MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lipase Color Reagent

Product Number: 80-2005-01; 80-2005-02; 80-5403-00

Kit Number: 905-B; 905-C; 905-D; 905-E

Synonym(s): Lip R1A; Lipase Reagent 1A; Lip Reagent 1A

Product Use: Component of Lipase Color kit. For use in the quantitative determination of pancreatic lipase in serum or plasma. For In Vitro Diagnostic Use Only.

Description: Powder preparation containing carbohydrate, enzymes and albumin (proteins), surfactant, buffers and salts.

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

Distributor

Genzyme Diagnostics
115 Summit Drive
Exton, PA 19341
USA
Phone: 800-999-6578

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555
CHEMTREC (U.S.): 800-424-9300
CHEMTREC (Outside U.S.): +1 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! 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 human serum albumin in this preparation was 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: off-white to pale yellow 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.

Potential Health Effects:

Skin	No data available.
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. CHIPS 2009 No. 716; 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)
Sucrose	57-50-1	200-334-9	< 75
EC R-Phrases: None	**EC Hazard Class:** None		
Albumin from human serum	70024-90-7	274-272-6	5 - 8
EC R-Phrases: None	**EC Hazard Class:** None		
Trade Secret Ingredient	Trade Secret	Trade Secret	2 - 4
EC R-Phrases: R20/21/22, R38, R41, R52	**EC Hazard Class:** Xn		
Glycerol phosphate oxidase	9046-28-0	232-932-0	1 - 4
EC R-Phrases: None	**EC Hazard Class:** None		
N-ethyl-N-sulfohydroxypropyl-M-toluidine sodium salt (TOOS)	82692-93-1	Not Assigned	1 - 3
EC R-Phrases: None	**EC Hazard Class:** None		
1,2-Diglyceride protein cofactor (PCDG)	Not Assigned	Not Assigned	1 - 3
EC R-Phrases: None	**EC Hazard Class:** None		
Adenosine 5'-triphosphate disodium salt	987-65-5	213-579-1	< 1
EC R-Phrases: None	**EC Hazard Class:** None		
Monoglyceride lipase	9040-75-9	Not Assigned	< 1
EC R-Phrases: None	**EC Hazard Class:** None		
Glycerol kinase	9030-66-4	232-862-0	< 1
EC R-Phrases: None	**EC Hazard Class:** None		
Ascorbate oxidase	9029-44-1	232-852-6	< 1
EC R-Phrases: None	**EC Hazard Class:** None		
Peroxidase	9003-99-0	232-668-6	< 0.1
EC R-Phrases: None	**EC Hazard Class:** None		

NOTE - Ascorbate oxidase - Enzyme source: Cucumber, Enzyme Commission number: 3.3.1
NOTE - Glycerol kinase - Enzyme source: Streptomyces canus, Enzyme Commission number: 2.7.1.30
NOTE - Glycerol phoshate oxidase - Enzyme source: Streptococcus sp., Enzyme Commission number: 1.1.3.21
NOTE - Monoglyceride lipase - Enzyme source: Bacillus sp., Enzyme Commission number: 3.1.1.23
NOTE - Peroxidase - Enzyme source: Horseradish, Enzyme Commission number: 1.11.1.7

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.

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 (NOx) and sulfur oxides (SOx).

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
Israel - Occupational Exposure Limits - TWAs		
Sucrose	57-50-1	10 mg/m3 TWA
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.

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:	Off-white to pale yellow powder	**pH:**	Not applicable
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		
Freezing Point:	Not applicable	**Vapor Density:**	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 serum in this preparation presents a risk for exposure to infectious agents.

Toxicology Data - Selected LD50s and LC50s

Adenosine 5'-triphosphate disodium salt	987-65-5	Oral LD50 Rat: >2 g/kg
Sucrose	57-50-1	Oral LD50 Rat: 29700 mg/kg
Trade Secret Ingredient	Trade Secret	Oral LD50 Rat: >1000 mg/kg; Dermal LD50 Rabbit: >1.9 mL/kg

Chronic Effects:

No data available.

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.

