



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Calibrator

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Liquid N-geneous™ Lipase Calibrator

Product Number: 80-5627-00; 80-6680-00; 80-6691-00

Synonym(s): Lipase Calibrator

Product Use: For use in the calibration of the Liquid N-geneous™ Lipase assay. For In Vitro Diagnostic Use Only.

Description: Lyophilized powder preparation containing bovine serum albumin, enzyme (protein), carbohydrate, and trace amount of stabilizer and preservative.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF

UK

Phone: 44 (0) 1732 220022

Manufacturer/Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. The bovine serum albumin (BSA) in this product is of US origin and meets the current standards for reduction of TSE (Transmissible Spongiform Encephalopathy) risk. The lipase in this preparation is derived from human pancreas. The donors have been tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions. Preparation appearance: white powder.

Routes of Exposure:

Occupational exposure routes may include inhalation, eye and skin contact.

Potential Health Effects:

Inhalation

No data available. Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.

Eye

No data available.

Skin

No data available.



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Potential Health Effects:

Ingestion No data available.
Chronic Effects No data available.
Target Organs Unknown.

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Bovine serum albumin, fraction V	9048-46-8	232-936-2	50 - 52
EC R-Phrases: None	EC Hazard Class: None		
Sucrose	57-50-1	200-334-9	40 - 45
EC R-Phrases: None	EC Hazard Class: None		
Lipase	9001-62-1	232-619-9	< 1
EC R-Phrases: None	EC Hazard Class: None		

NOTE - Lipase - Enzyme source: Human pancreas, Enzyme Commission number: 3.1.1.3

4. FIRST AID MEASURES

General Advice:

In the event of occupational exposure, follow company-specific bloodborne pathogen post-exposure requirements.

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Material may burn when exposed to sufficient heat.



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Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

Irritating or highly toxic gases may be generated by combustion, including carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x) and sulfur oxides (SO_x).

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid generating or inhaling dust. Wash hands thoroughly after handling.

Environmental Precautions:

No information available.

Methods and Materials for Containment and Clean-Up:

Decontaminate the spill site following standard procedures for biohazardous spills. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow universal/standard precautions when preparing or handling this material. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2-8°C (35-46°F). Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

ACGIH - Threshold Limits Values - Time Weighted Averages (TLV-TWA)

Sucrose 57-50-1 10 mg/m³ TWA

Australia - Occupational Exposure Standards - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

Canada - Quebec - Occupational Exposure Limits - TWAEVs

Sucrose 57-50-1 10 mg/m³ TWAEV

Korea - Occupational Exposure Limits - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs)

Sucrose 57-50-1 15 mg/m³ TWA (total dust); 5 mg/m³ TWA (respirable fraction)

Engineering Controls:

Preparation and handling of this preparation should be performed in accordance with universal/standard precautions. Use local exhaust ventilation. Facilities storing or using this preparation should be equipped with an eyewash fountain.



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Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective safety eye glasses or goggles.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White powder	pH:	7.0 - 7.1 at 25°C (prior to lyophilizing)
Odor:	Unknown	Solubility:	Water-soluble
Specific Gravity:	Not available	Vapor Pressure:	Not applicable
Boiling Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not available	Vapor Density:	Not applicable
Freezing Point:	Not applicable		
Flammability/Explosivity Limits in Air, Lower:	Not applicable		
Flammability/Explosivity Limits in Air, Upper:	Not applicable		
Auto-Ignition Temperature:	Not available		
Flash Point:	Not applicable		

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

The human source material in this preparation presents a risk for exposure to infectious agents.

Local Effects:

No data available.

Chronic Effects:

No data available.



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Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Remaining unused material and product waste should be treated as biohazardous/infectious waste and contaminated instruments and surfaces should be disinfected in accordance with your employer's universal/standard precautions.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

Bovine serum albumin, fraction V	9048-46-8	XU
Lipase	9001-62-1	XU
Sucrose	57-50-1	Present



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International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

Sucrose	57-50-1	Uncontrolled product according to WHMIS classification criteria
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Bovine serum albumin, fraction V	9048-46-8	Present
Lipase	9001-62-1	Present
Sucrose	57-50-1	Present

Inventory - Canada - Domestic Substances List (DSL)

Bovine serum albumin, fraction V	9048-46-8	Present
Sucrose	57-50-1	Present

Inventory - Canada - Organisms on the Domestic Substances List (DSL)

Lipase	9001-62-1	IUB #3.1.1.3
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Inventory - China

Bovine serum albumin, fraction V	9048-46-8	Present
Lipase	9001-62-1	Present
Sucrose	57-50-1	Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Bovine serum albumin, fraction V	9048-46-8	232-936-2
Lipase	9001-62-1	232-619-9
Sucrose	57-50-1	200-334-9

Inventory - Korea - Existing and Evaluated Chemical Substances

Bovine serum albumin, fraction V	9048-46-8	KE-05-0011
Lipase	9001-62-1	KE-22541
Sucrose	57-50-1	KE-17258

Canadian Hazardous Products:

WHMIS Status	Exempt
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European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).



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Disclaimer:

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