

# 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

**BioFX™ TMB Super Sensitive One Component HRP Microwell Substrate (TMBS)**

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

### 1.1. Product identifier

**Product Code(s)** TMBS  
**Product Name** BioFX™ TMB Super Sensitive One Component HRP Microwell Substrate  
**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 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** Chemctrec: 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**

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]  
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)
Citric acid monohydrate 5949-29-1	0.1 - <1	No data available	-	Eye Irrit. 2 (H319) STOT SE 3 (H335)	-	-	-

**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  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

**SECTION 4: First aid measures****4.1. Description of first aid measures**

<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	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 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** 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	Cyprus	Czech Republic	Denmark	Estonia	Finland
Citric acid monohydrate 5949-29-1	-	TWA: 4 mg/m <sup>3</sup>	-	-	-
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Citric acid monohydrate 5949-29-1	-	TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> Peak: 4 mg/m <sup>3</sup>	-	-
Chemical name	Sweden		Switzerland	United Kingdom	
Citric acid monohydrate 5949-29-1	-		TWA: 2 mg/m <sup>3</sup> STEL: 4 mg/m <sup>3</sup>	-	

**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** 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 and chemical properties**

<b>Physical state</b>	Liquid
<b>Appearance</b>	colorless to very light yellow liquid
<b>Color</b>	colorless to very light yellow
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	No data available	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known

<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	Acidic
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	Completely soluble	None known
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Vapor pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Relative vapor density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	
<b>Particle Size Distribution</b>	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

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	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
Citric acid monohydrate	= 3 g/kg ( Rat )	> 2000 mg/kg ( Rat )	-

#### 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 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.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Citric acid monohydrate	-	LC50: =1516mg/L (96h, Lepomis macrochirus)	-	-

**12.2. Persistence and degradability**

**Persistence and degradability** No information available.

**12.3. Bioaccumulative potential**

**Bioaccumulation**

**Component Information**

Chemical name	Partition coefficient
Citric acid monohydrate	-1.72

**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
Citric acid monohydrate	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**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

**SECTION 14: Transport information**

**IATA**

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

**IMDG**

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

**RID**

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

**ADR**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

**Persistent Organic Pollutants**

Not applicable

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

Not applicable

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

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Citric acid monohydrate - 5949-29-1	Product-type 1: Human hygiene

**International Inventories**

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

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** 05-Dec-2022

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

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**End of Safety Data Sheet**