

SAFETY DATA SHEETS

This SDS packet was issued with item:

078391871

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

078057833

MATERIAL SAFETY DATA SHEET

Section I – Product Information

Product Name or Identity:	PANAKARE PLUS TABLETS (Pancreatic Plus Tablets)		
Manufacturer's Name:	Neogen Corporation	Emergency Phone No.	859 254 1221
	944 Nandino Blvd.	Fax No.:	859 255 5532
	Lexington, KY 40511	e-mail:	inform@neogen.com
Date Prepared or Revised: 11/15/05			

Section II – Hazardous Ingredients / Identity Information

Hazardous Components (Specific Chemical Identity: Common Names) This product contains no hazardous ingredients.	OSHA PEL (Permissible Exposure Limits)	ACGIH TLV (Threshold Limit Value)	Toxicity Data LD ₅₀
Pancreatin-CAS 8049-47-6 Composed of: Lipase 9,400 USP Units/tablet Protease 57,000 USP Units/tablet Amylase 64,000 USP Units/tablet	N/A	Total dust 3 mg/m3	Rat, Mouse >10 g/kg
Vitamin A 1,000 IU/tablet			
Vitamin D-3 100 IU/tablet			
Vitamin E 10 IU/tablet			

Section III – Physical Characteristics

Boiling Point: N/A	Specific Gravity (H ₂ O = 1): N/A
Vapor Pressure (mm Hg.): N/A	Melting Point:
Vapor Density (AIR = 1): N/A	Evaporation Rate (Butyl Acetate = 1):
Solubility in Water: Partially Soluble	
Appearance and Odor: Light Brown-Grey Tablet, Slight Meaty Odor	

Section IV – Fire and Explosion Hazard Data

Flash Point (<i>Method Used</i>): N/A	Flammable Limits: LEL (Lower Explosive Limit) - N/A UEL (Upper Explosive Limit) - N/A
Extinguishing Media: Water spray, CO2, dry chemical powder, foam.	
Special Fire Fighting Procedures: Wear NIOSH-approved self-contained breathing apparatus.	
Unusual Fire and Explosion Hazards: Avoid breathing dust or fumes	

Section V – Reactivity Data

Stability	Unstable		Conditions to Avoid: None known
	Stable	X	
Incompatibility (<i>Materials to Avoid</i>): Strong oxidizing agents, heat			
Hazardous Decomposition or Byproducts: None known			
Hazardous Polymerization	May Occur		Conditions to Avoid: None known
	Will Not Occur	X	

Section VI – Health Hazard Data

Route(s) of Entry:	Inhalation-Moderate irritation	Skin, eyes-Moderate irritation	Ingestion-Not an ingestion hazard under normal conditions of use
Health Hazards (Acute and Chronic)	Avoid breathing dusts; inhalation may irritate the nose and respiratory tract and may cause asthma- like reaction. Once an allergy develops, even low exposure levels may trigger symptoms. Eye exposure can cause redness, tearing, and irritation.		
Carcinogenicity:	NTP-Not listed (National Toxicology Program)	IARC Monographs-Not listed (International Agency for Research in Cancer)	OSHA Regulated-No
Signs and Symptoms of Exposure: Prolonged contact may cause eye, skin or respiratory irritation			
Medical Conditions Generally Aggravated by Exposure: Skin dermatitis, asthma or other chronic respiratory conditions. Individuals with hypersensitivity to pancreatin or pork may be more likely to develop allergic reactions to this product.			
Emergency / First Aid Procedures	Ingestion: Not an ingestion hazard under normal use conditions.		
	Inhalation: Remove exposed subject to fresh air. If not breathing, perform artificial respiration. If breathing is difficult, administer oxygen(by trained personnel only). Keep subject warm. Seek immediate medical attention.		
	Eye Contact: First check victim for contact lenses and remove if present. Immediately flush eyes with plenty of water for at least 15 minutes while holding eyelids open. If symptoms such as redness or irritation develop or persist, get immediate medical attention.		
	Skin Contact: Remove contaminated clothing. Wash skin with soap and flush thoroughly with plenty of water. Obtain medical attention if irritation develops. Clean contaminated clothing by washing before reuse.		

