

DEERLAND ENZYMES PRODUCT SPECIFICATIONS

Product: ProHydrolase®  Product Number: 26351B

1. Product Description

1.1. Composition:

Ingredient	Manufacturing Target	Label claim per 10 mg
ProHydrolase®	4,500 HUT	3,500 HUT

A proprietary blend of proteases from *Bacillus subtilis* and *Ananas comosus*

*Enzymes are typically standardized with corn or tapioca maltodextrin.

2. Specification tests

2.1. *Enzyme Assays*

<u>Test Parameter</u>	<u>Specification</u>	<u>Method</u>
Protease Activity	> 4,500 HUT/dose	DEP002

2.2. *Physical/Chemical*

<u>Test Parameter</u>	<u>Specification</u>	<u>Method</u>
Color	Light Brown	Visual
Odor	Fermentation	Organoleptic
Texture	Fine Powder	Organoleptic
Bulk Density	> 0.30 g/ml	DEP054
Tapped Density	> 0.60 g/ml	DEP054
Mercury	< 1 ppm	DEP053 (ICP-MS)
Cadmium	< 1 ppm	DEP053 (ICP-MS)
Lead	< 1 ppm	DEP053 (ICP-MS)
Arsenic	< 1 ppm	DEP053 (ICP-MS)
Gluten	< 20 ppm	DEP159

2.3. *Microbiological Standards*

<u>Test Parameter</u>	<u>Specification</u>	<u>Method</u>
Total Aerobic Count	< 10,000 CFU/gram	DEP028
Yeast and Mold	< 100 CFU/gram	DEP030
Coliforms	< 30 CFU/gram	DEP029
Enterobacteriaceae	< 30 CFU/gram	DEP061
E. coli	Negative	DEP059
Salmonella	Negative	DEP034
Staphylococcus aureus	Negative	DEP060

3. Country of Origin

3.1. ProHydrolase® was manufactured in the United States from imported and domestic ingredients.

4. Statement of Ingredient Weights

4.1. The ingredient list contains enzymes that are sold and consumed on an activity basis. Occasionally, the concentration of the individual enzymes used in the formula will vary. This variation will result in a change to the milligram weight and is not considered a change in formulation.

5. Recommended Usage

5.1. One dose of ProHydrolase® (10mg) per gram of protein.

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6. Allergens

6.1. Soy and wheat are used in the fermentation media.

7. Regulatory

7.1. The ingredients used in this formulation are certified by the manufacturer to be BSE/TSE free.

7.2. The microorganisms used in the production of the enzymes in this formulation are certified by the manufacturer to be non-GMO.

7.3. This product has not been treated with radiation or ethylene oxide.

7.4. The ingredients used in ProHydrolase® are considered GRAS for food and were marketed as dietary supplements prior to 1994.

8. Packaging

8.1. The blend is packaged in 15 or 30 gallon DehydroDryDrum™ (28111/28110) that are double lined with polyethylene bags (29902).

8.2. A desiccant (23112) is placed between the liners to absorb moisture.

9. Labeling

9.1. Drums contain a label with the following information:

- ♦ Deerland logo, manufacturing address, and phone number.
- ♦ Product code, product description, and the lot number.
- ♦ PO number and customer code, if available.
- ♦ Quantity
- ♦ Storage conditions
- ♦ Safety Indicators

9.2. Drums contain a 3x5" bar code label with the following information:

- ♦ Product code, description, and date of manufacture
- ♦ Quantity

10. Storage

10.1. Store in an airtight container away from light and moisture, < 25°C. Optimum storage stability is obtained at refrigeration temperatures (4° - 8°C).

11. QA Retention

11.1. 100g of powder blend stored at 25°C for 4 years.

12. Stabilities

12.1. *The shelf life for this product is 24 months from the date of manufacture. The shelf life is extrapolated from actual stability results provided by the vendors of the individual ingredients.*

13. Additional

13.1. This product must be formulated with kosher ingredients only.

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14. Revisions

<u>Date</u>	<u>Submitted By</u>	<u>Reason for Revision</u>
08/03/12	LA	New
03/22/13	LA	Added kosher
08/19/13	LD	Added heavy metal testing
10/11/13	LD	Updated section 1.1
02/14/14	LD	Added appendix A, B
03/14/14	LD	Updated trademark and appendix information
04/09/14	LS	Updated Appendix E
04/18/14	LS	Removed 28110; added 28111
07/14/14	LS	Added Tapped Density; Added Appendix F; Update matches control specs.
08/28/14	PD	Added appendix G for sample bottles spec
09/26/14	LS	Remove 28110; add 28111
11/10/14	PD	Updated GMO statement, packaging
12/05/14	PD	Updated Appendix D
07/21/15	PD	Updated allergens, remove appendices, add DEP159, P spec
09/01/15	WH	Updated to include manufacturing target; updated Testing Spec to 4,500 HUT/dose

15. Approval Signatures

Technical Review:  Date: 9.1.15

Quality Approval:  Date: 9-2-15