

**SAFETY DATA SHEET**

**SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION**

<b>Product name</b>	Lipase Reagent
<b>Catalog number</b>	SA1045
<b>Product use</b>	For the quantitative determination of lipase activity in serum and lithium heparin plasma.
<b>Company name</b>	Alfa Wassermann Diagnostic Technologies, LLC
<b>Company address</b>	4 Henderson Drive West Caldwell, New Jersey 07006
<b>Country</b>	USA
<b>Telephone number</b>	1-800-220-4488
<b>Fax number</b>	1-973-276-0383
<b>Email</b>	info@alfawassermannus.com
<b>Website</b>	www.AWDT.us
<b>Emergency telephone number</b>	Toll Free: 1-866-419-ALFA (2532)

**SECTION 2 – HAZARDS IDENTIFICATION**

<b>Hazard classification</b>	<b>Lipase Reagent (Lyophilized):</b> This product is considered hazardous under 29 CFR 1910.1200. <b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> These products are not considered hazardous under 29 CFR 1910.1200.
<b>GHS label elements</b>	Not applicable.
<b>Signal word</b>	Not applicable.
<b>General hazard</b>	Caution.
<b>Potential health effects</b>	
<b>Routes of exposure</b>	Skin contact. Eye contact. Inhalation.
<b>Other hazards</b>	
<b>Eyes</b>	May cause irritation.
<b>Skin</b>	May cause irritation.
<b>Inhalation</b>	This mixture contains a small concentration of lipase, an enzyme with the potential to induce specific respiratory sensitization in certain individuals after repeated 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.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Chronic effects</b>	No data available.

**SECTION 3 – COMPOSITION/ INFORMATION ON INGREDIENTS**

<b>Hazardous Ingredients</b>	<b>CAS Number</b>	<b>%</b>
<b>Lipase Reagent (Lyophilized)</b>		
Sucrose	57-50-1	>70
Nonylphenol, branched, ethoxylated	68412-54-4	<4
Monoglyceride lipase	9040-75-9	<1
<b>Lipase Reagent Solvent</b>	The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.	
<b>Lipase Activator</b>		
<b>Lipase Calibrator</b>		
Sucrose	57-50-1	>40
Bovine serum albumin	70024-90-7	10 - 20
Lipase	9001-62-1	<1

**SECTION 4 – FIRST AID MEASURES**

<b>Skin contact</b>	Remove contaminated clothing and wash with soap and plenty of water. Seek medical attention.
<b>Eye contact</b>	Immediately flush with plenty of water or eye wash solution for up to ten minutes. Seek medical attention.
<b>Inhalation</b>	Remove victim to fresh air. Seek medical attention.
<b>Ingestion</b>	Wash out mouth thoroughly with water. Seek medical attention.

**SECTION 5 – FIRE-FIGHTING MEASURES**

<b>Flammable</b>	<b>Lipase Reagent (Lyophilized):</b> Yes <b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> No
<b>Hazardous combustion products</b>	<b>Lipase Reagent (Lyophilized) and Lipase Calibrator:</b> Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide. Nitrogen oxides. <b>Lipase Reagent Solvent and Lipase Activator:</b> None expected.
<b>Extinguishing media</b>	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
<b>Protection of firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Specific hazards arising from the chemical</b>	<b>Lipase Reagent (Lyophilized):</b> Substance may burn when exposed to sufficient heat. <b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> None known.
<b>Firefighting instructions</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

**SECTION 6 – ACCIDENTAL RELEASE MEASURES**

<b>Personal precautions</b>	Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing gloves appropriate protective clothing. Ensure adequate ventilation and treat material as you would hazardous materials.
<b>Environmental precautions</b>	Do not allow to enter drains, sewers or watercourses.
<b>Methods for containment and cleaning up</b>	Absorb spill with vermiculite or other inert material. Place in suitable container for prompt disposal. Label the container as potentially hazardous. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a fresh 1:10 dilution of common household bleach. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations.

**SECTION 7 – HANDLING AND STORAGE**

<b>Handling</b>	Wear safety glasses, disposable gloves and protective clothing. Wash thoroughly after handling. Handle and open container with care.
<b>Storage</b>	Store at 2-8°C.