Section VII – Precautions for Safe Handling and Use

Accidental Release Measures: Follow facility-specific procedures for spill response. Avoid dust generation; vacuum or wet mop. When cleaning spills, wear appropriate personal protective equipment and respirator. Practice contamination avoidance. For small spills of solid material, collect by carefully scooping or shoveling into a pan or drum and by moistening with water and wiping. Avoid spreading the compound as much as possible.
Waste Disposal Method: Disposal in dry landfill is acceptable. Ensure compliance with local, state and Federal regulations.
Handling and Storing: Read and follow all label directions.
Other Precautions: For veterinary use only.

Section VIII – Control Measures

Respiratory Protection (Specify Type): NIOSH-approved self-contained breathing apparatus		
Ventilation	Local Exhaust: General dilution or local exhaust	Special:
	Mechanical (General):	Other: Wear Tyvek suits for prolonged exposure
Protective Gloves: Rubber gloves		Eye Protection: Safety goggles or glasses
Other Protective Clothing or Equipment: Tyvek suits, eyewash.		
Work / Hygienic Practices: Avoid dusty, warm moist conditions. Wash with soap and water after use.		

This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Neogen Corporation shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute NO WARRANTY.

SECTION 1: Identification of the substance/mixture and of the company

1.1 Product identifier

- Product Name: **PanaKare™ Plus Tablets**
- Product Part Number(s): **09067, 09068**
- Brands: NeogenVet®

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Use of the substance/preparation: For use as a digestive aid in replacement therapy where digestion of protein, carbohydrate and fat is inadequate due to exocrine pancreatic insufficiency in dogs and cats.
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- Uses advised against: Use only as directed. See label cautions.

1.3 Details of the supplier of the safety data sheet

- Name of Manufacturer: Neogen Corporation
- Address of Manufacturer: 944 Nandino Blvd.
Lexington, Kentucky
USA
- Telephone: 859/254-1221
- Email: Inform@neogen.com

1.4 Emergency telephone number

- Emergency Telephone: Chemtrec: 1 (800) 424-9300
Outside USA and Canada: +1 (703) 527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (29 CFR 1910.1200)

- Skin irritation, Cat. 2, Eye irritation, Cat. 2A, Sensitization, respiratory, Cat. 1, Specific target organ toxicity (single exposure), Cat. 3

Classification (WHMIS 2015 HPR)

- Skin irritation, Cat. 2, Eye irritation, Cat. 2A, Sensitization, respiratory, Cat. 1, Specific target organ toxicity (single exposure), Cat. 3

Additional information: For full text of Hazard statements: see Section 16

2.2 Label elements



GHS07



GHS08

- Signal Word: Danger
- Symbols: GHS07, GHS08
- Hazard phrases
 - Causes skin irritation.
 - Causes serious eye irritation.
 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 - May cause respiratory irritation.
- Precautionary Phrases
 - Wash hands thoroughly after handling.
 - Wear protective gloves/protective clothing/eye protection/face protection.
 - Avoid breathing dust.
 - In case of inadequate ventilation wear respiratory protection.
 - If on skin: wash with plenty of soap and water.
 - If skin or eye irritation persists: Get medical advice/attention.
 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
 - If experiencing respiratory symptoms: call a poison center or doctor/physician.

SECTION 2: Hazards identification (continued)

Take off contaminated clothing and wash before reuse.
Call a poison center or doctor if you feel unwell.
Store locked up in a well-ventilated place. Keep container tightly closed.
Dispose of contents/container in accordance with local, state, national, or international regulations.

2.3 Other hazards

- Keep out of reach of children.

SECTION 3: Composition/information on ingredients**3.1 Substances****3.2 Mixtures**

This product is a mixture of the substances listed below with the addition of non-hazardous materials

Chemical	Concentration	CAS No.	H-Statements	Symbols
Pancreatic granules	40-50%	8049-47-6	H315, H319, H334, H335	GHS07, GHS08
Dicalcium phosphate	20-30%	7789-77-7	H315, H319, H335	GHS07

Ingredients not precisely identified are proprietary or non-hazardous. Values are not product specifications.

