

SAFETY DATA SHEETS

This SDS packet was issued with item:

078043594

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

078043578

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078043586 078043602

Identity: Product Name: Pancrezyme® Tablet or Powder

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Product Code 821004, 821008, 821012, 825100, 825500

Section I

Supplier Information:

Emergency Telephone Number

Name: VIRBAC CORP. (Virbac AH Inc.,
Allerderm®, Francodex®, Mardel®, St.
JON®, PMResources, Zema®)

Contact: POISON CONTROL CENTER or 911

Address: P. O. BOX 162059

City: FORT WORTH

Telephone Number for Information

State: TX 76161

Contact Virbac: 800/338-3659

Section II - Hazardous Ingredients/Identity Information

Hazardous Components (Special Chemical Identification; Common Name)	OSHA PEL	ACGIH TLV	STEL	CAS #	% (opt.)
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Pancrezyme® Tablets and Powder are exempt from the requirements of the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29CFR1910.1200). These products are exempt by OSHA because, under normal conditions of use, these formed products are believed to pose little risk to personnel who handle them in an occupational setting.

Lipase	Not Applicable	Not Applicable	Not Applicable		
Protease	Not Applicable	Not Applicable	Not Applicable		
Amylase	Not Applicable	Not Applicable	Not Applicable		

Section III - Physical/Chemical Characteristics

Boiling Point:	Not Applicable
Specific Gravity (H ₂ O = 1):	Not Applicable
Vapor Pressure (mm Hg):	Not Applicable
Melting Point:	Not Applicable
Vapor Density (AIR = 1):	Not Applicable
Evaporation Rate (Butyl Acetate = 1):	Not Applicable
Solubility in Water:	Not Applicable
Appearance and Odor:	Tablet or powder

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used):	Not Applicable
Flammable Limits:	LEL: Not Applicable UEL: Not Applicable
Extinguishing Media:	Water spray, dry chemical, carbon dioxide, or foam suitable for the surrounding fire and materials.
Special Firefighting Procedures:	Not Applicable.
Unusual Fire and Explosion Hazards:	Not Applicable

Section V - Reactivity Data

Stability	STABLE
Incompatibility	(Materials to Avoid): Strong Oxidizing Agents
Hazardous Decomposition or Byproducts:	Nature of decomposition products not known.
Hazardous Polymerization	WILL NOT OCCUR
Conditions to Avoid:	None known

Identity: Product Name: Pancrezyme® Tablet or Powder

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Product Code 821004, 821008, 821012, 825100, 825500

Section VI - Health Hazard Data

Routes of Entry: Inhalation? NO Skin? NO Ingestion? Yes

Health Hazards (Acute and Chronic): Hypersensitivity. Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Carcinogenicity: NTP? NO IARC Monographs? NO OSHA Regulated? NO

Signs and Symptoms of Exposure: May cause gastric mucous irritation.
Medical Conditions Generally Aggravated by Exposure: None Known

Emergency and First Aid Procedures

INGESTED: If large quantities are swallowed, call a physician or Poison Control Center.

SKIN CONTACT: Wash affected areas promptly and thoroughly with soap and water. Rinse thoroughly. If irritation occurs, get medical attention.

EYE CONTACT: Immediately rinse eyes with water for a minimum of 15 minutes assuring adequate flushing by separating the eyelids with fingers. Call a physician if irritation persists.

INHALATION: Not Applicable

Note to Physician:

Section VII - Precautions for Safe Handling and Use

Steps to be Taken in Case Material is Released or Spilled: Vacuum or sweep up spillage, place in a bag or appropriate container and hold for waste disposal. Ventilate area and wash spill site after spillage is picked up completely.

Waste Disposal Method: Dispose of in accordance with all applicable federal, state, and local laws.

Precautions to be Taken in Handling or Storage: Store tightly sealed in the original container at controlled room temperature 15°C to 30°C (59°F to 88°F).

Other Precautions: Keep out of the reach of children.

Section VIII - Control Measures

Respiratory Protection: Not necessary under recommended conditions of use.

Ventilation: Local Exhaust: Not Applicable
Special: Not Applicable
Mechanical (General): Not Applicable

Protective Gloves: Rubber gloves for prolonged or repeated exposure.

Eye Protection: Not necessary under recommended conditions of use.

Other Protective Clothing or Equipment: None required.

Work/Hygienic Practices: Read and follow directions on product label.

Section IX - Additional Information

Disclaimer of Expressed and Implied Warranties: This information is provided in good faith but without express or implied warranty. Buyer assumes all responsibility for safety and use not in accordance with label instructions.

