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PANCREATIN (Porcine) Enteric Coated

SPECIFICATION SHEET

DESCRIPTION

Is a highly active enzyme preparation derived from the porcine pancreas gland that contains Protease, Amylase and Lipase.

PHYSICAL PROPERTIES

Light tan to cream colored enteric coated beads, soluble in water, with characteristic odor and taste.

ENZYMATIC PROPERTIES

The optimum pH for the Protease is 7.4 to 8.2, the Amylase pH is 8.0, and the Lipase pH is 7.0 to 8.0. The optimum temperature for the Protease is 40°C, the Amylase optimum temperature is 40°C and the Lipase optimum temperature is 37°C.

ACTIVITY

The activity for the Protease, Amylase and Lipase are done according to the USP methods. The acceptance criteria for all enzyme assays is: NLT 85.0% and NMT 115.0% of the declared units of enzyme activity.*

COUNTRY OF ORIGIN USA

STORAGE/SHELF LIFE/STANDARD PACK SIZE

Product is stable for two years (24 months) if stored at or below 10° C in sealed poly bags in boxes or drums away from sunlight and high humidity. Product is packed in 25 kilo fiber drums or double-wall boxes.

HANDLING PRECAUTIONS

Avoid the formation of aerosol and dust of the product. Repeated inhalation of enzyme aerosol or dust may cause allergic type reactions in sensitized individuals. For detailed information please refer to the SDS.

Description	Specification	Method
Activity: Protease	150 USP/MG	USP
Amylase	150 USP/MG	USP
Lipase	30 USP/MG	USP
Identity:	Pancreatin Enteric Coated	FTIR
Moisture:	NMT 10%	Ohaus MB-45
Metals:		
Lead	NMT 5 ppm	SW-846 6020
Microbiological Data:		
TPC	<10,000 CFU/g	Soleris / AOAC 990.12
E.coli	Negative/10g	Soleris / AOAC 991.14
Enterococcus	<100 CFU/g	AOAC 2003.01
Salmonella**	Negative/25g	BAM Ch. 5 / AOAC 2011.03
Yeast	<1,000 CFU/g	Soleris / AOAC 997.02
Mold	<1,000 CFU/g	Soleris / AOAC 997.02
Coliforms	<100 CFU/g	Soleris / AOAC 991.14

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**If Enterococcus test results exceed 100 CFU/g then Salmonella testing is completed.

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