

Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

SECTION. 5 SUPPORTING DOCUMENTATION

ATTACH ANY STATEMENT FOR THE INGREDIENT THAT ARE APPLICABLE TO THIS INGREDIENT.

<u>EXAMPLES</u>	<u>ATTACHED: YES / NO / N-A</u>
• KOSHER / HALAL STATEMENT	Yes / see attached
• IRRADIATION STATEMENT	Yes / see attached
• ETO STATEMENT	Yes / see attached
• GMO STATEMENT	Yes / see attached
• MSDS SHEET	Yes / see attached
• HORMONE STATEMENT	Yes / see attached
• BSE / TSE STATEMENT	Yes / see attached
• ORGANIC CERTIFICATION STATEMENT	Yes / see attached
• CURRENT PRODUCT DATA SHEET	Yes / see attached PRID
• MANUFACTURING PROCESS FLOW CHART	Yes / see attached PRID
• STABILITY DATA	N/A
• MATERIAL EVALUATION FORM	N/A
• COUNTRY OF ORIGIN STATEMENT	Yes / see attached PRID

SECTION 6. ADDITIONAL INGREDIENT INFORMATION

RECOMMENDED STORAGE CONDITIONS:	Yes / see attached PRID
ADDITIONAL COMMENTS / INFORMATION:	

SECTION 7. CONTACT INFORMATION

CONTACT NAME:	John Garcia
TITLE:	Director of Sales
OFFICE PHONE:	402-835-5887
OTHER PHONE:	
E-MAIL;	jgarcia@americanlaboratories.com

BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL BE REQUIRED.

<i>John A. Garcia</i>	12/10/18
SIGNATURE	DATE

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SECTION 4. REGULATORY & LABELING INFORMATION

PATENT COVERAGE:	N/A	
GMP COMPLIANCE STANDARDS FOLLOWED (CITE):	21 CFR 110, 21 CFR 117	
IDENTIFY THE CRITICAL CONTROL POINTS THAT ARE MONITORED TO MAINTAIN GMP'S	HARPC plans vary by product and are reviewable during on-site audits.	
LIST ANY CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	N/A	
DATE & AGENCY OF MOST RECENT FACILITY INSPECTIONS (STATE, FEDERAL, OR FOREIGN AGENCY):		
DATE	INSPECTION AGENCY	RESULTS OF INSPECTION
November 2017	FDA	483 resolved and closed
FEED / FOOD INGREDIENT: AAFCO APPROVED YES / NO:	Unknown	
HOW INGREDIENT IS LISTED IN THE AAFCO OFFICIAL PUBLICATION:	N/A	
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	Please see attached product specification sheet.	
BIOASSAY METHOD (SPECIFY):	USP protease test, USP amylase test and USP Lipase test as applicable.	
ANIMAL HEALTH INGREDIENT: EXAMPLES OF STRUCTURE FUNCTION CLAIMS SUPPORTED BY RESEARCH / CLINICAL STUDIES	American Laboratories does not provide nutritional information.	
TARIFF CODE FOR IMPORT/EXPORT:	3507.90.7000	
ANY KNOWN RESTRICTIONS FOR USE IN OR WARNINGS FOR ANIMALS?	Labeling at the determination of the end user.	
ANY INTERACTION WITH OTHER INGREDIENTS OR DRUGS TO AVOID?	Unknown	

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SECTION 1. INGREDIENT & SUPPLIER INFORMATION

SUPPLIER (COMPANY) PROVIDING INGREDIENT:	American Laboratories, Inc.
INGREDIENT NAME & CODE:	Pancreatin Powder (PC 487) Pancreatin Powder 4 X Powder (PC 512) Pancreatin Powder 8 X Powder (PC 523) Pancreatin Powder 6 X Powder (PC 525)
GENERAL INGREDIENT INFORMATION:	See SDS

SECTION 2. MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURING SITE:	American Laboratories, Inc. 5036 South 33 rd Street Omaha, NE 68107
MODE OF MANUFACTURING	See attached processing procedure
DESCRIBE MANUFACTURING PROCESS (ATTACH FLOW CHART IF AVAILABLE):	See attached processing procedure
STERILIZATION OF FUMIGATION METHOD(S):	N/A
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	None known

SECTION 3. INGREDIENT PHYSICAL / CHEMICAL INFORMATION

COMMON OR USUAL NAME / OTHER NAMES:	See attached PRID (Product Information Data Sheet)
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	See PRID
% ACTIVE INGREDIENT:	See PRID
BIOASSAY METHOD (SPECIFY):	USP protease test, USP amylase test, and USP lipase test as applicable
PHYSICAL FORM OF THE INGREDIENT:	Powder
PARTICLE SIZE:	N/A
COUNTRY OF ORIGIN:	USA/Canada



National Animal Supplement Council



Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

NASC established a **Preferred Supplier Program** for companies who wish to provide products and services to NASC member companies, including raw materials (ingredients), contract manufacturing (dosage form products and feed supplements), analytical laboratory services and other services such as insurance, business consulting, legal expertise, etc.

