



MATERIAL SAFETY DATA SHEET

Lipase Color Calibrator

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lipase Color Calibrator

Product Number: 80-2002-01; 80-2002-02; 80-5627-00 ; 80-5672-00

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

Synonym(s): Lipase Calibrator; Lip Cal; Lipase Cal

Product Use: Component in some Lipase Color kits. For use in the calibration of the Lipase Color 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

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:

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.



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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)
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.



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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 (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)



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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:	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.



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Local Effects:

No data available.

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.

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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Lipase Color Calibrator

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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MSDS Origination Date: March 16, 2006

Version #: 5

Revision Date: June 30, 2009

Disclaimer:

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MATERIAL SAFETY DATA SHEET

Lipase Color Activator

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lipase Color Activator

Product Number: 80-2004-01; 80-2004-04; 80-2004-06; 80-6168-00; 80-6169-00

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

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: Aqueous solution containing buffers 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

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. May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation.
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.



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Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	92 - 95
EC R-Phrases: None	EC Hazard Class: None		
Deoxycholic acid	83-44-3	201-478-5	1 - 3
EC R-Phrases: None	EC Hazard Class: None		
4-Aminoantipyrine	83-07-8	201-452-3	< 1
EC R-Phrases: R22	EC Hazard Class: Xn		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

4. FIRST AID MEASURES

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:

Dilute aqueous solution not considered a fire hazard.

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:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

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



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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate ventilation. Avoid physical contact with material and avoid aerosol inhalation. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. 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 - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m³ Peak (inhalable fraction)

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m³ MAK (inhalable fraction)

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m³ TWA (exposure factor 2)

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

Engineering Controls:

This preparation is not expected to require special ventilation measures. 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.



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Personal Protective Equipment (PPE):

Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, yellow liquid	pH:	8.5 - 8.9
Odor:	Unknown	Solubility:	Water-soluble
Specific Gravity:	1.04	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not applicable	Vapor Density:	Not available
Freezing Point:	Not available		
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		

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:

Physical Properties - Chemical Incompatibilities

Sodium azide	26628-22-8	Incompatible with acids, with some metals. Forms explosion-sensitive compounds.
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Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

4-Aminoantipyrine	83-07-8	Oral LD50 Rat: 1700 mg/kg
Deoxycholic acid	83-44-3	Oral LD50 Rat: 1 g/kg
Sodium azide	26628-22-8	Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

Local Effects:

No data available.

Chronic Effects:

No data available.



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Carcinogenicity:**ACGIH - Threshold Limits Values - Carcinogens**

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Fish Species Data**

Sodium azide 26628-22-8 96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide 26628-22-8 Ignitable; Reactive

U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide 26628-22-8 waste number P105

14. TRANSPORT INFORMATION

Basic Shipping Description:

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



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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)

4-Aminoantipyrine	83-07-8	Present
Deoxycholic acid	83-44-3	Present
Sodium azide	26628-22-8	Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide	26628-22-8	1000 lb EPCRA RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide	26628-22-8	500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)
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U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide	26628-22-8	1.0 % de minimis concentration
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US State Regulations:

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide	26628-22-8	Present
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MATERIAL SAFETY DATA SHEET

Lipase Color Activator

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

4-Aminoantipyrine	83-07-8	Uncontrolled product according to WHMIS classification criteria
Sodium azide	26628-22-8	D1A

Canada - WHMIS - Ingredient Disclosure List

Sodium azide	26628-22-8	1 %
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide	26628-22-8	T+;R28 R32 N;R50-53
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide	26628-22-8	S:1/2-28-45-60-61
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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide	26628-22-8	ID Number 636, hazard class 2 - hazard to waters
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Inventory - Australia - Inventory of Chemical Substances (AICS)

4-Aminoantipyrine	83-07-8	Present
Deoxycholic acid	83-44-3	Present
Sodium azide	26628-22-8	Present

Inventory - Canada - Domestic Substances List (DSL)

4-Aminoantipyrine	83-07-8	Present
Deoxycholic acid	83-44-3	Present
Sodium azide	26628-22-8	Present

Inventory - China

4-Aminoantipyrine	83-07-8	Present
Deoxycholic acid	83-44-3	Present
Sodium azide	26628-22-8	Present

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

4-Aminoantipyrine	83-07-8	201-452-3
Deoxycholic acid	83-44-3	201-478-5
Sodium azide	26628-22-8	247-852-1

Inventory - Japan Existing and New Chemical Substances (ENCS)

4-Aminoantipyrine	83-07-8	9-62
Deoxycholic acid	83-44-3	9-826
Sodium azide	26628-22-8	1-482

Inventory - Korea - Existing and Evaluated Chemical Substances

4-Aminoantipyrine	83-07-8	KE-01297
Sodium azide	26628-22-8	KE-31357

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).