SECTION 4 First aid measures**4.1 Description of first aid measures**

- General
In case of doubt, or when symptoms persist, seek medical attention.
In general, this product is not hazardous to humans or animals, but like any other chemical, it should be treated with care, respect, and common sense.
- Contact with skin
Remove contaminated clothing.
Wash affected area with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Contaminated clothing should be laundered before reuse.
- Contact with eyes
If substance has gotten into eyes, immediately wash out with plenty of water for at least 15 minutes.
Irrigate eyes thoroughly while lifting eyelids.
Seek medical advice if irritation persists.
- Ingestion
Rinse mouth with water (do not swallow).
Never make an unconscious person vomit or drink fluids.
If medical advice is needed, have product container or label at hand.
- Inhalation
If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Call a poison center or doctor/physician if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

- The most important known symptoms are described in the labeling (see Section 2.2) and/or in Section 11.
- Discontinue use in animals with symptoms of sensitivity or allergy.

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.

SECTION 5: Fire-fighting measures

- 5.1 Extinguishing media
 - In case of fire: use water spray, foam, carbon dioxide or dry agent for extinction.
 - 5.2 Special hazards arising from the substance or mixture
 - Smoke from fires is toxic. Take precautions to protect personnel from exposure.
 - See Section 10.
 - 5.3 Advice for firefighters
 - Keep container(s) exposed to fire cool, by spraying with water.
 - Wear chemical protection suit and positive-pressure breathing apparatus, if necessary.
 - Wear protective clothing as per Section 8.
 - 5.4 Hazardous Combustion Products
 - May include carbon oxides.
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SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
 - Shut off all ignition sources.
 - Use non-sparking hand tools.
 - Avoid raising dust.
 - Wear protective clothing as per Section 8.
 - Wash thoroughly after dealing with spillage.
 - 6.2 Environmental Precautions
 - Do not allow to enter public sewers and watercourses.
 - Avoid releasing to the environment.
 - 6.3 Methods and material for containment and cleaning up
 - Sweep up and shovel.
 - Place in sealable container.
 - Seal containers and label them.
 - Seek expert advice for removal and disposal of all contaminated materials and wastes.
 - 6.4 Reference to other sections
 - See Section 7 for storage. For disposal, see Section 13.
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SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
 - Do not breathe dust.
 - Use only outdoors or in a well-ventilated area.
 - Avoid contact with skin and eyes.
 - Do not eat, drink or smoke when using this product.
 - Wash hands thoroughly after using this substance.
 - 7.2 Conditions for safe storage, including any incompatibilities
 - Store in a dry place at controlled room temperature.
 - Store locked up in a well-ventilated place.
 - Keep lid tightly closed when not in use.
 - Keep out of reach of children.
 - 7.3 Specific end use(s)
 - For use a digestive aid in replacement therapy where digestion of protein, carbohydrate and fat is inadequate due to exocrine pancreatic insufficiency in dogs and cats.
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters

Component	CAS No.	Value	Control Parameters	Basis
Cellulose	9004-34-6	TWA	15 mg/m ³	USA-OSHA Table Z-1 Limits for Air Contaminants - 1910.1000
		TWA	10 mg/m ³	USA-NIOSH Recommended Exposure Limits
		TWA	10 mg/m ³	USA-ACGIH Threshold Limit Values (TLV)

Not a dust exposure hazard in tablet form.

8.2 Exposure controls

- Engineering controls should be provided to prevent the need for ventilation.
- No respiratory protection is needed if ventilation/extraction is adequate, otherwise wear an approved NIOSH N95 dust mask.
- Wear protective gloves according to the concentration and amount of dangerous substance at the specific workplace.
- Wear safety glasses approved to standard for ANSI Z87, according to the concentration and amount of dangerous substance at the specific workplace.
- Wear suitable protective clothing in accordance with good industrial hygiene and safety practices in the event of prolonged exposure to bulk quantities.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Light brown-grey, round tablets
- Odor: Slight meaty odor
- pH: Not applicable
- Melting point/Range: Not determined
- Boiling Point/Range: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability: No information available
- Vapor Pressure: Not applicable
- Vapor Density: Not applicable
- Specific Gravity: No information available
- Solubility in water: Partially soluble in water
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: Product is not self-igniting
- Viscosity: Product is solid
- Explosive Properties: Product does not present an explosion hazard
- Oxidizing Properties: No information available

9.2 Other information

- No information available

SECTION 10: Stability and reactivity

10.1 Reactivity

- No information available

10.2 Chemical stability

- Considered stable under normal conditions.

