# 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<sup>™</sup> Protein-Free AP Stabilizer-CMIT/MIT (SAPF-CF01)

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

1.1. Product identifier			
Product Code(s)	SAPF-CF01		
Product Name	StabilZyme™ Protein-Free AP Stabilizer-CMIT/MIT		
Pure substance/mixture	Mixture		
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 sa	fety data sheet		
<u>Manufacturer</u>			

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

No information available

Emergency Telephone - Chemtrec: 1-800-424-9300 (US and Canada)/1-703-527-3887 (International shipments) Europe 112

### SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### 2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP] EUH208 - Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone May produce an allergic reaction.

EUH210 - Safety data sheet available on request

#### 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	-	-	-
5-Chloro-2-methyl- 3(2H)-isothiazolone, mixture with 2- methyl-3(2H)- isothiazolone 55965-84-9	<0.1	No data available	-	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH071)	0.06%<=C<0.6 % Skin Corr. 1C :: C>=0.6% Skin Irrit. 2 ::		100

### 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

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 skin with soap and water. 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	No information available.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to physicians	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	No information available.		
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	Ensure adequate ventilation.			
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 contain	inment 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	Ensure adequate ventilation.			
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 container tightly closed in a dry 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	Bu	Igaria	Croatia
Sucrose	-	-	TWA: 10 mg/m <sup>3</sup>	TWA: 1	0.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1					-	STEL: 20 mg/m <sup>3</sup>
5-Chloro-2-methyl-3(2H)-	-	TWA: 0.05 mg/m <sup>3</sup>	-		-	-
isothiazolone, mixture						
with 2-methyl-3(2H)-						
isothiazolone						
55965-84-9 Chemical name		Creek Depublie	Denmark	Га	tonia	Finland
•	Cyprus	Czech Republic	Denmark			Finiand
Sucrose 57-50-1	-	-	-	TWA:	10 mg/m <sup>3</sup>	-
Chemical name	France	Germany	Germany MAK	Gr	eece	Hungary
Sucrose	TWA: 10 mg/m <sup>3</sup>	-	-		-	-
57-50-1						
5-Chloro-2-methyl-3(2H)-	-	-	TWA: 0.2 mg/m <sup>3</sup>		-	-
isothiazolone, mixture			Peak: 0.4 mg/m <sup>3</sup>			
with 2-methyl-3(2H)- isothiazolone						
55965-84-9						
Chemical name	Ireland	Italy	Italy REL		atvia	Lithuania
Sucrose	TWA: 10 mg/m <sup>3</sup>	- Italy	TWA: 10 mg/m <sup>3</sup>		5 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1	STEL: 20 mg/m <sup>3</sup>		TWA. TO Hight	1 0 07 (.	o mg/m	TWA. TO Mg/m
Chemical name	Portugal	Romania	Slovakia	Slo	venia	Spain
Sucrose	TWA: 10 mg/m <sup>3</sup>	-	-		-	TWA: 10 mg/m <sup>3</sup>
57-50-1						
Chemical name	S	weden	Switzerland			ted Kingdom
Sucrose		-	-	TWA: 10		/A: 10 mg/m <sup>3</sup>
57-50-1				STEL: 20 mg/m <sup>3</sup>		EL: 20 mg/m <sup>3</sup>
5-Chloro-2-methyl-3(2)		-	TWA: 0.2 mg/m			-
isothiazolone, mixture wi			STEL: 0.4 mg/m <sup>3</sup>			
methyl-3(2H)-isothiazol 55965-84-9	one					
55965-64-9						

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) Predicted No Effect Concentration (PNEC) No information available. No information available.

8.2. Exposure controls

Personal protective equipment	
Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
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 a	nd chemical properties	
Physical state	Liquid	
Appearance	clear	
Color	colorless	
Odor	No information available.	
Odor threshold	No information available	
Property	<u>Values</u>	Remarks • Method
Melting point / freezing point	No data available	None known
Initial boiling point and boiling	No data available	None known
range		
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
рН	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 impac Sensitivity to static discharge	t None. 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.			
0.6. 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	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

#### Acute toxicity

Numerical measures of toxicity No information available

### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)- isothiazolone, mixture with 2- methyl-3(2H)-isothiazolone	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-

### 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	No information available.	
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 hazard	<u>s</u>	
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		

### **SECTION 12: Ecological information**

### 12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
5-Chloro-2-methyl-3(2H)- isothiazolone, mixture with 2-methyl-3(2H)- isothiazolone	EC50: 0.11 - 0.16mg/L (72h, Pseudokirchneriella subcapitata) EC50: 0.03 - 0.13mg/L (96h, Pseudokirchneriella subcapitata)	, , , , , , , , , , , , , , , , , , ,	-	EC50: =4.71mg/L (48h, Daphnia magna) EC50: 0.12 - 0.3mg/L (48h, Daphnia magna) EC50: 0.71 - 0.99mg/L (48h, Daphnia magna)

### 12.2. Persistence and degradability

Persistence and degradability No information available.

### 12.3. Bioaccumulative potential

### Bioaccumulation

#### Component Information

Chemical name	Partition coefficient
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-	-0.71 - 0.75
3(2H)-isothiazolone	

#### 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	
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-	The substance is not PBT / vPvB	
isothiazolone		

#### 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 products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

### **SECTION 14: Transport information**

### <u>IATA</u>

14.1 UN number or ID number Not regulated

StabilZyme<sup>™</sup> Protein-Free AP Stabilizer-CMIT/MIT (SAPF-CF01)

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<ul> <li>14.2 UN proper shipping name</li> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions</li> </ul>	Not regulated Not regulated Not regulated Not applicable None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None
ADR14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable 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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	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
- H310 Fatal 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
- H400 Very toxic to aquatic life
- H410 Very toxic to aquatic life with long lasting effects

### Leaend

SVHC: Substances of Very High Concern for Authorization:

Legend	Section 8: Exposure controls/personal protection	
TINIA	$T_{A}$ (time weighted every	OTEL

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 11-Apr-2023

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

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#### **End of Safety Data Sheet**