Prepared by QA Department
New MSDS Dated: September 19, 2003
Supersedes MSDS Date: Not Applicable



1. IDENTIFICATION

Product Name	PANCREZYME® Tablets
Recommended use of the chemical and restrictions on use	
Identified uses	Provides enzymes to support proper digestion in cats and dogs
Restrictions on Use	For animal use only.
Company Identification	Virbac AH, Inc. P.O. Box 162059 Fort Worth, Texas 76161 (800) 338-3659
Customer Information Number	
Emergency Telephone Number	
Chemtrec Number	(800) 424-9300
Other Emergency Number:	Poison Control Center: 1-800-222-1222 (human) HOT LINE NUMBER: 1-800-345-4735 (human and pet)
Issue Date	May 15, 2017
Supersedes Date	August 3, 2011

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2. HAZARDS IDENTIFICATION

Hazard Classification

This product is classified as not hazardous in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

Label Elements

Hazard Symbols
None

Signal Word: None

Hazard Statements

None

Precautionary Statements

Prevention

None

Response

None

Storage

None

Disposal

None

Other Hazards

Repeated inhalation of powders associated with tablets may cause respiratory sensitization in hypersensitive individuals.



2. HAZARD IDENTIFICATION

Specific Concentration Limits

The values listed below represent the percentages of ingredients of unknown toxicity.

Acute oral toxicity	0%
Acute dermal toxicity	>90%
Acute inhalation toxicity	>90%
Acute aquatic toxicity	>90%

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms:

This product is a mixture.

Component Name	CAS Number	Concentration
Pancreatin (porcine)	8049-47-6	See below

Each 425 mg contains:
Lipase 9000 USP units
Protease 57,000 USP units
Amylase 64,000 USP units

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eyes

Not an expected route of entry. If tablet contacts eye, flush thoroughly with water. If pain or irritation persists contact a physician.

Skin

If irritation develops wash skin thoroughly with soap and water. Obtain medical attention if redness or soreness persists.

Ingestion

Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Inhalation

Remove person to fresh air. Seek medical attention if symptoms persist.

Most important symptoms/effects, acute and delayed

Aside from the information found under Description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

Indication of immediate medical attention and special treatment needed

Notes to Physicians

Treat symptomatically.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Use extinguishing media appropriate for surrounding materials.



5. FIRE - FIGHTING MEASURES

Unusual Fire and Explosion Hazards

Can release hazardous vapors during a fire.

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

No specific measures recommended.

Environmental Precautions

Prevent the material from entering drains or watercourses.

Methods and materials for containment and cleaning up

Pick up and dispose of in accordance with all applicable local and national regulations. Prevent the material from entering drains or watercourses.

7. HANDLING AND STORAGE

Precautions for safe handling

Wear appropriate protective clothing.

Conditions for safe storage

Store tightly closed in original container in a cool, dry place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limits are listed below, if they exist.

Appropriate engineering controls

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.

Individual protection measures

Respiratory Protection

Not required under normal conditions of use.

Skin Protection

Gloves

Eye/Face Protection

Not required under normal conditions of use.

Body Protection

Normal work wear



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance		
	Physical State	Solid (tablet)
	Color	Off white to tan
Odor		Characteristic enzyme
Odor Threshold		No data available
pH		5.0 – 8.0
Relative Density		No data available
Boiling Range/Point (°C/F)		No data available
Melting Point (°C/F)		No data available
Flash Point (PMCC) (°C/F)		Not flammable
Vapor Pressure		No data available
Evaporation Rate (BuAc=1)		No data available
Solubility in Water		Partially
Vapor Density (Air = 1)		No data available
VOC		No data available
Partition coefficient (n-octanol/water)		Not applicable
Viscosity		Not applicable
Auto-ignition Temperature		No data available
Decomposition Temperature		No data available
Upper explosive limit		No data available
Lower explosive limit		No data available
Flammability (solid, gas)		No data available

10. STABILITY AND REACTIVITY

Reactivity

Data is not available.

Chemical Stability

Stable under normal conditions.

Possibility of hazardous reactions

Hazardous polymerization will not occur.

Conditions to Avoid

Heat - high temperatures

Incompatible Materials

Strong acids - strong bases - oxidizing agents

Hazardous Decomposition Products

Oxides of carbon

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Oral LD50 (rat) >10,000 mg/kg



11. TOXICOLOGICAL INFORMATION

Specific Target Organ Toxicity (STOT) – single exposure

No relevant studies identified.

Specific Target Organ Toxicity (STOT) – repeat exposure

No relevant studies identified.

Serious Eye damage/Irritation

No relevant studies identified.

Skin Corrosion/Irritation

No relevant studies identified.

Respiratory or Skin Sensitization

Pancreatin: May cause a reaction in individuals with pork allergies.

Pancreatin: May cause respiratory sensitization.

Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

Germ Cell Mutagenicity

No relevant studies identified.

Reproductive Toxicity

No relevant studies identified.

