

# Material Safety Data Sheet

Material Name: Pharmasperse® 416

MSDS ID: SPH-088

Issue Date: 01/18/11

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## \*\*\* Section 1 - Chemical Product and Company Identification \*\*\*

**Product Name:** Pharmasperse® 416

**Product Use:** Orally dispersible powders and sachets / Pharmaceutical and nutritional products.

### Company Identification

SPI Pharma, Inc.  
Rockwood Office Park  
503 Carr Road  
Wilmington, Delaware 19809

### Phone Numbers

**Emergency:** (800) 424-9300 CHEMTREC  
**Non-Emergency Safety & Health Information:** (302) 360-7200  
**Non-Emergency Environmental Information:** (302) 360-7200  
**Product Information and Customer Service:** (302) 360-7200

### General Comments

NOTE: Emergency telephone numbers are to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure, or accident involving chemicals. All non-emergency questions should be directed to customer service.

## \*\*\* Section 2 - Hazards Identification \*\*\*

### Emergency Overview

Product is a white to off-white powder. Combustible dust. This product can be irritating to the skin, eyes, digestive and respiratory tract.

### Hazard Statements

WARNING! Dusts from this product may be irritating to eyes, skin, and digestive and respiratory tracts. May form combustible (explosive) dust-air mixtures. Avoid dust generation and accumulation. Keep away from heat, sparks and flame.

### Potential Health Effects: Eyes

This product may cause irritation to the eyes.

### Potential Health Effects: Skin

This product may cause irritation to the skin.

### Potential Health Effects: Ingestion

Ingestion of small amounts would not be expected to produce toxicity. However, ingestion of large amounts can cause gastrointestinal irritation, nausea, and constipation.

### Potential Health Effects: Inhalation

Dusts of this product may cause irritation of the nose, throat, and respiratory tract.

### Medical Conditions Aggravated by Exposure

Respiratory disorders

**HMIS Ratings: Health: 1 Fire: 1 Reactivity: 0 Pers. Prot.:** safety glasses with side shield; chemical goggles, if dust is generated

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe \* = Chronic hazard

## \*\*\* Section 3 - Composition / Information on Ingredients \*\*\*

CAS #	Component	Percent
Proprietary	Proprietary component 1	30-60
Proprietary	Proprietary component 2	1-5
Proprietary	Proprietary component 3	0.1-1

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## Component Related Regulatory Information

This product may be regulated, have exposure limits or other information identified as the following: Calcium carbonates.

## Component Information/Information on Non-Hazardous Components

This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).

This product is regulated as a hazardous material by the Canadian Controlled Product Regulations.

## \*\*\* Section 4 - First Aid Measures \*\*\*

### First Aid: Eyes

Immediately flush eyes with copious amounts of water for at least 15 minutes. If necessary, seek medical attention.

### First Aid: Skin

For skin contact, wash immediately with soap and water. If irritation develops or persists, seek medical attention.

### First Aid: Ingestion

If material is swallowed in large amounts, get medical attention. Do not induce vomiting.

### First Aid: Inhalation

Move person to non-contaminated air. If symptoms develop, get medical attention.

### First Aid: Notes to Physician

Provide general supportive measures and treat symptomatically.

## \*\*\* Section 5 - Fire Fighting Measures \*\*\*

### General Fire Hazards

See Section 9 for Flammability Properties.

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

### Hazardous Combustion Products

Oxides of carbon.

### Extinguishing Media

Use dry chemical, carbon dioxide, regular foam or water. Apply extinguishing media carefully to avoid creating airborne dust.

### Fire Fighting Equipment/Instructions

Firefighters should wear full-face, self contained breathing apparatus and impervious protective clothing.

Firefighters should avoid inhaling any combustion products.

### NFPA Ratings: Health: 1 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

## \*\*\* Section 6 - Accidental Release Measures \*\*\*

### Containment Procedures

Contain the discharged material.

### Clean-Up Procedures

Wear appropriate protective equipment and clothing during clean-up. Eliminate ignition sources including sources of electrical, static or frictional sparks. Collect spill using a vacuum cleaner with a HEPA filter or wet and scoop up dry spills. Avoid sweeping spilled dry material. Thoroughly wash the area with water after a spill or leak clean-up. Collect material and place in appropriate container for disposal.

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## Evacuation Procedures

None necessary.

## Special Procedures

None.

## \*\*\* Section 7 - Handling and Storage \*\*\*

### Handling Procedures

Avoid getting this material in contact with skin or eyes. Avoid breathing dust from this material. Wear appropriate skin and eye protection when handling this material. Prevent physical damage to package. Keep this product from heat, sparks, or open flame. Use non-sparking tools when opening or closing containers. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

### Storage Procedures

Warehouse storage should be in accordance with the package directions, if any. Materials should be kept dry and protected from the elements. Keep separated from incompatible materials.

## \*\*\* Section 8 - Exposure Controls / Personal Protection \*\*\*

### Exposure Guidelines

#### A: General Product Information

Follow all applicable exposure limits.

