SEKISUI

8/5/2011

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 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Liquid N-geneous™ Lipase Reagent 2

Product Number: 80-6669-00; 80-6688-00; 80-6690-00; 80-6693-00; 80-6701-00; 90-6706-141

Synonym(s): Lipase Substrate

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 buffers, co-enzyme, substrate, detergent, stabilizer, and solvent.

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:

WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May be irritating to the skin or respiratory system. May be severely irritating to the eyes. Combustible liquid and vapor. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: slightly turbid, orange liquid.

Routes of Exposure:

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

Potential Health Effects:

Inhalation	Prolonged vapor inhalation may cause drowsiness, dizziness, headache and irritation of the nasal passages and throat.
Eye	Eye contact or vapor may cause severe irritation, redness, watering, stinging, pain and blurred vision.
Skin	Skin contact may cause irritation, dryness, rash and burning sensation. Skin contact with significant chemical absorption may result in symptoms similar to those specified for inhalation and ingestion.
Ingestion	Ingestion may cause nausea, vomiting, diarrhea, cramps, drowsiness and sore throat.
Chronic Effects	Prolonged or repeated skin contact may cause dermatitis.
Target Organs	Central nervous system, eyes and skin.

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.

According to ACGIH, propanol is a confirmed animal carcinogen with unknown relevance to humans.

Potential Environmental Effects:

No data available.

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		
n-Propanol	71-23-8	200-746-9	10
EC R-Phrases: R11, R41, R67	**EC Hazard Class:** Xi, F		
Tartaric acid	87-69-4	201-766-0	< 2
EC R-Phrases: None	**EC Hazard Class:** None		
Colipase (pancreatic lipase cofactor)	55126-92-6	259-490-1	0.1 - 5
EC R-Phrases: None	**EC Hazard Class:** None		
Stabilizer	Trade Secret	Trade Secret	1
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	< 0.1
EC R-Phrases: R35	**EC Hazard Class:** C		
1,2-o-Dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester	Not Assigned	Not Assigned	< 0.1
EC R-Phrases: None	**EC Hazard Class:** None		
Proprietary preservative	Mixture	Mixture	< 0.1
EC R-Phrases: R10, R20/21/22, R34, R43, R50/53	**EC Hazard Class:** C, N		

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek immediate 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 immediate medical attention.

Skin Contact:

In case of contact, immediately 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 and seek immediate medical attention. If vomiting occurs, lean sitting person forward, if lying down, roll them onto their left side (head-down position if possible), to maintain an airway and prevent aspiration.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Combustible liquid and vapor.

Suitable Extinguishing Media:

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) and carbon dioxide (CO2).

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:

No information available.

Methods and Materials for Containment and Clean-Up:

Ventilate area. Eliminate sources of ignition. Absorb spill with inert sorbent. The use of a commercial, solvent spill absorbant product that contains activated carbon is recommended. These absorbants help to reduce vapors and decrease flammability by increasing the flash point. Use clean non-sparking tools to collect absorbed material. 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). Keep containers tightly closed in a dry, cool and well-ventilated place. 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)		
n-Propanol	71-23-8	100 ppm TWA
Australia - Occupational Exposure Standards - STELs		
n-Propanol	71-23-8	250 ppm STEL; 614 mg/m3 STEL
Australia - Occupational Exposure Standards - TWAs		
n-Propanol	71-23-8	200 ppm TWA; 492 mg/m3 TWA
Canada - Quebec - Occupational Exposure Limits - STEVs		
n-Propanol	71-23-8	250 ppm STEV; 614 mg/m3 STEV
Canada - Quebec - Occupational Exposure Limits - TWAEVs		
n-Propanol	71-23-8	200 ppm TWAEV; 492 mg/m3 TWAEV
China - Occupational Exposure Limits - Permissible Concentration-Short Term (PC-STEL)		
n-Propanol	71-23-8	300 mg/m3 STEL
China - Occupational Exposure Limits - Permissible Concentration-Time Weighted Average (PC-TWA)		
n-Propanol	71-23-8	200 mg/m3 TWA
Korea - Occupational Exposure Limits - STELs		
n-Propanol	71-23-8	250 ppm STEL; 625 mg/m3 STEL
Korea - Occupational Exposure Limits - TWAs		
n-Propanol	71-23-8	200 ppm TWA; 500 mg/m3 TWA
U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs)		
n-Propanol	71-23-8	200 ppm TWA; 500 mg/m3 TWA

