



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
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, 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.



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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.



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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, 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.



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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)

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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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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