

SAFETY DATA SHEETS

This SDS packet was issued with item:

078938406

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

078938407

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 1 of 10

Revision date: 10.01.2021

Pancresorb[™] Pancreatic Enzyme Tablets

SECTION 1: Identification

Product Identifier

Product Name: Pancresorb[™] Pancreatic Enzyme Tablets

Product code: 21295415, 21295416

Recommended Use of the Product and Restriction on Use

Relevant Identified Uses: 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.

Reasons Why Uses Advised Against: Not determined or not applicable.

Manufacturer or Supplier Details

Supplier:

United States

Aspen Veterinary Resources, LTD.

3155 W. Heartland Drive

Liberty, MO 64068

1-800-792-1238

Emergency Telephone Number:

United States

CHEMTREC

Within USA and Canada: 1-800-424-9300 (24 hours)

Outside USA and Canada: +1-703-527-3887 (24 hours)

SECTION 2: Hazard(s) Identification

GHS Classification:

Skin irritation, category 2

Eye irritation, category 2A

Respiratory sensitization, category 1

Skin sensitization, category 1

Specific target organ toxicity - single exposure, category 3, respiratory tract irritation

Label elements

Hazard Pictograms:



Signal Word: Danger

Hazard statements:

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 2 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

H315 Causes skin irritation

H319 Causes serious eye irritation

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317 May cause an allergic skin reaction

H335 May cause respiratory irritation

Precautionary Statements:

P102 Keep out of reach of children

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

P284 Wear respiratory protection

P272 Contaminated work clothing must not be allowed out of the workplace

P271 Use only outdoors or in a well-ventilated area

P321 Specific treatment (see Sections 4 - 8 of this SDS and any supplemental information on the product label)

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P362 Take off contaminated clothing and wash it before reuse

P333+P313 If skin irritation or rash occurs: Get medical advice/attention

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337+P313 If eye irritation persists: Get medical advice/attention

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

P312 Call a POISON CENTER or doctor/physician if you feel unwell

P403+P233 Store in a well-ventilated place. Keep container tightly closed

P405 Store locked up

P501 Dispose of contents/container in accordance with local, national, regional and international regulations.

Hazards Not Otherwise Classified: None

SECTION 3: Composition/Information on Ingredients

Identification	Name	Weight %
CAS Number: 8049-47-6	Pancreatin	40-50
CAS Number: 7789-77-7	Calcium dihydrate hydrogen phosphate	20-30

Additional Information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200).

SECTION 4: First Aid Measures

Description of First Aid Measures

General Notes:

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 3 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Show this Safety Data Sheet to the doctor in attendance.

After Inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If exposed, seek medical advice/attention.

After Skin Contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After Eye Contact:

Rinse eyes with plenty of gently flowing lukewarm water for 15 minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After Swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most Important Symptoms and Effects, Both Acute and Delayed

Acute Symptoms and Effects:

Skin contact may result in redness, pain, burning and inflammation.

Eye contact may result in irritation, redness, pain, inflammation, itching, burning and tearing.

Inhalation exposure may cause allergy, asthma symptoms or breathing difficulties. Symptoms may include cough, chronic phlegm, shortness of breath, wheezing and chest tightness. Symptoms may be delayed.

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Inhalation may have adverse effects on the respiratory tract. Symptoms may include cough, breathing difficulties, sore throat and inflammation of the mucous membrane lining the respiratory tract.

Delayed Symptoms and Effects:

Effects are dependent on exposure (dose, concentration, contact time).

Immediate Medical Attention and Special Treatment

Specific Treatment:

If respiratory symptoms persist, seek medical attention.

Notes for the Doctor:

Treat symptomatically.

SECTION 5: Firefighting Measures

Extinguishing Media

Suitable Extinguishing Media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable Extinguishing Media:

Do not use water jet.

Specific Hazards During Fire-Fighting:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special Protective Equipment for Firefighters:

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 4 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental Release Measures

Personal Precautions, Protective Equipment, and Emergency Procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and Material for Containment and Cleaning Up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to Other Sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and Storage

Precautions for Safe Handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for Safe Storage, Including Any Incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

Occupational Exposure Limit Values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Cellulose	9004-34-6	TLV-TWA: 10 mg/m ³ (8 hr)
NIOSH	Cellulose	9004-34-6	REL-TWA: 10 mg/m ³ ([up to 10 hr], Total)
	Cellulose	9004-34-6	REL-TWA: 5 mg/m ³ ([up to 10 hr], Respirable)
OSHA	Cellulose	9004-34-6	8-Hour TWA-PEL: 5 mg/m ³ (Respirable fraction)
	Cellulose	9004-34-6	8-Hour TWA-PEL: 15 mg/m ³ (Total dust)

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 5 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Country (Legal Basis)	Substance	Identifier	Permissible concentration
United States(California)	Cellulose	9004-34-6	8-Hour TWA: 10 mg/m ³ (Particulate not otherwise regulated, total dust)
	Cellulose	9004-34-6	8-Hour TWA: 5 mg/m ³ (Particulate not otherwise regulated, respirable fraction)

Biological Limit Values:

No biological exposure limits noted for the ingredient(s).