Aspiration Hazard

Not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity

No relevant studies identified.

Mobility in soil

No relevant studies identified.

Persistence/Degradability

Product is readily biodegradable.

Bioaccumulative Potential

No relevant studies identified.

Other adverse effects

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Dispose of in accordance with all applicable local and national regulations.



14. TRANSPORT INFORMATION

Contact supplier for transport information.

15. REGULATORY INFORMATION

United States TSCA Inventory

This product is excluded from the US EPA Toxic Substance Control Act and is regulated under the Food, Drug and Cosmetic Act.

California Proposition 65

This product contains the following materials which the State of California has found to cause cancer, birth defects or other reproductive harm: None

SARA Title III Sect. 311/312 Categorization

None

SARA Title III Sect. 313

The following chemicals are listed in Section 313 at or above de minimis concentrations: None

16. OTHER INFORMATION

Legend

ACGIH: American Conference of Governmental Industrial Hygienists

BOD: Biological Oxygen Demand

CAS#: Chemical Abstracts Service Number

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

N/A: Denotes no applicable information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

TSCA: Toxic Substance Control Act

Revision Date: May 15, 2017

Replaces: August 3, 2011

Changes made: Update to GHS.

Information Source and References

This SDS is prepared by Hazard Communication Specialists based on information provided by internal company references.

Prepared By: EnviroNet LLC.

PANCREZYME is a registered trademark of Virbac AH, Inc.



16. OTHER INFORMATION

The information and recommendations presented in this SDS are based on sources believed to be accurate. Virbac AH, Inc. assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the material for their particular purposes. In particular, we make **NO WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED**, with respect to such information, and we assume no liability resulting from its use. Users should ensure that any use or disposal of the material is in accordance with applicable Federal, State, and local laws and regulations.



MATERIAL SAFETY DATA SHEET
PANCREZYME® Powder
Product Codes: 821008 and 821012

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

Product Name PANCREZYME® Powder
Product Description For treatment of pancreatic insufficiency in cats and dogs
Manufacturer/Supplier Virbac AH, Inc.
Address P.O. Box 162059
Fort Worth, Texas 76161
Phone Number (800) 338-3659
Chemtrec Number (24 hour) (800) 424-9300
Other Emergency Numbers: Poison Control Center: 1-800-222-1222
MSDS Revision Date: August 3, 2011
Supersedes MSDS Dated: March 19, 2009

Material Safety Data Sheet in compliance with OSHA's Hazcom Standard (29 CFR 1910.1200)

2. HAZARDS IDENTIFICATION

Emergency Overview
CAUTION!

May cause adverse gastrointestinal effects.
May cause allergic respiratory or skin reaction.
Keep out of reach of children.

Routes of Entry

Eye contact - Skin contact - Ingestion - Inhalation

Carcinogenic Status

Not considered carcinogenic by NTP, IARC, and OSHA.

Target Organs

Eye - Skin - Respiratory Tract - Gastrointestinal Tract

Health Effects - Eyes

Contact may cause eye irritation.

Health Effects - Skin

Contact with skin may cause irritation and skin sensitization.

Health Effects - Ingestion

Ingestion of this material may cause gastrointestinal effects such as nausea, vomiting and diarrhea.

Health Effects - Inhalation

Inhalation may cause irritation of respiratory tract and respiratory sensitization in hypersensitive individuals.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	CAS Number	Concentration
Pancreatin	8049-47-6	See below
Sucrose	57-50-1	<50%
Inorganic compound	N.A.	≤ 10%
Each 2.8 grams (1 tsp.) contains:		
Lipase	71,400 USP units	
Protease	388,000 USP units	
Amylase	460,000 USP units	



4. FIRST AID MEASURES

Eyes

Immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

Skin

Wash skin thoroughly with soap and water. Obtain medical attention if redness or soreness persists.

Ingestion

Contact a physician immediately if ingested. Physician may call a poison control center for advice concerning human ingestion.

Inhalation

Not applicable

Advice to Physicians

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Use extinguishing media appropriate for surrounding materials.

Unusual Fire and Explosion Hazards

This product is a dust and if significant amounts are suspended in air may pose an explosion risk during a fire.

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Sweep and dispose of small amounts in trash. Large amounts should be disposed of in a sanitary landfill.

7. HANDLING AND STORAGE

Store in original container at temperatures below 77° F (25° C). Keep out of sunlight. Keep container tightly closed in a cool dry place. Keep away from children. Wash hands after dispensing and before eating, drinking or smoking. Use product on or before expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Standards

Exposure limits are listed below, if they exist.

