

IMPORTANT NOTICE CONCERNING MATERIAL SAFETY DATA SHEET/SAFETY DATA SHEET INFORMATION

Dear Valued Customer,

Sekisui Diagnostics (formerly Genzyme Diagnostics) is working to update all existing documentation in light of the change to our company name and corporate ownership. This includes the (Material) Safety Data Sheets ((M)SDSs) provided with our products.

The following contact information relative to (M)SDSs has changed effective immediately:

Corporate Headquarters:

Sekisui Diagnostics, LLC
31 New York Avenue
Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Manufacturer:

Sekisui Diagnostics, LLC
31 New York Avenue
Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Emergency Telephone Numbers:

Americas: 1-760-476-3962
Europe, Middle East & Africa: +1-760-476-3961
Asia Pacific: +1-760-476-3960
Access Code: 333512

Please feel free to use the information provided above to contact us with any questions pertaining to (M)SDSs.



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Liquid N-geneous™ Lipase Reagent 1

Product Number: 80-6668-00; 80-6687-00 ; 80-6689-00; 80-6692-00; 80-6700-00; 90-6706-140

Synonym(s): Lipase Buffer

Product Use: Component of Liquid N-geneous™ Lipase Reagent kit. For the quantitative measurement of lipase activity in serum and plasma. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing buffer, preservative, and detergent.

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

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:

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, slightly 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. 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.



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	85 - 90
EC R-Phrases: None	EC Hazard Class: None		
TAPS free acid	29915-38-6	249-954-1	5 - 10
EC R-Phrases: None	EC Hazard Class: None		
Sodium deoxycholate	302-95-4	206-132-7	1 - 3
EC R-Phrases: None	EC Hazard Class: None		
Proprietary non-ionic detergent	Trade Secret	Trade Secret	< 1
EC R-Phrases: R22, R38, R41, R52	EC Hazard Class: Xn, N		
Sodium hydroxide	1310-73-2	215-185-5	< 0.6
EC R-Phrases: R35	EC Hazard Class: C		
Sodium azide	26628-22-8	247-852-1	0.05
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Calcium acetate	62-54-4	200-540-9	< 0.01
EC R-Phrases: None	EC Hazard Class: None		

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.



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

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.

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:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, slightly yellow liquid	pH:	8.15 - 8.35 @ 25°C
Odor:	Unknown	Solubility:	Water-soluble
Specific Gravity:	Not available	Vapor Pressure:	Not available



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

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:

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:**Toxicology Data - Selected LD50s and LC50s**

Sodium deoxycholate 302-95-4 Oral LD50 Rat: 1370 mg/kg

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



MATERIAL SAFETY DATA SHEET
Liquid N-geneous™ Lipase Reagent 1

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:

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.

14. TRANSPORT INFORMATION

Basic Shipping Description:

International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316

Proper Shipping Name: Chemical Kit

Hazard Class: 9

Hazard Label: Miscellaneous

Packing Group: PG II

Excepted Quantity

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)

Sodium deoxycholate	302-95-4	Present
TAPS free acid	29915-38-6	Present



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

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 deoxycholate	302-95-4	Uncontrolled product according to WHMIS classification criteria
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium deoxycholate	302-95-4	Present
TAPS free acid	29915-38-6	Present

Inventory - Canada - Domestic Substances List (DSL)

Sodium deoxycholate	302-95-4	Present
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Inventory - Canada - Non-Domestic Substances List (NDSL)

TAPS free acid	29915-38-6	Present
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Inventory - China

Sodium deoxycholate	302-95-4	Present
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Inventory - EU List of Notified Chemical Substances (ELINCS)

TAPS free acid	29915-38-6	EEC No. 445-030-9
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium deoxycholate	302-95-4	206-132-7
TAPS free acid	29915-38-6	249-954-1

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium deoxycholate	302-95-4	KE-10812
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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.

MSDS Origination Date: March 31, 2005

Version #: 3

Revision Date: October 28, 2008



MATERIAL SAFETY DATA SHEET

Liquid N-geneous™ Lipase Reagent 1

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.