Information on Monitoring Procedures:

Not determined or not applicable.

Appropriate Engineering Controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal Protection Equipment

Eye and Face Protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and Body Protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory Protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General Hygienic Measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and Chemical Properties

Information on Basic Physical and Chemical Properties

Appearance	Light brown-grey, round tablets
Odor	Slight meaty odor
Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 6 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Product is not self-igniting
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Product is solid
Kinematic viscosity	Not determined or not available.
Explosive properties	Product does not present an explosion hazard
Oxidizing properties	Product is not classified as an oxidizer

SECTION 10: Stability and Reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical Stability:

Stable under recommended handling and storage conditions.

Possibility of Hazardous Reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to Avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible Materials:

None known.

Hazardous Decomposition Products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological Information

Acute Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data:

Name	Route	Result
Pancreatin	oral	LD50 Rat: >10000 mg/kg
Cellulose	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 Rat: > 5.8 mg/L (4 hr [dust])
	oral	LD50 Rat: > 5000 mg/kg

Skin Corrosion/Irritation

Assessment:

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 7 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Causes skin irritation.

Product Data:

No data available.

Substance Data:

Name	Result
Pancreatin	Causes skin irritation.
Calcium dihydrate hydrogen phosphate	Causes skin irritation.

Serious Eye Damage/Irritation

Assessment:

Causes serious eye irritation.

Product Data:

No data available.

Substance Data:

Name	Result
Pancreatin	Causes serious eye irritation.
Calcium dihydrate hydrogen phosphate	Causes serious eye irritation.

Respiratory or Skin Sensitization

Assessment:

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Product Data:

No data available.

Substance Data:

Name	Result
Pancreatin	May cause an allergic skin reaction.
	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens: Not applicable

Germ Cell Mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Reproductive Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 8 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Substance Data: No data available.

Specific Target Organ Toxicity (Single Exposure)

Assessment:

May cause respiratory irritation.

Product Data:

No data available.

Substance Data:

Name	Result
Pancreatin	May cause respiratory irritation.
Calcium dihydrate hydrogen phosphate	May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure)

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Information on Likely Routes of Exposure:

No data available.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

Refer to Section 4 of this SDS.

Other Information:

No data available.

SECTION 12: Ecological Information

Acute (Short-Term) Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

Chronic (Long-Term) Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

Persistence and Degradability

Product Data: No data available.

Substance Data: No data available.

Bioaccumulative Potential

Product Data: No data available.

Substance Data: No data available.

Mobility in Soil

Product Data: No data available.

Substance Data: No data available.

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 9 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

Results of PBT and vPvB assessment

Product Data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance Data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Other Adverse Effects: No data available.

SECTION 13: Disposal Considerations

Disposal Methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport Information

United States Transportation of Dangerous Goods (49 CFR DOT)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

International Maritime Dangerous Goods (IMDG)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

SECTION 15: Regulatory Information

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.10.2016

Page 10 of 10

Revision date: 10.01.2021

Pancresorb™ Pancreatic Enzyme Tablets

United States Regulations

Inventory Listing (TSCA): All ingredients are listed-active or exempt.

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export Notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 Extremely Hazardous Substances: None of the ingredients are listed.

SARA Section 313 Toxic Chemicals: None of the ingredients are listed.

CERCLA: None of the ingredients are listed.

RCRA: None of the ingredients are listed.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know:

9004-34-6	Cellulose	Listed
-----------	-----------	--------

New Jersey Right to Know:

9004-34-6	Cellulose	Listed
-----------	-----------	--------

New York Right to Know:

8049-47-6	Pancreatin	Listed
-----------	------------	--------

Pennsylvania Right to Know:

9004-34-6	Cellulose	Listed
-----------	-----------	--------

California Proposition 65: None of the ingredients are listed.

SECTION 16: Other Information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

NFPA: 3-0-0

HMIS: 3-0-0

Initial Preparation Date: 03.10.2016

Revision date: 10.01.2021

Revision Notes:

Revision Date	Notes
2021-10-01	Rev. 2; Updated classification and additional occupational exposure limits reported.

Additional information:

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.

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

End of Safety Data Sheet