

NATURAL HEALTH PRODUCT

ALPHA-AMYLASE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date January 26, 2024

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
4-alpha-D-Glucan glucanohydrolase	<ul style="list-style-type: none"> • 1,4-alpha-D-Glucan glucanohydrolase • alpha-Amylase • Diastase • Fungal diastase • Taka-Diastase (Aspergillus) 	<ul style="list-style-type: none"> • <i>Aspergillus niger</i> • <i>Aspergillus flavus</i> var. <i>oryzae</i> 	Whole
		<i>Hordeum vulgare</i>	Seed
		<i>Rhizopus oryzae</i>	Whole

References: Proper name: IUBMB 2023; Common names: IUBMB 2023; Source information: CABI 2023; COL 2023; USDA 2023; FCC 8 2012.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

Digestive enzyme

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

No to exceed 150,000 FCC DU of enzymatic activity, per day; and 34,000 FCC DU per single dose (FCC 8 2012; Glade et al. 2001)

Notes

- The Quantity per dosage unit must be the enzymatic activity (FCC unit). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity.
- One alpha-amylase dextrinizing unit (DU) is defined as the quantity of alpha-amylase that will dextrinize soluble starch in the presence of an excess of beta-amylase at the rate of 1 g/h at 30° (FCC 8 2012).

Direction(s) for use

All products

Take with food/meal.

Enteric-coated products

Swallow whole/Do not crush or chew (CPS 2008).

Duration(s) of use

Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

Risk information

Caution(s) and warning(s)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes.**

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Martindale 2023).

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID. Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): ALPHA-AMYLASE ACTIVITY (NON-BACTERIAL).
- Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product label.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient in each capsule alpha-Amylase (<i>Aspergillus niger</i> – whole)	XX FCC DU (YY mg)
Uses Digestive enzyme	
Warnings	
If applicable: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame	
Ask a health care practitioner before use if: • you are pregnant or breastfeeding. • you have diabetes.	
Stop use if hypersensitivity/allergy occurs.	
Directions Adults 18 years and older: • Take X capsule(s), X times a day • Take with food/meal • Ask a health care practitioner for prolonged use. <i>Enteric-coated products</i> • Swallow whole/Do not crush or chew.	
Other information (Add storage information)	
Non-medicinal ingredients List all NMIs	
Questions? Call 1-XXX-XXX-XXXX	

References cited

COL: Catalogue of Life [Accessed 2023 September 11]. Available from: <http://www.catalogueoflife.org>

CABI 2023: Centre for Agriculture and Bioscience International. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International). [Accessed 2023 September 11]. Available from: <http://www.speciesfungorum.org>

CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008.

FCC 8 2012: Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

Glade MJ, Kendra D, Kaminski MV. Improvement in protein utilization in nursing-home patients on tube feeding supplemented with an enzyme product derived from *Aspergillus niger*

and bromelain. *Nutrition* 2001;17(4):348–350.

IUBMB 2023: IUBMB Enzyme Nomenclature. London (GB): Queen Mary, University of London. [α -amylase: CAS 9000-90-2, EC 3.2.1.1 created 1961; Accessed 2023 September 11]. Available from: <https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/1.html>

Martindale 2023: Sweetman SC, editor. *Martindale: The Complete Drug Reference*. London (GB): Pharmaceutical Press. [Amylase: syn: EC 3.2.1.1 (α -amylase), CAS 9000- 85-5 (bacterial α -amylase); 9000-90-2 (porcine α -amylase, pancreatic); Accessed 2023 September 11]. Available from: <http://www.medicinescomplete.com>

USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2023 September 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

References reviewed

Cichoke AJ. Pancreatic Enzymes. In: Pizzorno JE, Murray MT, editors. *Textbook of Natural Medicine*, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006 p. 1131- 1146.

Nature's Sources. AbsorbAid® A natural Approach...Unlike Antacids and Acid Blockers. Frequently Asked Questions. [Accessed 2012 March 28]. Available from: http://www.naturessources.com/absorbaid_faq.asp