

Safety Data Sheet

Material Name: Pharmasperse® 416

SDS #: E065
Issue Date: 17/06/2010

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*** Section 1 - Identification of the Substance / Preparation and of the Company / Undertaking ***

Product Code SPI-1115

Product Name: Pharmasperse®

Company Identification

SPI Pharma, Inc.

Chemin du Vallon du Maire

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Use of the Substance / Preparation:

Orally dispersable powders and sachets / Pharmaceutical and nutritional products.

Substance Registration Number(s):

Substances contained in this product are exempt from REACH registration.

*** Section 2 - Hazards Identification ***

Substance / Preparation Classification

This product is hazardous according to EC Directives 67/548/EEC or 1999/45/EC. Xi; R36/37/38

Human and Environmental Hazards

Irritating to eyes, respiratory system and skin.

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

EC #	Component	Percent	Symbols	Risks
Proprietary	Proprietary component 1 Proprietary	30-60	None	None
Proprietary	Proprietary component 2 Proprietary	1-5	None	None

Component Related Regulatory Information

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

Substance Registration Number(s):

Substances contained in this product are exempt from REACH registration.

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush eyes with large amounts of water. If irritation persists or develops, get medical attention.

First Aid: Skin

For skin contact, wash 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. Never give anything by mouth to a victim who is unconscious or is having convulsions.

First Aid: Inhalation

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

*** Section 5 - Fire-Fighting Measures ***

General Fire Hazards

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.

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Suitable Extinguishing Media

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

Unsuitable Extinguishing Media

A solid stream of water may scatter burning product.

Hazardous Combustion Products

Oxides of carbon.

Fire Fighting Equipment / Instructions

Firefighters should wear full-face, self contained breathing apparatus and impervious protective clothing. Firefighters should avoid inhaling any combustion products.

*** 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.

Evacuation Procedures

None necessary.

Personal Precautions

Wear appropriate protective equipment and clothing during clean-up.

Environmental Precautions

Do not flush material to drains or allow to enter drains.

*** 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.

Specific Use

Direct compressible tablet/Nutritional product.

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

Exposure Guidelines

A: General Product Information

Follow all applicable exposure limits.

B: Substance Exposure Limits

Proprietary component 1 (Proprietary)

France: 10 mg/m3 VME
Portugal: 10 mg/m3 TWA (particulate matter containing no asbestos and < 1% crystalline silica)
Spain: 10 mg/m3 VLA-ED

Proprietary component 2 (Proprietary)

ACGIH: 10 mg/m3 TWA
Belgium: 10 mg/m3 TWA
Greece: 10 mg/m3 TWA (inhalable fraction); 5 mg/m3 TWA (respirable fraction)
Ireland: 10 mg/m3 TWA (total inhalable dust); 4 mg/m3 TWA (respirable dust)
Portugal: 10 mg/m3 TWA
Spain: 10 mg/m3 VLA-ED

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Occupational Exposure 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

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

Personal Protective Equipment: Hands

Use impervious gloves.

Personal Protective Equipment: Respiratory

In case of insufficient ventilation wear suitable respiratory protection.

Personal Protective Equipment: General

Use good industrial hygiene practices in handling this material.

Environmental Exposure Controls

Do not release product into open sewers or waterways.

*** Section 9 - Physical and Chemical Properties ***

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

*** Section 10 - Stability and Reactivity ***

Chemical Stability

Stable at normal temperatures and pressure.

Conditions to Avoid

Incompatible materials. Avoid dispersion of dust in air.

Materials to Avoid

Acids, halogens, strong oxidizing agents.

Hazardous Decomposition Products

Oxides of carbon, oxides of calcium.

Hazardous Polymerization

Hazardous polymerization has not occurred under normal temperatures and pressures.