MATERIAL SAFETY DATA SHEET

Lipase Color Activator

MSDS Origination Date: March 16, 2006

Version #: 4

Revision Date: July 01, 2009

Disclaimer:

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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.



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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 phosphate 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



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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 (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.



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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	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		



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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.)



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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
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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
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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
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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



MATERIAL SAFETY DATA SHEET

Lipase Color Reagent

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).

MSDS Origination Date: September 15, 2005

Version #: 4

Revision Date: July 01, 2009

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MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lipase Color Solvent

Product Number: 80-2003-00; 80-2003-01; 80-2003-04; 80-2003-06; 80-6170-00; 80-6171-00

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

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: Aqueous solution containing cholic acid, trace amounts of salts, preservative and surfactant.

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
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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. May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation.
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.



MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

Potential Environmental Effects:

No data available.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	> 98
EC R-Phrases: None	EC Hazard Class: None		
Cholic acid, free acid	81-25-4	201-337-8	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

4. FIRST AID MEASURES

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:

Dilute aqueous solution not considered a fire hazard.

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:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

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



MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate ventilation. Avoid physical contact with material and avoid aerosol inhalation. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. 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 - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m³ Peak (inhalable fraction)

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m³ MAK (inhalable fraction)

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m³ TWA (exposure factor 2)

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

Engineering Controls:

This preparation is not expected to require special ventilation measures. 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.



MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

Personal Protective Equipment (PPE):

Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	6.6 - 7.0
Odor:	Unknown	Solubility:	Water-soluble
Specific Gravity:	1.04	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not applicable	Vapor Density:	Not available
Freezing Point:	Not available		
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		

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:

Physical Properties - Chemical Incompatibilities

Sodium azide	26628-22-8	Incompatible with acids, with some metals. Forms explosion-sensitive compounds.
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Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

Cholic acid, free acid	81-25-4	Oral LD50 Mouse: 4950 mg/kg
Sodium azide	26628-22-8	Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

Chronic Effects:

No data available.

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

Sodium azide	26628-22-8	A4 - Not Classifiable as a Human Carcinogen
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Mutagenicity:

No data available.



MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Fish Species Data**

Sodium azide	26628-22-8	96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide	26628-22-8	Ignitable; Reactive
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U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide	26628-22-8	waste number P105
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14. TRANSPORT INFORMATION

Basic Shipping Description:

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



MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

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)

Cholic acid, free acid	81-25-4	Present
Sodium azide	26628-22-8	Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide	26628-22-8	1000 lb EPCRA RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide	26628-22-8	500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)
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U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide	26628-22-8	1.0 % de minimis concentration
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US State Regulations:

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide	26628-22-8	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

Sodium azide	26628-22-8	D1A
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Canada - WHMIS - Ingredient Disclosure List

Sodium azide	26628-22-8	1 %
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide	26628-22-8	T+;R28 R32 N;R50-53
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide	26628-22-8	S:1/2-28-45-60-61
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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide	26628-22-8	ID Number 636, hazard class 2 - hazard to waters
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Cholic acid, free acid	81-25-4	Present
Sodium azide	26628-22-8	Present

Inventory - Canada - Domestic Substances List (DSL)

Cholic acid, free acid	81-25-4	Present
Sodium azide	26628-22-8	Present

Inventory - China

Cholic acid, free acid	81-25-4	Present
Sodium azide	26628-22-8	Present

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

Cholic acid, free acid	81-25-4	201-337-8
Sodium azide	26628-22-8	247-852-1

Inventory - Japan Existing and New Chemical Substances (ENCS)

Cholic acid, free acid	81-25-4	4-787
Sodium azide	26628-22-8	1-482

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide	26628-22-8	KE-31357
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Canadian Hazardous Products:

WHMIS Status	Exempt
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MATERIAL SAFETY DATA SHEET

Lipase Color Solvent

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).

MSDS Origination Date: March 16, 2006

Version #: 4

Revision Date: June 30, 2009

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