

1. Product and Company Identification

Material name	Lipase Color Calibrator
Version #	01
Issue date	03-04-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number / Product number	Kit number: 905-B, 905-E, Product number: 80-2002-01, 80-5627-00, 80-5672-00, 80-5672-01
Product use	For calibration of the Lipase Color assay. For In Vitro Diagnostic use only.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazards Identification

Physical state	Solid.
Appearance	White solid.
Emergency overview	The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. The lipase in this mixture is derived from human pancreas. The donors have been 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 The bovine serum albumin (BSA) in this product is of US origin and meets the current standards for reduction of TSE (TransmissibleSpongiform Encephalopathy) risk.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	This mixture contains a small concentration of lipase, an enzyme with the potential to induce specific 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.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	None known.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Sucrose	57-50-1	>40
Bovine Serum albumin	70024-90-7	10 - 20
Lipase	9001-62-1	<1

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

Move 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.

General advice

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties

This product is not flammable.

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

None known.

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.

Hazardous combustion products

Fire will generate toxic and irritating gases. Carbon oxides. Nitrogen oxides. Sulfur 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.

Environmental precautions

Do not allow to enter drains, sewers or watercourses.

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up

Absorb spill with vermiculite or other inert material. 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

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

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

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/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

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

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Total dust.

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

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

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

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

Exposure guidelines

Follow standard monitoring procedures.

Engineering controls

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.

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

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	White solid.
Physical state	Solid.
Form	Solid.
Color	White.
Odor	Not available.
Odor threshold	Not available.
pH	7 - 7.1 @25°C (prior to lyophilizing)
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Soluble.
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	Material is stable under normal conditions.
Conditions to avoid	Avoid high temperatures.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. Carbon oxides. Nitrogen oxides. Sulfur oxides.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sucrose (CAS 57-50-1)		
Acute		
<i>Oral</i>		
LD50	Rat	29700 mg/kg
Sensitization	The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals. Respiratory sensitization to lipase (enzyme) by workers in the dairy and detergent industry has been reported.	
Acute effects	May cause discomfort if swallowed. The human serum in this mixture presents a risk for exposure to infectious agents.	
Local effects	Ingestion may cause irritation and malaise.	
Chronic effects	Repeated inhalation may result in respiratory sensitization.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
ACGIH Carcinogens		
Sucrose (CAS 57-50-1)	A4 Not classifiable as a human carcinogen.	
Epidemiology	No epidemiological data is available for this product.	
Mutagenicity	Not classified.	
Reproductive effects	Not classified.	
Symptoms and target organs	Direct contact with skin and eyes may cause irritation.	
Further information	No other specific acute or chronic health impact noted.	

12. Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the 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 completely soluble in water.

13. Disposal Considerations

Disposal instructions	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
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Waste from residues / unused products Dispose in accordance with all applicable regulations.

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 not hazardous according to OSHA 29CFR 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.

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

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
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

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

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

Not listed.

US. Massachusetts RTK - Substance List

Sucrose (CAS 57-50-1) Listed.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

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 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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