Product as supplied:

PNOG: Particulates Not Otherwise Classified

ACGIH: TLV, particulates 3 mg/m³

Sucrose

ACGIH: TLV 10 mg/m³ TWA 8h

OSHA: PEL 5 mg/m³, respirable fraction

OSHA: PEL 15 mg/m³, total dust

Engineering Control Measures

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection

Not required under normal conditions of use. Avoid creation of airborne dust.

Hand Protection

Gloves

Eye Protection

Not required under normal conditions of use. Use eyewear if conditions are dusty.

Body Protection

Normal work wear.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Powder
Color	Yellow
Odor	Meaty
pH	6.5 - 7.5 (10% solution)
Specific Gravity	0.9
Boiling Range/Point (°C/F)	Not applicable
Melting Point (°C/F)	Not applicable
Flash Point (PMCC) (°C/F)	Not flammable
Explosion Limits (%)	No data available
Vapor Pressure	Not applicable
Density	No data available
Solubility in Water	Partly soluble
Vapor Density (Air = 1)	Not applicable

10. STABILITY AND REACTIVITY

Stability

Stable under normal conditions.

Conditions to Avoid

Heat, sparks, flames - high temperatures - sources of ignition - contact with incompatible materials

Materials to Avoid

Strong acids - strong oxidizing agents – reacts violently with bromine trifluoride and lithium – mineral acids, excess alkali hydroxides or carbonates may render pancreatin inactive

Hazardous Polymerization

Will not occur.

Hazardous Decomposition Products

Oxides of carbon

11. TOXICOLOGICAL INFORMATION

See product insert and/or packaging for additional information.

Acute Toxicity

Pancreatin: LD50 (rat) >10,000 mg/kg

Specific Target Organ Systemic Toxicity (single and repeat)

No relevant studies identified.

Serious Eye damage/Eye Irritation

No relevant studies identified.



11. TOXICOLOGICAL INFORMATION

Skin Corrosion/Irritation

No relevant studies identified.

Respiratory or Skin Sensitization

Pancreatin: May cause a reaction in individuals with pork allergies.

Pancreatin: May cause respiratory and skin sensitization.

Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

Germ Cell Mutagenicity

No relevant studies identified.

Toxicity to Reproduction

No relevant studies identified.

12. ECOLOGICAL INFORMATION

Mobility

No relevant studies identified.

Persistence/Degradability

No relevant studies identified.

Bio-accumulation

No relevant studies identified.

Ecotoxicity

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

Contact supplier for transport information.

15. REGULATORY INFORMATION

US REGULATIONS (Federal, State) and INTERNATIONAL CHEMICAL REGISTRATION LAWS

TSCA Listing

This product contains ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Inventory.

DSL (Canadian) Listing

This product contains ingredients that have not been verified for listing on the Domestic Substance List (DSL).

WHMIS Classification

This product is not a controlled substance under WHMIS.

This product was classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations and the MSDS contains all the information required by these regulations.

MA Right To Know Law

This product contains the following chemicals on the Massachusetts Right to Know Law: Sucrose Dust (57-50-1)



15. REGULATORY INFORMATION

PA Right To Know Law

This product contains the following chemicals on the Pennsylvania Hazardous Substance List:
Sucrose (57-50-1)

NJ Right To Know Law

This product contains the following chemicals on the New Jersey Workplace Hazardous Substance List: None

California Proposition 65

This product contains the following materials which the State of California has found to cause cancer, birth defects or other reproductive harm: None

SARA Title III Sect. 311/312 Categorization

Immediate (Acute) Health Hazard, Delayed (Chronic) Health Hazard

SARA Title III Sect. 313

This product contains the following chemicals that are listed in Section 313 at or above de minimis concentrations: None

16. OTHER INFORMATION

NFPA Ratings

NFPA Code for Flammability - 1
NFPA Code for Health - 2
NFPA Code for Reactivity - 0
NFPA Code for Special Hazards – 0

HMIS Ratings

HMIS Code for Flammability - 1
HMIS Code for Health - 2
HMIS Code for Reactivity - 0
HMIS Code for Personal Protection - See Section 8

Abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists
BOD: Biological Oxygen Demand
CAS#: Chemical Abstracts Service Number
FIFRA: Federal Insecticide, Fungicide and Rodenticide Act
IARC: International Agency for Research on Cancer
LC50: Lethal Concentration 50%
LD50: Lethal Dose 50%
N/A: Denotes no applicable information found or available
NTP: National Toxicology Program
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit
STEL: Short Term Exposure Limit
TLV: Threshold Limit Value
TSCA: Toxic Substance Control Act



MATERIAL SAFETY DATA SHEET
PANCREZYME[®] Powder
Product Codes: 821008 and 821012

16. OTHER INFORMATION

For further Information call: (800) 338-3659
Prepared By: EnviroNet LLC

PANCREZYME is a registered trademark of Virbac AH, Inc.

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