## **SAFETY DATA SHEETS**

## This SDS packet was issued with item:

078043586

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).

078043594 078043602

MATERIAL SAFETY DATA SHEET MSDS# 3510-266 Identity: Product Name: Pancrezyme® Tablet or Powder Page 1 of 2 Product Code 821004, 821008, 821012, 825100, 825500 Section I Supplier Information: Emergency Telephone Number VIRBAC CORP. (Virbac AH Inc., Contact: POISON CONTROL CENTER or 911 Name: Allerderm®, Francodex®, Mardel®, St. JON®, PMResources, Zema®) P. O. BOX 162059 Address: City: FORT WORTH Telephone Number for Information State: TX 76161 Contact Virbac: 800/338-3659 Section II - Hazardous Ingredients/Identity Information OSHA PEL ACGIH TI V STFL CAS# Hazardous Components % (opt.) (Special Chemical Identification; Common Name) 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 (H2O = 1): Not Applicable Vapor Pressure (mm Hg): Not Applicable Not Applicable Melting Point: Vapor Density (AIR = 1): Not Applicable Evaporation Rate (Butyl Acetate = 1): Not Applicable Not Applicable Solubility in Water: 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

Incompatibility

Conditions to Avoid:

STABLE (Materials to Avoid): Strong Oxidizing Agents

Hazardous Decomposition or Byproducts: Nature of decomposition products not known. Hazardous Polymerization WILL NOT OCCUR None known

MATERIAL SAFETY DATA SHEET MSDS # 3510-266					
Identity: Product N	ame: Pancrezyme® Tab Product Cod	let or Powder de 821004, 821008, 821012, 8	25100, 825500	Page 2 of 2	
Section VI - Health H					
Routes of Entry:	Inhalation? NO	Skin? NO	Ingestion?	Yes	
Health Hazards (Acute a		sitivity. Prolonged or repeated exp nsitive individuals.	osure may cause a	llergic reactions in	
Carcinogenicity:	NTP? NO	IARC Monographs? NO	O OSHA Re	gulated? NO	
Signs and Symptoms of Medical Conditions Gen	Exposure: May cause go erally Aggravated by Exposu	astric mucous irritation. ure: None Known			
Emergency and First Aid	Procedures				
INGESTED: If					
	irritation occurs, get medical		ater. Kinse thoroug	niy.	
EYE CONTACT: In	nmediately rinse eyes with w	vater for a minimum of 15 minutes igers. Call a physician if irritation p		flushing by	
	ot Applicable	goro. Oan a physician in intration p	persists.		
Note to Physician:					
Section VII - Brecaut	ions for Safe Handling a	and Hea			
	ise Material is Released or S		n snillage place in	a bag or	
Oleps to be Taken in Oa	se material is Neleased of O	appropriate containe  Ventilate area and w  up completely.	er and hold for waste	e disposal.	
Waste Disposal Method	E	Dispose of in accord	lance with all applic	able federal, state,	
Precautions to be Taken in Handling or Storage:		Store tightly sealed i	Store tightly sealed in the original container at controlled room temperature 15°C to 30°C (59°F to 88°F).		
Other Precautions:		room temperature 15 Keep out of the reac		3 88°F).	
Castley VIII Cast	Manager				
Section VIII - Contro		ammanded conditions of use			
Respiratory Protection: Ventilation	Local Exhaust:	ommended conditions of use. Not Applicable			
Y OTHER BOTT	Special:	Not Applicable			
	Mechanical (General):	Not Applicable			
Protective Gloves:		Rubber gloves for prolonged of			
Eye Protection:	Fault-mark	Not necessary under recommended conditions of use.			
		None required.  Read and follow directions on	product label		
TTOINTINGIETHO FRACTICES	2.	read and follow directions on	product label.		
Section IX - Addition	al Information	E. 6			
		is information is provided in good y and use not in accordance with I		press or implied	
Prepared by QA Departs	ment				
New MSDS Dated: Sep	tember 19, 2003				
Supercedes 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

Customer Information Number (800) 338-3659

**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.

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#### 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 NameCAS NumberConcentrationPancreatin (porcine)8049-47-6See 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.

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#### 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

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#### 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
Boiling Range/Point (°C/F)
Melting Point (°C/F)
Flash Point (PMCC) (°C/F)
Vapor Pressure
Evaporation Rate (BuAc=1)
No data available
No data available
No data available

Solubility in Water Partially

Vapor Density (Air = 1)

VOC

No data available
No data available
Not applicable

octanol/water)

Viscosity

Auto-ignition Temperature

Decomposition Temperature
Upper explosive limit
Lower explosive limit
Flammability (solid, gas)

Not applicable
No data available
No data available
No data available
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.

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#### 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.

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## 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.

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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 NameCAS NumberConcentrationPancreatin8049-47-6See belowSucrose57-50-1<50%Inorganic compoundN.A. $\leq 10\%$ 

Each 2.8 grams (1 tsp.) contains: Lipase 71,400 USP units Protease 388,000 USP units Amylase 460,000 USP units

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PANCREZYME® Powder Product Codes: 821008 and 821012

## 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:

PNOC: Particulates Not Otherwise Classified

ACGIH: TLV, particluates 3 mg/m<sup>3</sup>

## **Sucrose**

ACGIH: TLV 10 mg/m<sup>3</sup> TWA 8h

OSHA: PEL 5 mg/m<sup>3</sup>, respirable fraction

OSHA: PEL 15 mg/m<sup>3</sup>, total dust **Engineering Control Measures** 

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

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PANCREZYME® Powder Product Codes: 821008 and 821012

## 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 Not applicable Melting Point (°C/F) Flash Point (PMCC) (°C/F) Not flammable No data available **Explosion Limits (%)** 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.

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PANCREZYME® Powder Product Codes: 821008 and 821012

#### 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)

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PANCREZYME® Powder Product Codes: 821008 and 821012

## 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

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PANCREZYME® Powder Product Codes: 821008 and 821012

## 16. OTHER INFORMATION

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

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