

as of 1/27/17  
044/17/2



**PHARMACAL**

**SAFETY DATA SHEET**

Issue Date 02-Jun-2014

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Version 1

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

Product identifier

**Product Name** PRN Pharmacal Vetadryl 10 mg

Other means of identification

**Product Code** PRN FP 30032945

**NDC Number** 49427-329-45

Recommended use of the chemical and restrictions on use

**Recommended Use** Pharmaceutical.

**Uses advised against** No information available.

Details of the supplier of the safety data sheet

**Supplier**  
Pegasus Laboratories, Inc.  
8809 Ely Road  
Pensacola, FL 32514

**Company Name**  
Pegasus Laboratories, Inc.  
8809 Ely Road  
Pensacola, FL 32514

Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

**2. HAZARDS IDENTIFICATION**

Classification

**OSHA Regulatory Status**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

**Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

**Appearance** Tablet Biconvex round  
Scored on one side and debossed on the other

**Physical state** Solid

**Odor** No information available

Hazards not otherwise classified (HNOC)

Product is intended for consumption. Please see the product label for instructions for use and precautions.

Other Information



**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place.

**Incompatible materials** Incompatible with oxidizing agents. Bleaching agent.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust

*NIOSH IDLH Immediately Dangerous to Life or Health*

**Other Information** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering Controls** Showers  
Eyewash stations  
Ventilation systems.

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

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

**Skin and body protection** Wear protective gloves and protective clothing.

**Respiratory protection** If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

**General Hygiene Considerations** Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

**Physical state** Solid

Appearance	Tablet Biconvex round Scored on one side and debossed on the other	Odor	No information available
Color	Brown	Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not Applicable	
Melting point/freezing point	No information available	
Boiling point / boiling range	No information available	
Flash point	No information available	
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Specific Gravity	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition coefficient	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Oxidizing properties	No information available	

**Other Information**

Density No information available

## 10. STABILITY AND REACTIVITY

**Reactivity**

No data available

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions**

None under normal processing.

**Hazardous polymerization**

Will not occur.

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

Incompatible with oxidizing agents. Bleaching agent.

**Hazardous Decomposition Products**

May emit toxic fumes under fire conditions. Carbon dioxide (CO<sub>2</sub>). Carbon monoxide. Nitrogen oxides (NO<sub>x</sub>). Hydrocarbons.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure****Product Information**

Inhalation May cause irritation of respiratory tract.

Eye contact May cause irritation.

**Skin Contact** May cause irritation.  
**Ingestion** May cause irritation.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose 9004-34-6	-	-	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h

**Information on toxicological effects**

**Symptoms** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Sensitization** No information available.  
**Germ cell mutagenicity** No information available.  
**Carcinogenicity** No information available.  
**Reproductive toxicity** No information available.  
**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organ Effects** Eyes, Respiratory system, Skin.  
**Aspiration hazard** No information available.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 72% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document  
**ATEmix (inhalation-dust/mist)** 5.8 mg/L

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

100% of the mixture consists of components(s) of unknown hazards to the aquatic environment

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Other adverse effects**

No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container.

**14. TRANSPORT INFORMATION**

**DOT**

**Description**

The following guidelines apply for domestic ground transport. If shipping by air or ocean, please contact our Transportation Dept.

MEDICINES, NOI NMFC 58770, SUB 2

## 15. REGULATORY INFORMATION

This chemical is classified as a food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, and is therefore subject to labeling requirements under the Food and Drug Administration. These requirements differ from the classification criteria and hazard information required for safety data sheets and workplace labeling of chemicals.

### U.S. EPA Label Information

EPA Pesticide Registration Number Not Applicable

### International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed
ENCS	Not Listed
IECSC	Not Listed
KECL	Not Listed
PICCS	Not Listed
AICS	Not Listed

### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

Chemical Name	TSCA	DSL	NDSL	EINECS	ELINCS	ENCS	IECSC	KECL	PICCS	AICS
Di-Tab (Dibasic Calcium Phosphate Dihydrate)		X					X		X	X
Microcrystalline Cellulose	X	X		X		X	X	X	X	X
Diphenhydramine HCl		X		X		X				X

### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

#### SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

### US State Regulations

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose 9004-34-6	X	X	X

**International Regulations**

Chemical Name	Carcinogenicity	Exposure Limits
Microcrystalline Cellulose		Mexico: TWA 10 mg/m <sup>3</sup> Mexico: STEL 20 mg/m <sup>3</sup>

**16. OTHER INFORMATION**

<b>NFPA</b>	Health hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties -
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

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End of Safety Data Sheet