*** Section 11 - Toxicological Information ***

Acute Toxicity

A: General Product Information

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

B: Component Analysis - LD50/LC50

Proprietary component 1 (Proprietary)

Oral LD50 Rat 6450 mg/kg

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Repeated Dose Toxicity

Excessive ingestion of Proprietary component 1 may cause hypercalcemia, alkalosis, nephrocalcinosis and azotemia.

Skin Effects

Exposure to this product will likely cause irritation to the skin.

Eye Effects

Exposure to this product will likely cause irritation to the eyes.

Ingestion Effects

Exposure to this product will likely cause irritation to the gastrointestinal system.

Inhalation Effects

Exposure to this product will likely cause irritation to the respiratory system.

Carcinogenicity

A: General Product Information

No carcinogenicity data available for this product.

B: Substance Carcinogenicity

None of the substances in this preparation are listed by IARC, Austria, Belgium, Denmark, France, Germany, Ireland, Luxembourg, Netherlands, Spain, or United Kingdom.

Mutagenicity

None identified.

Reproductive Effects

None identified.

Teratogenicity

None identified.

Sensitization

None identified.

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No data available for this product as a whole.

Additional manufacturer data for Proprietary component 1: LC50 Fish >200 mg/L

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

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

Mobility

No information available for the product.

Persistence & Degradation

No information available for the product.

Bioaccumulative Potential

No information available for the product.

Other Adverse Effects

None identified.

Environmental Fate

No information available.

*** Section 13 - Disposal Considerations ***

Waste Disposal Instructions

Dispose of as special waste in compliance with local and national regulations.

Disposal of Contaminated Packaging

Empty containers should be taken for local recycling or waste disposa.

*** Section 14 - Transportation Information ***

International Transportation Regulations

Not regulated as dangerous goods.

*** Section 15 - Regulatory Information ***

EU Marking and Labelling according to 67/548/EEC and/or 1999/45/EC:

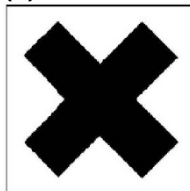
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Symbol(s)



Risk Phrases

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety Phrases

S24/25 Avoid contact with skin and eyes.

S22 Do not breathe dust.

Chemical Safety Assessment Information

None necessary.

Other Information

A: General Product Information

No additional information available.

B: Substance Analysis - Inventory

Component/CAS	EC #	EEC	CAN	TSCA
Proprietary component 1 Proprietary	Proprietary	EINECS	DSL	Yes
Proprietary component 2 Proprietary	Proprietary	EINECS	DSL	Yes

C: EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances Subject to Authorisation

No components of this material are listed on the Candidate List of Substances Subject to Authorisation.

D: EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorisation

No components of this material are listed in Annex XIV to REACH on Substances Subject to Authorisation.

*** Section 16 - Other Information ***

Recommended Restrictions on Use

None identified.

Key / Legend

ACGIH = American Conference of Governmental Industrial Hygienists. AICS = Australian Inventory of Chemical Substances. CAS = Chemical Abstract Service. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act. CFR = Code of Federal Regulations. CHEMTREC = Chemical Transportation Emergency Center. DSL = Canadian Domestic Substance List. EINECS = European Inventory of New and Existing Chemical Substances. EPA = Environmental Protection Agency. HEPA = High Efficiency Particulate Air. HMIS = Hazardous Materials Identification System. IARC = International Agency for Research on Cancer. IDLH = Immediately Dangerous to Life and Health. MITI = Japanese Ministry of International Trade and Industry. NDSL = Canadian Non-Domestic Substance List. NFPA = National Fire Protection Association. NIOSH = National Institute of Occupational Safety and Health. NJTSR = New Jersey Trade Secret Registry. NTP = National Toxicology Program. OSHA = Occupational Safety and Health Administration. NA = Not available or Not Applicable. SARA = Superfund Amendments and Reauthorization Act. TDG = Transportation of Dangerous Goods. TLV = Threshold Limit Value. TSCA = Toxic Substances Control Act. WHMIS = Workplace Hazardous Materials Information System.

Revision History

New SDS: 17/06/2010