

ORIGINAL SUBMISSION

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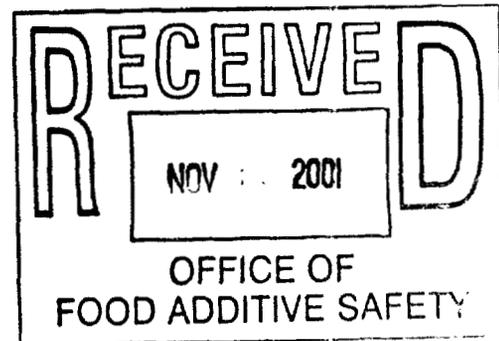


# ENZYME TECHNICAL ASSOCIATION

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November 8, 2001



Office of Premarket Approval  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

**RE: GRAS Notification – Exemption Claim for Ten Microbially-Derived Enzyme Preparations that are the Subject of a GRAS Affirmation Petition, GRASP 3G0016**

Dear Sir or Madam:

Pursuant to proposed 21C.F.R. §§ 170.36(c)(1), 170.36(g)(2), and the Food and Drug Administration ("FDA") preamble discussion concerning the submission of a Generally Recognized As Safe ("GRAS") notification based on a previously filed GRAS affirmation petition, 62 Fed. Reg. 18938, 18953-18954 (April 17, 1997), the Enzyme Technical Association is hereby providing FDA with notice that it has determined, based on history of use, that ten microbially-derived enzyme preparations -- *Aspergillus niger* (carbohydrase, catalase, glucose oxidase, pectinase, protease), *Aspergillus oryzae* (carbohydrase, protease), *Kluyveromyces marxianus* (lactase), *Rhizopus oryzae* (carbohydrase), and *Saccharomyces cerevisiae* (invertase) -- as direct human food ingredients, are GRAS and therefore are exempt from statutory premarket approval requirements. These ten enzymes are also the subjects of a GRAS Affirmation Petition 3G0016 submitted by the Ad Hoc Enzyme Technical Committee (now known as the Enzyme Technical Association ("ETA")) to the FDA.

The following information is provided in accordance with the proposed regulation.

Proposed § 170.36(g)(2)(i): Name and address of the notifier.

Enzyme Technical Association  
1800 Massachusetts Avenue, N.W.  
Second Floor  
Washington, DC 20036

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Proposed § 170.36(g)(2)(ii): The applicable GRAS affirmation petition number.

A GRAS Affirmation Petition for animal-derived, plant-derived, and microbially-derived enzyme preparations was originally submitted by the Ad Hoc Enzyme Technical Committee (now known as ETA) and assigned a petition number, GRASP 3G0016. The FDA filed GRASP 3G0016 on April 12, 1973 (38 Fed. Reg. 9256). The petition was amended on June 12, 1973 (38 Fed. Reg. 15471), August 29, 1984 (49 Fed. Reg. 34305), and June 23, 1987 (52 Fed. Reg. 23607) to include other plant-derived and microbially-derived enzyme preparations. This notification addresses only the ten microbial enzyme preparations named above for which FDA action is pending.

Proposed § 170.36(g)(2)(iii): The common or usual name of the substance (i.e., the notified substance).

Listed below are the common or usual names for the substances for the ten microbial enzyme preparations for which the GRAS affirmation petition was submitted and this notification is made.

NAME OF ENZYME PREPARATION	MICROBIAL SOURCE
Carbohydrase	<i>Aspergillus niger</i>
Carbohydrase	<i>Aspergillus oryzae</i>
Carbohydrase	<i>Rhizopus oryzae</i>
Catalase	<i>Aspergillus niger</i>
Glucose Oxidase	<i>Aspergillus niger</i>
Invertase	<i>Saccharomyces cerevisiae</i>
Lactase	<i>Kluyveromyces marxianus</i>
Pectinase	<i>Aspergillus niger</i>
Protease	<i>Aspergillus niger</i>
Protease	<i>Aspergillus oryzae</i>

Proposed § 170.36(g)(2)(iv): Applicable conditions of use.

As discussed in greater detail in GRASP 3G0016 as amended, the ten microbial enzyme preparations are direct human food ingredients. The uses of the enzyme preparations are for multiple technical effects:

The enzyme preparations are GRAS for use in food at levels not to exceed Good Manufacturing Practices ("GMPs").

The data and information to support the above uses are contained in GRASP 3G0016, as amended.

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Proposed § 170.36(g)(2)(v): Basis for GRAS determination.

The basis for this GRAS determination is through experience based on common use in food.

Proposed § 170.36(g)(2)(vi): Availability of information.

The complete record that supports the GRAS determination has been submitted to the agency in the above referenced GRASP 3G0016, as amended. The complete file is at FDA.

Sincerely,

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Jack Harris, Chair  
Enzyme Technical Association

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SUBMISSION END

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