Amylase, alpha-

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=amylase.alpha2⟨=eng

Extracted: 2025-08-26T06:30:23.659349

ALPHA-AMYLASE (PDF Version - 78 KB) 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 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 on the label. Date May 30, 2025 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 1,4-alpha-D-Glucan glucanohydrolase alpha-Amylase Diastase Fungal diastase Taka-Diastase (Aspergillus) Aspergillus niger Aspergillus flavus var. oryzae Whole Hordeum vulgare Seed Rhizopus oryzae whole References: Proper name: IUBMB 2025; Common names: IUBMB 2025; Source information: CABI 2025; COL 2025; USDA 2025; FCC 2024. 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. Note: Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when alpha-amylase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application. 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 2024; 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 30º (FCC 2024). Direction(s) for use All products Take with a meal/food. 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 (Brayfield and Cadart 2025). 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. References cited Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2025. [Accessed 2025 April 25]. Available from: https://www.medicinescomplete.com/#/browse/martindale COL 2025: Catalogue of Life [Accessed 2025 April 25]. Available from: http://www.catalogueoflife.org CABI 2025: Centre for Agriculture and Bioscience International. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International). [Accessed 2025 April 25]. 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 2024: Food Chemicals Codex. 14th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024. 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 2025: IUBMB Enzyme Nomenclature. London (GB): Queen Mary, University of London. [α-amylase: CAS 9000-90-2, EC 3.2.1.1 created 1961; Accessed 2025 April 25]. Available from: https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/1.html USDA 2025: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2025 April 25]. 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. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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

DOSAGE FORM(S)

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. Note:Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when alpha-amylase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.

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 (Brayfield and Cadart 2025).

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 CONDITION(S)

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.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
4-alpha-D-Glucan glucanohydrolase	1,4-alpha-D-Glucan glucanohydrolasealpha-AmylaseDiastaseFungal diastaseTaka-Diastase	Aspergillus nigerAspergillus flavus var. oryzae	Whole (Aspergill
Hordeum vulgare	Seed		
Rhizopus oryzae	whole		