



Material Safety Data Sheet

Section I: Product and Company Information

Product Trade Name *STABILZYME® AP CONJUGATE STABILIZER*

Product Number..... **SA01-0050, SA01-1000, SA01-2000**

Chemical Nature Aqueous, protein-containing mixture preserved with 0.02% methylisothiazolone and 0.02% bromonitrodioxane

Product Use Description..... For in-vitro diagnostic purposes

Manufacturer's Name..... SurModics, Inc.
Address..... 9924 West 74th Street
Eden Prairie, MN 55344 US

Emergency Telephone Number CHEMTREC: 1-800-424-9300 (US and Canada)
1-703-527-3887 (International shipments)

Telephone Number for Information.... (952) 829-2700

Fax Number (952) 829-2743

Prepared by Clinical & Regulatory Affairs

Section II: Hazards Identification

EMERGENCY OVERVIEW:

No health hazard is anticipated during normal handling and use.

Based on percentages of hazardous ingredients in this product, this product is not classified as “dangerous” under EU Directives (67/548/EEC and 1999/45/EC) or hazardous under US OSHA Hazard Communication regulations (29 CFR 1910.1200).

POTENTIAL HEALTH EFFECTS:

Skin: No evidence of adverse effects.
Eyes: No evidence of adverse effects.
Ingestion: No evidence of adverse effects.
Inhalation: No evidence of adverse effects.

Carcinogenicity

No component of this product presents at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP, IARC, or OSHA.

Section III: Composition/Information on Ingredients

Ingredient Name	CAS #	%	EINECS #	EU Classification (See Section XVI)
Proprietary formulation; no hazardous components above 1% or carcinogens above 0.1%	None	100%	None	Not Classified
Methylisothiazolone	2682-20-4	0.02%	220-239-6	N, C, R20/21/22-34-43-50/53, S24-26-36/37/39-45-60-61
Bromonitrodioxane	30007-47-7	0.02%	250-001-7	Xn, R22, S36/37/39

Section IV: First Aid Measures

Eye Exposure..... No adverse acute effects are expected via this route of entry. In case of contact, wash eyes immediately with large amounts of water or normal saline for at least 15 minutes, lifting the upper and lower lids to assure adequate flushing. Seek medical attention if irritation develops.

Skin Exposure No adverse acute effects are expected via this route of entry. Flush with water, and then thoroughly wash affected area with soap and water.

Ingestion No data on ingestion of the material is available. If swallowed, consult with medical staff or poison control center to determine if any immediate response or follow-up actions are recommended.

Inhalation No adverse acute effects are expected via this route of entry. No special first aid measures are necessary; inhalation or aspiration unlikely.

Notes to Physicians None

Section V: Fire Fighting Measures

NFPA Hazard Classification Health: 0 Flammability: 0 Reactivity: 0 Other:

Extinguishing Media No restriction; use appropriate agent for surrounding fire

Fire Fighting Procedure Wear full protective clothing, including self-contained breathing apparatus. Although presenting no special fire hazard in normal use, the material will burn and could contribute to an existing fire.

Hazardous Combustion

Products Toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Unusual Fire and Explosion

Hazards None

Section VI: Accidental Release Measures

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Wear suitable laboratory protective clothing. Absorb spill with inert material and then place in a disposal container. Wash the area of the spill thoroughly with soap and water.

Section VII: Handling and Storage

HANDLING:

Refer to Section VIII for recommended precautionary measures when handling *StabilZyme AP Conjugate Stabilizer*.

STORAGE:

Store refrigerated or at room temperature.

Section VIII: Exposure Control / Personal Protection

OSHA HAZARDOUS COMPONENTS (29 CFR 1910.1200):

	Exposure Limits	
	OSHA PEL	ACGIH TLV
None	None Established	None Established

ENGINEERING CONTROLS:

Not respirable as a liquid.

