



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.

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16. OTHER INFORMATION

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