Engineering Controls:

Use local exhaust ventilation. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits may be exceeded (if applicable), engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant respirator use. In such cases an air purifying respirator equipped with organic vapor cartridges selected to provide a filtration efficiency appropriate to your workplace is recommended.
Eye/Face	Wear appropriate protective chemical safety 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:	Slightly turbid orange liquid	**pH:**	5.4 - 5.6 @ 25°C
Odor:	Mild alcohol odor	**Solubility:**	Water-miscible
Specific Gravity:	Not available	**Vapor Pressure:**	Not available
Boiling Point:	Not available	**Partition Coefficient (n-octanol/water):**	Not available
Melting Point:	Not applicable		
Freezing Point:	Not available	**Vapor Density:**	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: 23 °C (73.4 °F) 74°F [n-Propanol]

10. STABILITY AND REACTIVITY

Chemical Stability:

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

Conditions to Avoid:

Avoid heat, flames, sparks and ignition sources.

Incompatible Materials:

Avoid strong oxidizing agents.

Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

n-Propanol	71-23-8	Inhalation LC50 Rat: >9.8 mg/L/4H; Oral LD50 Rat: 1870 mg/kg; Dermal LD50 Rabbit: 4049 mg/kg

Irritation:

Skin Open Draize Test, Rabbit, mild, 580 mg/24 hr (n-Propanol)
Eye Standard Draize Test, Rabbit, severe, 4 mg (n-Propanol)

Chronic Effects:

Prolonged or repeated skin contact may cause dermatitis.

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

n-Propanol	71-23-8	A4- Not Classifiable as a Human Carcinogen

Canada - Manitoba - Occupational Exposure Limits - Carcinogens

n-Propanol	71-23-8	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

n-Propanol	71-23-8	96 Hr LC50 Pimephales promelas: 4480 mg/L [flow-through]

Ecotoxicity - Microtox Data

n-Propanol	71-23-8	5 min EC50 Photobacterium phosphoreum: 17700 mg/L; 15 min EC50 Photobacterium phosphoreum: 8686 mg/L; 12 Hr EC50 Nitrosomonas: 980 mg/L; 5 Hr EC50 Escherichia coli: 45000 mg/L

Ecotoxicity - Water Flea Data

n-Propanol	71-23-8	48 Hr EC50 Daphnia magna: 3642 mg/L

Persistance and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

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

n-Propanol	71-23-8	Toxic; Ignitable

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)

n-Propanol	71-23-8	Present
Tartaric acid	87-69-4	Present

US State Regulations:

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

n-Propanol	71-23-8	Present

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		
n-Propanol	71-23-8	B2, D2B
Tartaric acid	87-69-4	E
Canada - WHMIS - Ingredient Disclosure List		
n-Propanol	71-23-8	1 %
EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification		
n-Propanol	71-23-8	F;R11□Xi;R41□R67
EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases		
n-Propanol	71-23-8	S:2-7-16-24-26-39
Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes		
n-Propanol	71-23-8	ID Number 176, hazard class 1 - low hazard to waters
Inventory - Australia - Inventory of Chemical Substances (AICS)		
n-Propanol	71-23-8	Present
Tartaric acid	87-69-4	Present
Inventory - Canada - Domestic Substances List (DSL)		
n-Propanol	71-23-8	Present
Tartaric acid	87-69-4	Present
Inventory - China		
n-Propanol	71-23-8	Present
Tartaric acid	87-69-4	Present
Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)		
Colipase (pancreatic lipase cofactor)	55126-92-6	259-490-1
n-Propanol	71-23-8	200-746-9
Tartaric acid	87-69-4	201-766-0
Inventory - Japan Existing and New Chemical Substances (ENCS)		
n-Propanol	71-23-8	2-207
Tartaric acid	87-69-4	2-1456
Inventory - Korea - Existing and Evaluated Chemical Substances		
n-Propanol	71-23-8	KE-29362
Tartaric acid	87-69-4	KE-10801

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class Xi - Irritant

Symbols

Risk Phrases

R41 Risk of serious damage to eyes.

Safety Phrases

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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

Disclaimer:

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