10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

- Avoid contact with moisture.

10.5 Incompatible materials

- None known

10.6 Hazardous Decomposition Products

- None known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- No experimental test data available for mixture
 - ATEmix = 5,747 mg/kg (oral)
 - Contact with skin
Causes skin irritation.
 - Contact with eyes
Causes serious eye irritation
 - Ingestion
Product is not toxic, but may cause irritation of the throat and/or nausea in sensitive individuals.
 - Inhalation
May cause respiratory irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 - Carcinogenicity
Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens.
Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112.
Not listed in OSHA standard 1910.1003 Carcinogens.
 - Mutagenicity
No evidence of mutagenic effects.
 - Teratogenicity
No evidence of teratogenic effects.
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SECTION 12: Ecological information

12.1 Toxicity

- This product is not classified as hazardous to the environment under U.S. regulations.

12.2 Persistence and degradability

- No information available

12.3 Bioaccumulation Potential

- No information available

12.4 Mobility in soil

- No information available

12.5 Results of PBT and vPvB assessment

- PBT/vPvB assessment not available

12.6 Other Adverse Effects

- To the best of our knowledge, the properties of this material have not been fully evaluated.
 - On available data, substance is not harmful to the environment.
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SECTION 13: Disposal considerations

Waste treatment methods

- Disposal should be in accordance with local, state, national, or international regulations.
 - Do not discharge into drains or the environment, dispose to an approved waste disposal facility.
 - Do not reuse empty containers.
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SECTION 14: Transport information

14.1 UN Number

- Not classified as hazardous for transport

14.2 UN Proper Shipping Name

- Not applicable

14.3 Transport hazard class(es)

- Not applicable

SECTION 14: Transport information (continued)

14.4 Packing group

- Not applicable

14.5 Environmental hazards

- Not Classified

14.6 Special precautions for user

- Not Classified

14.7 Domestic Surface Transport (US DOT)

- Proper Shipping Name: Not applicable
- DOT UN No.: Not applicable
- DOT Hazard Class: Not applicable
- DOT Packing Group: Not applicable

14.8 International Road/Rail (ADR/RID)

- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable
- Tunnel Code: Not applicable

14.9 Ocean/Sea (IMO/IMDG)

- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Packing Group: Not applicable

14.10 Air (ICAO/IATA)

- Proper Shipping Name: Not applicable
- ICAO Un No.: Not applicable
- ICAO Hazard Class: Not applicable
- ICAO Packing Group: Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- The labeling requirements of Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Following is the hazard information as required on the drug label:

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

KEEP OUT OF REACH OF CHILDREN

For animal use only

- NDC: 59051-9067-5, 59051-9067-7

15.2 United States Regulatory Information

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

The material does not contain any chemical components with known CAS numbers that exceed the threshold (de minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Toxic Substance Control Act (TSCA)

All components of this material are either listed or exempt from listing on the TSCA Inventory.

SECTION 15: Regulatory information (continued)State Right-to-Know

Massachusetts

Cellulose, CAS No. 9004-34-6 (Not a dust exposure hazard in tablet form)

New Jersey

Cellulose, CAS No. 9004-34-6 (Not a dust exposure hazard in tablet form)

Pennsylvania

Cellulose, CAS No. 9004-34-6 (Not a dust exposure hazard in tablet form)

15.3 Canadian Regulatory Information

- This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR). The labelling may differ subject to the requirements of the Food and Drugs Act (FDA).
- WHMIS Classification: Exempt
- Inventory Status
 - Domestic Substances List (DSL) Listed
 - Non-Domestic Substances List (NDSL) Not listed

SECTION 16: Other information

Document Number: SDS-0015, PanaKare Plus Tablets

Date of Preparation: November 18, 2015

Revision: Rev. 0

Replaces: New issue

Text not given with phrase codes where they are used elsewhere in this safety data sheet: H315: Causes skin irritation. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation.

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