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
Product Code 821004, 821008, 821012, 825100, 825500

Section I

Supplier Information:

Name: VIRBAC CORP. (Virbac AH Inc., Allerderm®, Francodex®, Mardel®, St. JON®, PMResources, Zema®)
Address: P. O. BOX 162059
City: FORT WORTH
State: TX 76161

Emergency Telephone Number

Contact: **POISON CONTROL CENTER or 911**

Telephone Number for Information
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.)

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_2O = 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

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
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.

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.

SAFETY DATA SHEET
PANCREZYME® Powder

1. IDENTIFICATION

Product Name	PANCREZYME® Powder
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	June 8, 2017
Supersedes Date	December 21, 2016

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
Serious eye damage/eye irritation - Category 2A
Skin corrosion/irritation - Category 2
Skin Sensitizer -1B
Respiratory Sensitizer -1

Label Elements
Hazard Symbols



Signal Word: Danger

Hazard Statements
Causes serious eye irritation.
Causes skin irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

Precautionary Statements
Prevention
Wear eye protection, face protection, and protective gloves.
Wash hands thoroughly after handling.
Avoid breathing dust.
In case inadequate ventilation wear respiratory protection.
Contaminated work clothing must not be allowed out of the workplace.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

2. HAZARDS IDENTIFICATION

Response
If on skin: wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs, 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 eye irritation persists, get medical advice/attention.
If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a poison center or doctor.
Storage
None
Disposal
Dispose of contents/container in accordance with local and national regulations.

Other Hazards
None

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	8049-47-6	See below
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

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

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

4. FIRST AID MEASURES

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.

Unusual Fire and Explosion Hazards
May cause allergic respiratory reaction. 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

Personal precautions, protective equipment and emergency procedures
Wear appropriate protective clothing.

Environmental Precautions
Prevent the material from entering drains or watercourses.

Methods and materials for containment and cleaning up
Sweep up and transfer into suitable containers for recovery or disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Wear appropriate protective clothing. Avoid contact with skin, eyes and clothing. Wash and remove contaminated clothing before reuse. Wash hands thoroughly after handling and before eating, drinking or smoking.

Conditions for safe storage
Store in original container in a cool, dry place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Exposure limits are listed below, if they exist.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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. Avoid creation of airborne dust.
Skin Protection
Gloves
Eye/Face Protection
Safety glasses or goggles.
Body Protection
Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Solid (powder)
Color	Off-white to tan
Odor	Characteristic enzyme odor
Odor Threshold	No data available
pH	No data available
Specific Gravity	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 soluble
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.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

10. STABILITY AND REACTIVITY

Conditions to Avoid
Heat - high temperatures

Incompatible Materials
None known.

Hazardous Decomposition Products
Oxides of carbon

11. TOXICOLOGICAL INFORMATION

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

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
Pancreatin: Causes serious eye irritation.

Skin Corrosion/Irritation
Pancreatin: Causes skin irritation.

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.

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.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

12. ECOLOGICAL INFORMATION

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
Health Hazards: Skin irritation, Eye irritation, Respiratory Sensitization, Skin Sensitization

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

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

16. OTHER INFORMATION

STEL: Short Term Exposure Limit
TLV: Threshold Limit Value
TSCA: Toxic Substance Control Act

Revision Date: June 8, 2017
Replaces: December 22, 2016
Changes made: Changed identified use.

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.

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.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460