Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for Lipase

Name of the ingredient

Lipase (ABN)

Definition of the ingredient

Lipase (triacylglycerol acylhydrolase) is an enzyme derived from the fungus, *Rhizopus arrhizus* (formally known as *Rhizopus oryzae)*, via a fermentation process. During the recovery phase of production, manufacturers destroy *Rhizopus arrhizus* before removing the non- proteinaceous material away from lipase. Lipase recovered from the fermentation broth is usually present in an aqueous solution or processed to a dried state.

CAS No.: 9001-62-1

EC No.: 3.1.1.3

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Liquid or powder
Identification		
Lipase activity	FCC	Complies
Assay		
Lipase activity	FCC	No less than 85.0% and no more than 115.0% of the declared activity expressed as LipU*
Notes: *LipU = LU = lipase unit		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Heavy metals (as lead)	FCC	No more than 30 ppm
Lead	FCC	No more than 5 ppm
Other organic or inorganic impurities or toxins		
Mycotoxins and aflatoxins	FCC, AOAC	Not detected
Antibiotic activity	JECFA	Not detected
Microbiology		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 100 *'Microbiological Standards for Medicines'* mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 11 of the Order.		

Key to abbreviations:

AOAC = Association of Analytical Communities Official Methods of Analysis 16th Ed. AOAC

FCC = Food Chemicals Codex

JECFA = Joint FAO/ WHO Expert Committee on Food Additives in FAO Food and Nutrition Paper No.52 (Addendum 9)

ppm = Parts per million