The goal of the program is to prequalify vendors so that NASC members may accept and use products or services from Preferred Suppliers without additional vendor qualification procedures required under NASC cGMPs.

There are four categories of **NASC Preferred Suppliers**: Raw Material Suppliers, Contract Manufacturers, Analytical Laboratories and Service Providers.

The qualification procedure includes providing information to NASC on the scope of company operations, quality compliance program certifications, statements and additional documentation specific to the type of supplier, e.g., data sheets for each ingredient a Raw Material Supplier would like to qualify and include in the program.

Preferred Supplier Non-Botanical Ingredient Data Sheet

All Raw Material Suppliers must provide the information requested in this form as part of the qualification procedure for a single non-botanical ingredient. Any fields not applicable to the company or ingredient should be completed by entering N/A.

Please return copies of the requested certifications and the completed form electronically to Bill Bookout at b.bookout@nasc.cc or mail to:

NASC
PO Box 5168
Sun City West, AZ 85376

Contact Bill Bookout at the NASC office (760-751-3360, X1) with any questions about the **Preferred Supplier Program**.



4410 SOUTH 102ND STREET

OMAHA, NEBRASKA 68127

PHONE: 402-339-2494

FAX: 402-339-0801

EMAIL: sales@americanlaboratories.com

PRODUCT INFORMATION

DATE: November 29, 2018

PRODUCT: Pancreatin Powder (PC 487)

Generally Recognized as Safe:

Pancreatin has been affirmed as Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA), per the Code of Federal Regulations (CFR) Title 21, Section 184.1583.

BSE / TSE:

The active ingredient of Pancreatin Powder is processed from porcine raw materials derived from animals slaughtered in USDA inspected establishments located in the United States of America. All animals have passed both ante and post-mortem examinations by a licensed veterinarian and have been found fit for human use.

Porcine animals are not considered a "TSE-relevant species" as defined in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products" and are therefore excluded from the scope of this regulation.

We add an amount of bovine lactose to this product to standardize the potency to the required levels. The lactose is processed using bovine milk sourced from healthy bovine animals under the same conditions as milk collected for human consumption. Bovine lactose and milk products in general have never been shown to contain the BSE infectious agent. Milk and milk products (e.g. Lactose Powder) are excluded from the scope of the TSE (BSE) guidance set forth in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products".

ALLERGEN:

Per the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), the allergens of concern are: milk or milk products, egg or egg products, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybean or soy-based products (the FDA's "Big 8" allergens). No FALCPA listed allergenic materials are used in the processing of the active ingredient. Although the non-active ingredient is milk derived, the vendor/manufacturer of this diluent has indicated that the manufacturing process employed removes all measurable traces of allergenic milk proteins from their end lactose product. Therefore, following our supplier's recommendation, we will not label this, and other products formulated with this diluent with a FALCPA applicable allergen warning.

GLUTEN:

No Gluten or ingredients containing Gluten (Wheat, oats, barley, rye) are used in the manufacture of this product. This product is not tested for the presence of Gluten.

IRRADIATION / ETO:

This product is not treated with Ethylene Oxide (ETO), nor is this product irradiated.

GMO / GE:

American Laboratories does not genetically modify our products in any way, and to the best of our knowledge, none of our products contain genetically engineered ingredients.

KOSHER:

This product is not Kosher certified.

HALAL:

This product is not Halal certified.

ORGANIC:

This product is not Organic certified.

HORMONE:

Glands and tissues from animals do contain naturally occurring hormones. American Laboratories does not use any hormones in the processing of our products, nor do we test for the presence of any natural or non-natural hormones in our products.



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PRODUCT INFORMATION

DATE: November 29, 2018

PRODUCT: Pancreatin 4 X Powder (PC 512)

Generally Recognized as Safe:

Pancreatin has been affirmed as Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA), per the Code of Federal Regulations (CFR) Title 21, Section 184.1583.

