SAFETY DATA SHEET

1. Identification

Product identifier **Lipase Color Reagent**

Other means of identification

Kit number / Product number Kit number: 905-B, 905-E, Product number: 80-2005-01, 80-2005-02, 80-2005-05, 80-2005-11, 905-B, 905-E

Recommended use Component of Lipase Color kit. For the quantitative measurement of pancreatic lipase activity in serum or plasma. For In Vitro Diagnostic Use Only.

Recommended restrictions Use in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters
Sekisui Diagnostics, LLC
4 Hartwell Place, Lexington, MA 02421, USA
www.sekisuidiagnostics.com
Phone: +1-800-332-1042

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. Hazard(s) identification

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. In case of inadequate ventilation wear respiratory protection.

Response If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.

Storage None.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sucrose	57-50-1	> 70
Nonylphenol, branched, ethoxylated	68412-54-4	< 4
Oxidase, glycerol phosphate	9046-28-0	<2

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

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Call a physician if symptoms develop or persist.

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

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.

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

Most important symptoms/effects, acute and delayed Ingestion may cause irritation and malaise. May cause allergic respiratory reaction.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. The effects might be delayed.

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

5. Fire-fighting measures

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical Material may form irritating and toxic gaseous oxides at high temperatures.

Special 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.

General fire hazards Material may burn when exposed to sufficient heat.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Avoid dust formation. 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.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Environmental precautions Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe handling Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes. Persons susceptible for allergic reactions should not handle this product. Wash thoroughly after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities 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. 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.

ACGIH

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Unspecified.

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

U.S. - NIOSH

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	REL	10 mg/m3	Total.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values No biological exposure limits noted for the ingredient(s).

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

Individual protection measures, such as personal protective equipment

Eye/face protection Wear approved safety glasses or goggles.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

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

Respiratory protection Wear NIOSH approved respirator appropriate for airborne exposure at the point of use. In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance Off-white powder.

Physical state Solid.

Form Solid.

Color Off-white.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Soluble.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Polymerization will not occur.
Conditions to avoid	Dust generation.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	None.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause allergic respiratory reaction.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Ingestion may cause irritation and malaise.

Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	May cause eye irritation.

Respiratory or skin sensitization

Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization	No data available.
Germ cell mutagenicity	Not classified.
Carcinogenicity	No data available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Chronic effects	Repeated inhalation may result in respiratory sensitization.
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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.

Partition coefficient n-octanol / water (log Kow)

Sucrose (CAS 57-50-1)	-3.7

Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
Hazardous waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
US state regulations	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. Massachusetts RTK - Substance List

Sucrose (CAS 57-50-1)

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

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Sucrose (CAS 57-50-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

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)	No
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)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 09-June-2015

Revision date -

Version # 01

NFPA ratings

References

ACGIH
EPA: AQUIRE database
IARC Monographs. Overall Evaluation of Carcinogenicity
HSDB (2005)
National Toxicology Program (NTP) Report on Carcinogens

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