#### B: Component Exposure Limits

##### Proprietary component 1 (Proprietary)

OSHA (Final):	15 mg/m <sup>3</sup> TWA (total dust); 5 mg/m <sup>3</sup> TWA (respirable fraction)
OSHA	15 mg/m <sup>3</sup> TWA (total dust); 5 mg/m <sup>3</sup> TWA (respirable fraction)
(Vacated):	
NIOSH:	10 mg/m <sup>3</sup> TWA (total dust); 5 mg/m <sup>3</sup> TWA (respirable dust)
Alberta:	10 mg/m <sup>3</sup> TWA
British	10 mg/m <sup>3</sup> TWA (total dust); 3 mg/m <sup>3</sup> TWA (respirable fraction)
Columbia:	20 mg/m <sup>3</sup> STEL
New	10 mg/m <sup>3</sup> TWA (particulate matter containing no asbestos and < 1% crystalline silica)
Brunswick:	
NW Territories:	5 mg/m <sup>3</sup> TWA (respirable mass); 10 mg/m <sup>3</sup> TWA (total mass)
Nunavut:	5 mg/m <sup>3</sup> TWA (respirable mass); 10 mg/m <sup>3</sup> TWA (total mass)
Quebec:	10 mg/m <sup>3</sup> TWAEV (Limestone, total dust, containing no asbestos and less than 1% crystalline silica)
Saskatchewan:	10 mg/m <sup>3</sup> TWA 20 mg/m <sup>3</sup> STEL
Yukon:	30 mppcf TWA; 10 mg/m <sup>3</sup> TWA 20 mg/m <sup>3</sup> STEL

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## **Proprietary component 2 (Proprietary)**

ACGIH: 10 mg/m<sup>3</sup> TWA  
OSHA (Final): 15 mg/m<sup>3</sup> TWA (total dust); 5 mg/m<sup>3</sup> TWA (respirable fraction)  
OSHA 15 mg/m<sup>3</sup> TWA (total dust); 5 mg/m<sup>3</sup> TWA (respirable fraction)  
(Vacated):  
NIOSH: 10 mg/m<sup>3</sup> TWA (total dust); 5 mg/m<sup>3</sup> TWA (respirable dust)  
Alberta: 10 mg/m<sup>3</sup> TWA  
British Columbia: 10 mg/m<sup>3</sup> TWA (total dust); 3 mg/m<sup>3</sup> TWA (respirable fraction)  
Columbia:  
Manitoba: 10 mg/m<sup>3</sup> TWA  
New Brunswick: 10 mg/m<sup>3</sup> TWA  
Newfoundland & Labrador: 10 mg/m<sup>3</sup> TWA  
Nova Scotia: 5 mg/m<sup>3</sup> TWA (respirable mass); 10 mg/m<sup>3</sup> TWA (total mass)  
Nunavut: 10 mg/m<sup>3</sup> TWA  
Ontario: 5 mg/m<sup>3</sup> TWA (respirable mass); 10 mg/m<sup>3</sup> TWA (total mass)  
Prince Edward Island: 10 mg/m<sup>3</sup> TWAEV (revoked July 1, 2010, total dust); 10 mg/m<sup>3</sup> TWAEV (effective July 1, 2010)  
Quebec: 10 mg/m<sup>3</sup> TWA  
Saskatchewan: 10 mg/m<sup>3</sup> TWAEV (total dust, containing no asbestos and less than 1% crystalline silica)  
20 mg/m<sup>3</sup> STEL  
Yukon: 30 mppcf TWA; 10 mg/m<sup>3</sup> TWA  
20 mg/m<sup>3</sup> STEL

## **Proprietary component 3 (Proprietary)**

Quebec: 6 mg/m<sup>3</sup> TWAEV (respirable dust, containing no asbestos and less than 1% crystalline silica)

## **Engineering Controls**

Provide adequate local exhaust ventilation to maintain worker exposure below exposure limits. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent escape of dust into the work area (i.e. there is no leakage from the equipment).

## **PERSONAL PROTECTIVE EQUIPMENT**

### **Personal Protective Equipment: Eyes/Face**

Wear safety glasses with side shields; chemical goggles if dust is generated.

### **Personal Protective Equipment: Skin**

Use impervious gloves. Work clothing sufficient to prevent all skin contact should be worn, such as coveralls and long sleeves.

### **Personal Protective Equipment: Respiratory**

If ventilation is not sufficient to effectively prevent buildup of dust, appropriate NIOSH respiratory protection must be provided.

### **Personal Protective Equipment: General**

Use good industrial hygiene practices in handling this material.