BSE / TSE:

The active ingredient of Pancreatin 4 X Powder is processed from porcine raw materials derived from animals slaughtered in USDA inspected establishments located in the United States of America. All animals have passed both ante and post-mortem examinations by a licensed veterinarian and have been found fit for human use.

Porcine animals are not considered a "TSE-relevant species" as defined in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products" and are therefore excluded from the scope of this regulation.

We add an amount of bovine lactose to this product to standardize the potency to the required levels. The lactose is processed using bovine milk sourced from healthy bovine animals under the same conditions as milk collected for human consumption. Bovine lactose and milk products in general have never been shown to contain the BSE infectious agent. Milk and milk products (e.g. Lactose Powder) are excluded from the scope of the TSE (BSE) guidance set forth in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products".

ALLERGEN:

Per the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), the allergens of concern are: milk or milk products, egg or egg products, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybean or soy-based products (the FDA's "Big 8" allergens). No FALCPA listed allergenic materials are used in the processing of the active ingredient. Although the non-active ingredient is milk derived, the vendor/manufacturer of this diluent has indicated that the manufacturing process employed removes all measurable traces of allergenic milk proteins from their end lactose product. Therefore, following our supplier's recommendation, we will not label this, and other products formulated with this diluent with a FALCPA applicable allergen warning.

GLUTEN:

No Gluten or ingredients containing Gluten (Wheat, oats, barley, rye) are used in the manufacture of this product. This product is not tested for the presence of Gluten.

IRRADIATION / ETO:

This product is not treated with Ethylene Oxide (ETO), nor is this product irradiated.

GMO / GE:

American Laboratories does not genetically modify our products in any way, and to the best of our knowledge, none of our products contain genetically engineered ingredients.

KOSHER:

This product is not Kosher certified.

HALAL:

This product is not Halal certified.

ORGANIC:

This product is not Organic certified.

HORMONE:

Glands and tissues from animals do contain naturally occurring hormones. American Laboratories does not use any hormones in the processing of our products, nor do we test for the presence of any natural or non-natural hormones in our products.



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PRODUCT INFORMATION

DATE: November 29, 2018

PRODUCT: Pancreatin 8 X Powder (PC 523)

Generally Recognized as Safe:

Pancreatin has been affirmed as Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA), per the Code of Federal Regulations (CFR) Title 21, Section 184.1583.

BSE / TSE:

The active ingredient of Pancreatin 8 X Powder is processed from porcine raw materials derived from animals slaughtered in USDA inspected establishments located in the United States of America. All animals have passed both ante and post-mortem examinations by a licensed veterinarian and have been found fit for human use.

Porcine animals are not considered a "TSE-relevant species" as defined in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products" and are therefore excluded from the scope of this regulation.

We add an amount of bovine lactose to this product to standardize the potency to the required levels. The lactose is processed using bovine milk sourced from healthy bovine animals under the same conditions as milk collected for human consumption. Bovine lactose and milk products in general have never been shown to contain the BSE infectious agent. Milk and milk products (e.g. Lactose Powder) are excluded from the scope of the TSE (BSE) guidance set forth in Ph. Eur. General Chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products".

ALLERGEN:

Per the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), the allergens of concern are: milk or milk products, egg or egg products, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybean or soy-based products (the FDA's "Big 8" allergens). No FALCPA listed allergenic materials are used in the processing of the active ingredient. Although the non-active ingredient is milk derived, the vendor/manufacturer of this diluent has indicated that the manufacturing process employed removes all measurable traces of allergenic milk proteins from their end lactose product. Therefore, following our supplier's recommendation, we will not label this, and other products formulated with this diluent with a FALCPA applicable allergen warning.

GLUTEN:

No Gluten or ingredients containing Gluten (Wheat, oats, barley, rye) are used in the manufacture of this product. This product is not tested for the presence of Gluten.

IRRADIATION / ETO:

This product is not treated with Ethylene Oxide (ETO), nor is this product irradiated.

GMO / GE:

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HALAL:

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ORGANIC:

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HORMONE:

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PRODUCT INFORMATION

DATE: November 29, 2018

PRODUCT: Pancreatin 6 X Powder (PC 525)

Generally Recognized as Safe:

Pancreatin has been affirmed as Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA), per the Code of Federal Regulations (CFR) Title 21, Section 184.1583.

BSE / TSE:

The active ingredient of Pancreatin 6 X Powder is processed from porcine raw materials derived from animals slaughtered in USDA inspected establishments located in the United States of America. All animals have passed both ante and post-mortem examinations by a licensed veterinarian and have been found fit for human use.

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