PERSONAL PROTECTIVE EQUIPMENT:

- Safety goggles or glasses with side shields
- Protective clothing – lab coat
- Protective gloves – disposable rubber gloves

GENERAL HYGIENE CONTROLS:

- Practice good chemical hygiene when handling
- Avoid contact with eyes, skin and clothing
- Do not ingest material
- Safety shower and eyewash station available near location of use

Section IX: Physical and Chemical Properties

Flash Point	Not Available	Specific Gravity (H₂O=1)	Not Available
Flammable Limits	Not Available	Melting Point	Not Available
Auto-Ignition Temperature	Not Available	Freezing Point	Not Available
Flammability (solid, gas)	Not Flammable	Evaporation Rate	Not Available
Explosive Properties	Not Explosive	Boiling Point	100°C
Oxidizing Properties	Not an Oxidizer	Viscosity	Not Available
Vapor Pressure (mmHg)	Not Available	pH	5.5 - 6.5
Vapor Density (AIR=1)	Not Available	Percent Volatiles	Not Available
Relative Density	Not Available	Solubility in Water	Complete
Partial coefficient:			
n-octanol/water	Not Available		
Appearance	Clear, pale yellow liquid		
Physical State	Liquid		
Odor	None		

Section X: Stability and Reactivity Data

Stability	Chemically stable under ordinary conditions of use and storage.
Conditions to Avoid	None known
Materials to Avoid	None known
Hazardous Decomposition or Byproducts.....	Toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
Hazardous Polymerization	Will not occur

Section XI: Toxicological Information

Though complete toxicity information on **StabilZyme AP Conjugate Stabilizer** is not available, none of its components are known to be toxic or hazardous at use concentrations. No component of this product presents at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP, IARC, or OSHA.

The product contains the mercury-free preservatives, methylisothiazolone (0.02%) and bromonitrodioxane (0.02%), which can produce adverse health effects in their concentrated forms.

Bromonitrodioxane:

Acute Oral Toxicity (LD50): 455 mg/kg [rat], 590 mg/kg [mouse]

Section XII: Ecological Information

No data available.

Section XIII: Disposal Considerations

APPROPRIATE WASTE DISPOSAL METHOD:

Observe all federal, state and local laws when considering most appropriate disposal method.

Section XIV: Transport Information

UN Number.....	Non-regulated, non-hazardous for transport
UN Proper Shipping Name.....	Non-regulated, non-hazardous for transport
Transport Hazard Class(es)	Non-regulated, non-hazardous for transport
Packing Group	Non-regulated, non-hazardous for transport
Environmental Hazard	Not Available
Reportable Quantity (RQ)	None known
Emergency Telephone Number	CHEMTREC: 1-800-424-9300 (US and Canada)
(During Transport)	1-703-527-3887 (International shipments)
Special Precautions for User	None known

Section XV: Regulatory Information

US FEDERAL REGULATIONS

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT):
Not Applicable.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):
Not Listed.

INTERNATIONAL REGULATIONS

There are no hazardous ingredients in an amount that requires identification and labeling according to European Community Directives.

EUROPEAN UNION'S REACH (REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS)
This product meets the definition of a "preparation." The aggregate volume of each non-exempt substance in this product does not exceed the 1 metric ton per year threshold; therefore, registration is not required.

This safety data sheet has been prepared to comply with the requirements of Annex II, European Community Regulation No. 1907/2006 (REACH) and ANSI Z400.1-2004 guidelines.

Section XVI: Other Information

EU CLASSIFICATION:

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|-------------------|--|
| Hazard Code: | N = Dangerous for the environment
C = Corrosive
Xn = Harmful |
| Risk Statement: | 20/21/22 = Harmful by inhalation, in contact with skin and if swallowed
22 = Harmful if swallowed
34 = Causes burns
43 = May cause sensitization by skin contact
50/53 = Very toxic to aquatic organisms, may cause long-term adverse effects |
| Safety Statement: | 24 = Avoid contact with skin
26 = In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
36/37/39 = Wear suitable protective clothing, gloves and eye/face protection
45 = In case of accident or if you feel unwell, seek medical advice immediately
60 = This material and/or its container must be disposed of as hazardous waste
61 = Avoid release to the environment. |

<i>The above product information is believed to be correct, but SurModics, Inc. makes no representation of its accuracy or completeness. Persons receiving this information must exercise their independent judgment in determining the product's safety and suitability for its intended use. SURMODICS, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF THE PRODUCT OR RELIANCE UPON THIS INFORMATION.</i>
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