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## \*\*\* Section 9 - Physical & Chemical Properties \*\*\*

<b>Appearance:</b>	White to off-white powder	<b>Odor:</b>	Odorless
<b>Physical State:</b>	Solid	<b>Odor Threshold:</b>	Not available
<b>pH:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Vapor Density:</b>	Not available	<b>Boiling Point:</b>	Not available
<b>Melting Point:</b>	Not available	<b>Decomposition Temperature:</b>	Not available
<b>Solubility (H2O):</b>	Not available	<b>Specific Gravity:</b>	Not available
<b>Evaporation Rate:</b>	Not available	<b>Viscosity:</b>	Not available
<b>Molecular Weight:</b>	Not available	<b>Octanol/H2O Coeff.:</b>	Not available
<b>Coeff. Water/Oil Dist.:</b>	Not available	<b>Flash Point:</b>	Not available
<b>Auto Ignition:</b>	Not available	<b>Flash Point Method:</b>	Not available
<b>UFL:</b>	Not available	<b>Sens. to Mechanical Impact:</b>	Not available
<b>LFL:</b>	Not available	<b>Sens. to Static Discharge:</b>	Not available
<b>Explosive Properties:</b>	Not available	<b>Oxidizer Potential:</b>	Not available

## \*\*\* Section 10 - Chemical Stability & Reactivity Information \*\*\*

### Chemical Stability

Stable at normal temperatures and pressure.

### Chemical Stability: Conditions to Avoid

Incompatible materials. Avoid dispersion of dust in air.

### Incompatibility

Acids, halogens, metals, and strong oxidizing agents.

### Hazardous Decomposition

Oxides of carbon, oxides of calcium.

### Possibility of Hazardous Reactions

Hazardous polymerization has not occurred under normal temperatures and pressures.

## \*\*\* Section 11 - Toxicological Information \*\*\*

### Acute Dose Effects

#### A: General Product Information

Exposure to this product will likely cause irritation to the eyes, skin, gastrointestinal and respiratory system.

Additional manufacturer data for calcium carbonate: Oral LD50 Rat 6450 mg/kg

#### B: Component Analysis - LD50/LC50

No LD50/LC50's are available for this product's components and/or the components toxicity values do not result in any hazardous classifications.

### Repeated Dose Effects

Excessive ingestion of calcium carbonate may cause hypercalcemia, alkalosis, nephrocalcinosis and azotemia.

### Carcinogenicity

#### A: General Product Information

No carcinogenicity data available for this product.

#### B: Component Carcinogenicity

##### Proprietary component 2 (Proprietary)

ACGIH: A4 - Not Classifiable as a Human Carcinogen

### Mutagenicity

None identified.

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## Teratogenicity

None identified.

## Reproductive Toxicity

None identified.

## Sensitization

None identified.

## Target Organ Effects

None identified.

### \*\*\* Section 12 - Ecological Information \*\*\*

## Ecotoxicity

### A: General Product Information

No data available for this product as a whole.

Additional manufacturer data for calcium carbonate: LC50 Fish >200 mg/L

### B: Component Analysis - Ecotoxicity - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

## Environmental Fate

No data available for this product.

### \*\*\* Section 13 - Disposal Considerations \*\*\*

## US EPA Waste Number & Descriptions

### A: General Product Information

Material, if discarded, is not expected to be a characteristic hazardous waste under RCRA. Wastes must be tested using methods described in 40 CFR Part 261 to determine if it meets applicable definitions of hazardous wastes.

### B: Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

## Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

### \*\*\* Section 14 - Transportation Information \*\*\*

## US DOT Information

**Shipping Name:** Not regulated as a hazardous material.

## TDG Information

**Shipping Name:** Not regulated as a dangerous good.

### \*\*\* Section 15 - Regulatory Information \*\*\*

## US Federal Regulations

### A: General Product Information

No information available.

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## B: Component Analysis

None of this products components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

## SARA Sections 311/312 (40 CFR 370 Subparts B and C)

Acute Health: Yes Chronic Health: No Fire: No Pressure: No Reactive: No

## State Regulations

### A: General Product Information

No information available.

### B: Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
Proprietary component 1	Proprietary	No	Yes	Yes	Yes	Yes	Yes
Proprietary component 2	Proprietary	No	Yes	Yes	No	Yes	Yes
Proprietary component 3	Proprietary	No	Yes	Yes	No	Yes	No

## Canadian WHMIS Information

### A: General Product Information

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

This product is a controlled product under the Canadian Workplace Hazardous Materials Information System (WHMIS).

### B: Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

WHMIS Class: D2B

## Additional Regulatory Information

### A: General Product Information

All ingredients are on the U.S. TSCA Inventory. All components are on the Canadian Domestic Substances or Non-Domestic Substances Inventory Lists.

### B: Component Analysis - Inventory

Component	CAS #	TSCA	EEC	CAN
Proprietary component 1	Proprietary	Yes	EINECS	NDSL
Proprietary component 2	Proprietary	Yes	EINECS	DSL
Proprietary component 3	Proprietary	Yes	No	DSL

## \*\*\* Section 16 - Other Information \*\*\*

## Other Information

Reasonable care has been taken in the preparation of this information, but the manufacturer makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The manufacturer makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use.

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### Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; NFPA = National Fire Protection Association; HMIS = Hazardous Material Identification System; CERCLA = Comprehensive Environmental Response, Compensation and Liability Act; SARA = Superfund Amendments and Reauthorization Act; DSL = Canadian Domestic Substance List; EINECS = European Inventory of New and Existing Chemical Substances; WHMIS = Workplace Hazardous Materials Information System; FFDCa = Federal Food Drug and Cosmetic Act

End of Sheet SPH-088