MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**N-geneous® LDL-ST Cholesterol Calibrator**
Version #	01
Issue date	01-23-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Part No.	80-5666-02, 267208; , CALI-70-5849
Product use	For use in the calibration of the N-geneous® LDL-ST Cholesterol assay. For In Vitro Diagnostic use only.
Synonym(s)	Liquid N-geneous® LDL-ST Calibrator * N-geneous® LDL-ST Cholesterol LDL Calibrator
Manufacturer information	
Corporate Headquarters	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

2. Hazards Identification

Physical state	Solid.
Appearance	Pale yellow pellet.
Emergency overview	CAUTION The human serum albumin in this mixture was tested by U.S. Food and Drug Administration-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 mixture in accordance with universal/standard precautions. May cause skin and eye irritation.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Eye contact. Skin contact.
Eyes	May cause eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.
Skin	Contact may cause skin irritation. Sodium azide may be absorbed through the skin and result in systemic effects. Prolonged contact may cause dryness of the skin.
Inhalation	Inhalation of dusts may produce respiratory irritation.
Ingestion	Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.
Target organs	Sodium azide: Cardiovascular system. Central nervous system
Chronic effects	No data available.
Signs and symptoms	Ingestion may cause irritation and malaise.
Potential environmental effects	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Sucrose	57-50-1	90

Components	CAS #	Percent
Sodium azide	26628-22-8	0.3

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Ingestion If material is ingested, immediately contact a poison control center.

Notes to physician Provide general supportive measures and treat symptomatically.

5. Fire Fighting Measures

Flammable properties Substance may burn when exposed to sufficient heat.

Extinguishing media

Suitable extinguishing media Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Protection of firefighters

Specific hazards arising from the chemical Substance may burn when exposed to sufficient heat.

Protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide. Nitrogen oxides.

6. Accidental Release Measures

Personal precautions Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material.

Environmental precautions Do not allow to enter drains, sewers or watercourses. This mixture 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 for containment Avoid generation and spreading of dust.

Methods for cleaning up Scoop up released material. Decontaminate the spill site following standard procedures for biohazardous, chemical spills. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Do not breathe dust from this material. Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage Store in a closed container away from incompatible materials. Store at 2-8°C (35-46°F).

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3
		0.11 ppm
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	Vapor.
		0.29 mg/m3	
		0.11 ppm	Vapor.
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
		0.11 ppm	Vapor.
Sucrose (CAS 57-50-1)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Total dust.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
		0.11 ppm
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

Exposure guidelines Follow standard monitoring procedures.

Engineering controls Use local exhaust ventilation. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal protective equipment

Eye / face protection Wear approved safety glasses or goggles.

Skin protection Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

General hygiene considerations Do not breathe dust. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Pale yellow pellet.

Physical state Solid.

Form Pellets.

Color	Pale yellow
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Soluble in water.
Specific gravity	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Stable under normal storage and handling conditions.
Conditions to avoid	None under normal conditions.
Incompatible materials	Strong oxidizing agents. Acids. Metals.
Hazardous decomposition products	Thermal decomposition of this product can generate carbon monoxide, carbon dioxide and nitrogen oxides.
Possibility of hazardous reactions	Polymerization will not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Acute		
Dermal		
LD50	Rabbit	20 mg/kg
Oral		
LD50	Rat	27 mg/kg
Sucrose (CAS 57-50-1)		
Acute		
Oral		
LD50	Rat	29700 mg/kg

Sensitization	Not classified.
Acute effects	May cause discomfort if swallowed.
Local effects	May cause skin and eye irritation.
Chronic effects	No data available.
Carcinogenicity	Not classified.

ACGIH Carcinogens

Sodium azide (CAS 26628-22-8)	A4 Not classifiable as a human carcinogen.
Sucrose (CAS 57-50-1)	A4 Not classifiable as a human carcinogen.

Epidemiology	No epidemiological data is available for this product.
Mutagenicity	No data available.
Reproductive effects	No data available.
Symptoms and target organs	Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicological data

Components		Species	Test Results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia pulex)	2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	0.68 mg/l, 96 hours

Ecotoxicity Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Accumulation Not available.

Partition coefficient

Sucrose (CAS 57-50-1) -3.7

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

Disposal instructions Dispose in accordance with all applicable regulations. 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.

Waste from residues / unused products Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 LBS

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8) 500 LBS

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium azide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A)	No
Section 311/312 (40 CFR 370)	No
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
Canadian regulations	This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.
WHMIS status	Non-controlled
State regulations	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Sodium azide (CAS 26628-22-8)	Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8)	Listed.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8)	Listed.
Sucrose (CAS 57-50-1)	Listed.

US. New Jersey Worker and Community Right-to-Know Act

Sodium azide (CAS 26628-22-8)	500 LBS

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8)	Listed.
Sucrose (CAS 57-50-1)	Listed.

Mexico regulations	This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions	Use in accordance with supplier's recommendations.
Further information	These warnings apply to the lyophilized product. Do not allow undiluted product in large quantities to reach ground water, water bodies, or sewage systems. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 Instability: 0

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