Persistance 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)

Adenosine 5'-triphosphate disodium salt	987-65-5	Present
Albumin from human serum	70024-90-7	Present
Glycerol kinase	9030-66-4	XU
Peroxidase	9003-99-0	XU
Sucrose	57-50-1	Present
Trade Secret Ingredient	Trade Secret	XU

U.S. - TSCA (Toxic Substances Control Act) - Section 8(a) - PAIR - Reporting List

Trade Secret Ingredient	Trade Secret	Effective 2/10/00, Reporting 4/10/00

U.S. - TSCA (Toxic Substances Control Act) - Section 8(d) - 716.120(d) - Health and Safety Reporting

Trade Secret Ingredient	Trade Secret	(Only those chemical substances specifically listed within this category are subject to all provisions of part 716 for the time period from the effective date of the rule until the sunset date.)

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
Trade Secret Ingredient	Trade Secret	D2B
Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes		
Trade Secret Ingredient	Trade Secret	hazard class 2 - hazard to waters
Inventory - Australia - Inventory of Chemical Substances (AICS)		
Adenosine 5'-triphosphate disodium salt	987-65-5	Present
Albumin from human serum	70024-90-7	Present
Glycerol kinase	9030-66-4	Present
Glycerol phosphate oxidase	9046-28-0	Present
Peroxidase	9003-99-0	Present
Sucrose	57-50-1	Present
Trade Secret Ingredient	Trade Secret	Present
Inventory - Canada - Domestic Substances List (DSL)		
Adenosine 5'-triphosphate disodium salt	987-65-5	Present
Albumin from human serum	70024-90-7	Present
Ascorbate oxidase	9029-44-1	Present
N-ethyl-N-sulfohydroxypropyl-M-toluidine sodium salt (TOOS)	82692-93-1	Present
Peroxidase	9003-99-0	Present
Sucrose	57-50-1	Present
Trade Secret Ingredient	Trade Secret	Present
Inventory - Canada - Organisms on the Domestic Substances List (DSL)		
Glycerol kinase	9030-66-4	IUB #2.7.1.30
Glycerol phosphate oxidase	9046-28-0	IUB #1.1.3.21
Inventory - Canada - Organisms on the Non-Domestic Substances List (NDSL)		
Peroxidase	9003-99-0	IUB #1.11.1.7
Inventory - China		
Adenosine 5'-triphosphate disodium salt	987-65-5	Present
Albumin from human serum	70024-90-7	Present
Glycerol kinase	9030-66-4	Present
Glycerol phosphate oxidase	9046-28-0	Present
Peroxidase	9003-99-0	Present
Sucrose	57-50-1	Present
Trade Secret Ingredient	Trade Secret	Present
Inventory - EU List of Notified Chemical Substances (ELINCS)		
N-ethyl-N-sulfohydroxypropyl-M-toluidine sodium salt (TOOS)	82692-93-1	EEC No. 420-430-6
Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)		
Adenosine 5'-triphosphate disodium salt	987-65-5	213-579-1
Albumin from human serum	70024-90-7	274-272-6
Ascorbate oxidase	9029-44-1	232-852-6
Glycerol kinase	9030-66-4	232-862-0
Glycerol phosphate oxidase	9046-28-0	232-932-0
Peroxidase	9003-99-0	232-668-6
Sucrose	57-50-1	200-334-9
Inventory - Japan Existing and New Chemical Substances (ENCS)		
Adenosine 5'-triphosphate disodium salt	987-65-5	9-48
Trade Secret Ingredient	Trade Secret	Present
Inventory - Korea - Existing and Evaluated Chemical Substances		
Adenosine 5'-triphosphate disodium salt	987-65-5	KE-00238
Ascorbate oxidase	9029-44-1	KE-01946
Glycerol kinase	9030-66-4	KE-21797

Inventory - Korea - Existing and Evaluated Chemical Substances

Glycerol phosphate oxidase	9046-28-0	KE-18027
Peroxidase	9003-99-0	KE-28159
Sucrose	57-50-1	KE-17258
Trade Secret Ingredient	Trade Secret	Present

Canadian Hazardous Products:

WHMIS Status Exempt

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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