

SAFETY DATA SHEET



This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

StabilZyme™ Protein-Free AP Stabilizer (SAPF)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Code(s) SAPF
Product Name StabilZyme™ Protein-Free AP Stabilizer
Pure substance/mixture Mixture

Contains 3(2H)-Isothiazolone, 2-methyl-

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use For laboratory use
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Surmodics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344 USA
Telephone: 952-500-7000
For further information, please contact.

1.4. Emergency telephone number

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

Emergency Telephone - §45 - (EC)1272/2008

Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin sensitization Category 1 - (H317)

2.2. Label elements

Contains 3(2H)-Isothiazolone, 2-methyl-



Signal word

Warning

Hazard statements

H317 - May cause an allergic skin reaction
 EUH071 - Corrosive to the respiratory tract

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
 P280 - Wear protective gloves
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
 P362 + P364 - Take off contaminated clothing and wash it before reuse
 P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	1 - <10	No data available	200-334-9	No data available	-	-	-
3(2H)-Isothiazolone, 2-methyl- 2682-20-4	<0.1	No data available	220-239-6	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH071)	Skin Sens. 1A :: C>=0.0015%	10	1

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Product is or contains a sensitizer. May cause sensitization by skin contact.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

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

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure Limits**

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³	TWA: 10.0 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³
3(2H)-Isothiazolone, 2-methyl- 2682-20-4	-	TWA: 0.05 mg/m ³	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sucrose 57-50-1	-	-	-	TWA: 10 mg/m ³	-
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-	-	-
3(2H)-Isothiazolone, 2-methyl- 2682-20-4	-	-	TWA: 0.2 mg/m ³ Peak: 0.4 mg/m ³	-	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m ³ STEL: 20 mg/m ³	-	TWA: 10 mg/m ³	TWA: 5 mg/m ³	TWA: 10 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sucrose	TWA: 10 mg/m ³	-	-	-	TWA: 10 mg/m ³

57-50-1			
Chemical name	Sweden	Switzerland	United Kingdom
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³ STEL: 20 mg/m ³
3(2H)-Isothiazolone, 2-methyl- 2682-20-4	-	TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³	-

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

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

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance clear
Color colorless
Odor No information available.
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	Neutral
pH (as aqueous solution)	No data available	None known

Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Completely soluble	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

- Inhalation** Specific test data for the substance or mixture is not available.
- Eye contact** Specific test data for the substance or mixture is not available.
- Skin contact** May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
- Ingestion** Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity

Numerical measures of toxicity
No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
3(2H)-Isothiazolone, 2-methyl-	232 - 249 mg/kg (Rat) = 120 mg/kg (Rat)	= 200 mg/kg (Rabbit)	= 0.11 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

- Skin corrosion/irritation** No information available.
- Serious eye damage/eye irritation** No information available.
- Respiratory or skin sensitization** May cause sensitization by skin contact.
- Germ cell mutagenicity** No information available.
- Carcinogenicity** No information available.
- Reproductive toxicity** No information available.
- STOT - single exposure** No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
3(2H)-Isothiazolone, 2-methyl-	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused Dispose of in accordance with local regulations. Dispose of waste in accordance with

products environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
3(2H)-Isothiazolone, 2-methyl- - 2682-20-4	75.	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sucrose - 57-50-1	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status
NZIoC	Contact supplier for inventory compliance status

Legend:

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- IECSC** - China Inventory of Existing Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AIIC** - Australian Inventory of Industrial Chemicals
- NZIoC** - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

- EUH071 - Corrosive to the respiratory tract
- H301 - Toxic if swallowed
- H311 - Toxic in contact with skin
- H314 - Causes severe skin burns and eye damage
- H317 - May cause an allergic skin reaction
- H318 - Causes serious eye damage
- H330 - Fatal if inhaled

StabilZyme™ Protein-Free AP Stabilizer (SAPF)

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)
Ceiling Maximum limit value * Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 08-Dec-2022

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The above product information is believed to be correct, but Surmodics, Inc. makes no representation of its accuracy or

StabilZyme™ Protein-Free AP Stabilizer (SAPF)

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.
©2022 Surmodics, Inc. All rights reserved. SURMODICS, STABILZYME and the SURMODICS logo are trademarks of Surmodics, Inc. and/or its affiliates.

End of Safety Data Sheet