**SECTION 8 – EXPOSURE CONTROL/ PERSONAL PROTECTION**

<b>Exposure limits</b>		
<b>Component</b>	<b>Type</b>	<b>Value</b>
<b>Lipase Reagent (Lyophilized) and Lipase Calibrator</b>		
Sucrose (CAS 57-50-1)	ACGIH TLV: TWA	10 mg/m <sup>3</sup>
	OSHA: PEL	15 mg/m <sup>3</sup>
		5 mg/m <sup>3</sup>
<b>Personal protective equipment</b>	<input checked="" type="checkbox"/> Gloves <input type="checkbox"/> Respirator <input checked="" type="checkbox"/> Eye <input type="checkbox"/> Footwear <input checked="" type="checkbox"/> Clothing <input type="checkbox"/> Other	

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b>Properties</b>	<b>Lipase Reagent (Lyophilized)</b>	<b>Lipase Reagent Solvent</b>	<b>Lipase Activator</b>	<b>Lipase Calibrator</b>
<b>Physical state</b>	Solid.	Liquid	Liquid	Solid.
<b>Color</b>	Off-white to pale yellow.	Clear, colorless	Off-white.	White.
<b>Odor</b>	Not available.	Not available.	Not available.	Not available.
<b>pH value</b>	Not available.	6.6 - 7.0	8.5 - 8.9	7.0 - 7.1 at 25°C (prior to lyophilizing)
<b>Boiling point (°C)</b>	Not available.	Not available.	Not available.	Not available.
<b>Melting point (°C)</b>	Not available.	Not available.	Not available.	Not available.
<b>Flash point</b>	Not available.	Not available.	Not available.	Not available.
<b>Ignition temperature</b>	Not available.	Not available.	Not available.	Not available.
<b>Vapor pressure</b>	Not available.	Not available.	Not available.	Not available.
<b>Vapor density</b>	Not available.	Not available.	Not available.	Not available.
<b>Specific gravity</b>	Not available.	Not available.	1	Not available.
<b>Solubility in water</b>	Soluble.	Soluble.	Soluble.	Soluble.

## SECTION 10 – STABILITY AND REACTIVITY

<b>Chemical stability</b>	Stable under normal conditions.
<b>Incompatible materials</b>	<b>Lipase Reagent (Lyophilized), Lipase Calibrator and Lipase Activator:</b> Strong oxidizers, strong acids and strong bases. <b>Lipase Reagent Solvent:</b> Unknown.
<b>Hazardous decomposition products</b>	<b>Lipase Calibrator and Lipase Reagent (Lyophilized):</b> Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. Carbon oxides. Nitrogen oxides. Sulfur oxides. <b>Lipase Reagent Solvent and Lipase Activator:</b> None expected.
<b>Conditions to avoid</b>	Keep away from heat, high temperatures and direct sunlight.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.

## SECTION 11 – TOXICOLOGICAL INFORMATION

<b>Toxicological data</b>	
<b>Component</b>	<b>Test Results</b>
<b>Lipase Reagent (Lyophilized) and Lipase Calibrator</b>	
Sucrose (CAS 57-50-1)	Acute Oral LD50 Rat: 29700 mg/kg
<b>Acute effects</b>	May cause discomfort if swallowed. The human serum in the lipase reagent (lyophilized) and lipase calibrator presents a risk for exposure to infectious agents.
<b>Chronic effects</b>	<b>Lipase Calibrator:</b> Repeated inhalation may result in respiratory sensitization.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.

## SECTION 12 – ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	<b>Lipase Reagent (Lyophilized):</b> Expected to be toxic to aquatic organisms. May cause long-term adverse effects in the environment.  <b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> 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.
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## SECTION 13 – DISPOSAL CONSIDERATIONS

<b>Waste disposal</b>	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/ standard precautions.  Dispose in accordance with all applicable regulations.
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## SECTION 14 – TRANSPORT INFORMATION

<b>DOT/ IATA/ IMDG/ TDG</b>	<b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> Not regulated as a hazardous material.
<b>DOT/ IATA/ IMDG/ TDG</b>	<b>Lipase Reagent (Lyophilized)</b> UN Number: 3077 Environmentally hazardous substance, solid, N.O.S. (Nonylphenol, branched, ethoxylated).

**SECTION 15 – REGULATORY INFORMATION**

<b>US federal regulations</b>	<b>Lipase Reagent (Lyophilized):</b> This product is considered hazardous under 29 CFR 1910.1200. <b>Lipase Reagent Solvent, Lipase Activator and Lipase Calibrator:</b> These products are not considered hazardous under 29 CFR 1910.1200.
<b>Hazard symbol</b>	Not applicable.
<b>Warnings</b>	Caution.

**SECTION 16 – OTHER INFORMATION**

<b>Supplier's notes</b>	This safety data sheet has been compiled, controlled and approved in accordance with the regulations in force. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions. We reserve the right to revise the Safety Data Sheet periodically as new information becomes available.
<b>Recommended restrictions on use</b>	For in vitro diagnostic use only.
<b>Disclaimer of expressed and implied warranties</b>	Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purposes.
<b>Preparation information</b>	P/N 701197-136 Rev B 8/14

**END OF SDS**