

Reproductive Toxicity Data : There are no reproductive toxicity data on this product. Based on the data of the individual components, including the active ingredient (DOCP), this product is not expected to present a reproductive toxicity hazard.

Teratogenicity (birth defects) Data : There are no teratogenicity data on this product. Based on the data of the individual components, including the active ingredient (DOCP), this product is not expected to present a teratogenicity hazard.

Mutagenicity Data : There are no mutagenicity data on this product. Based on the data of the individual components, including the active ingredient (DOCP), this product is not expected to present a mutagenicity hazard.

Chronic/Carcinogenicity Data	:	There are no chronic effects or carcinogenicity data on this product. Based on the data of the individual components, including the active ingredient (DOCP), this product is not expected to present a chronic toxicity or carcinogenicity hazard.

12. ECOLOGICAL INFORMATION

Ecological Data on the Product

Ecotoxicological Data	:	No ecotoxicological data are available on this product.
Environmental Fate Data	:	No environmental fate data are available on this product.
Physical/Chemical Properties	:	See Section 9.

Ecological Data on DOCP

Ecotoxicological Data	:	No ecotoxicological data are available on DOCP.
Environmental Fate Data	:	No environmental fate data are available on DOCP. The log K_{ow} is predicted to be 5.07
Physical/Chemical Properties	:	No physical/chemical properties data are available on DOCP.

13. DISPOSAL CONSIDERATIONS

Waste Classification	:	If discarded in its manufactured form, this product is a hazardous waste under RCRA (U.S.) and CEPA (Canada). However, it is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste.
U.S. EPA Waste Number	:	D009
Canada CEPA Waste Number	:	L19
Special Instructions	:	Do not release this product to the environment. Dispose as a hazardous waste in conformance with all federal/national, state/provincial, and local regulations.

14. TRANSPORT INFORMATION

U.S. DOT

UN Number	:	
Hazard Class	:	
Packing Group	:	
Proper Shipping Name	:	
Label	:	
Marine Pollutant	:	
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

Canadian TDG

UN Number	:	
Hazard Class	:	
Packing Group	:	
Proper Shipping Name	:	
Label	:	
Marine Pollutant	:	
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

IMDG

UN Number	:	
Hazard Class	:	
Packing Group	:	
Proper Shipping Name	:	
Label	:	
Marine Pollutant	:	
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

ICAO/IATA

UN Number	:	
Hazard Class	:	
Packing Group	:	
Proper Shipping Name	:	
Label	:	
Marine Pollutant	:	
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

15. REGULATORY INFORMATION

OSHA Classification	:	This product is generally not considered to be hazardous under the OSHA Hazard Communication Standard.
WHMIS Classification	:	This product is not classified as a hazardous (controlled) product under the CPR.

WHMIS Statement	:	*This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR*.
U.S. FDA	:	This product is regulated as a veterinary product under the U.S. Federal Food, Drug, and Cosmetic Act.
Waste Classification	:	If discarded in its manufactured form, this product is a hazardous waste under RCRA (U.S.) and CEPA (Canada). However, it is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste. See Section 13 for additional information.
EPCRA/SARA III	:	This product contains mercury which is subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR 372. Mercury is present at a maximum level of 12 ppm in this product.
International Regulations	:	This product may be regulated by various countries' drug-regulating agencies.
California Proposition 65	:	This product is in compliance with California Proposition 65.

16. OTHER INFORMATION

Label Text	:	See product packaging/labeling.
Hazard Rating System	:	HMIS Label: · Health = 1 · Flammability = 0 · Physical Hazard = 0
Disclaimer	:	The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release 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 or in any process, unless specified in the text.

PERCORTEN® - V

Previous MSDS Version Date	:	March 22, 1994 October 31, 2000 June 10, 2009