BioFX® AP-Yellow One Component Microwell Substrate (pNPP) with Stabilizing Pellets

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Date of issue: 15-May-2015

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

1.1. Product identifier

Product form: Mixture
Product name: BioFX® AP-Yellow One Component Microwell SUBSTRATE (pNPP) with Stabilizing Pellets
Product code: PNPS
Product group: Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture: For laboratory use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344 USA
Phone: (952) 500-7000
Fax: (952) 500-7001

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Irrit. 2 H315
Eye Dam. 1 H318
Carc. 2 H351
STOT RE 2 H373

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Full text of H-phrases: see section 16

SECTION 3: Hazards and Precautions for Use

3.1. Hazards for personnel

No additional information available

3.2. Hazards for equipment

No additional information available

3.3. Hazards for the environment

No additional information available

3.4. Transport information

No additional information available

3.5. Storage

No additional information available

3.6. Disposal

No additional information available

3.7. Other information

No additional information available

SECTION 4: First-Aid Measures

4.1. FIrst-aid measures

Full text of P-phrases: see section 16

SECTION 5: Fire-Fighting Measures

5.1. Fire-fighting measures

No additional information available

5.2. Spill procedure

No additional information available

5.3. Fire extinguishing media

No additional information available

5.4. Special protective equipment

No additional information available

SECTION 6: Initial and Further Treatment

6.1. Immediate measures at the site of the accident

No additional information available

6.2. Further treatment

No additional information available

SECTION 7: Handling and Storage

7.1. Handling

No additional information available

7.2. Storage

No additional information available

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

No additional information available

8.2. Personal protective equipment

No additional information available

SECTION 9: Physical and Chemical Properties

9.1. Information on physical and chemical properties

No additional information available

9.2. Stability

No additional information available

9.3. Reactive tendencies

No additional information available

SECTION 10: Stability and Reactivity

10.1. Stability

No additional information available

10.2. Reactivity

No additional information available

SECTION 11: Toxicological Information

11.1. Toxicological effects

No additional information available

11.2. Ecotoxicological data

No additional information available

SECTION 12: Ecotoxicological Data

12.1. Data on biodegradability

No additional information available

12.2. Deterioration of the environment

No additional information available

SECTION 13: Disposal Considerations

13.1. Disposal methods

No additional information available

13.2. Special disposal considerations

No additional information available

SECTION 14: Transport Information

14.1. Transport risk phrases

No additional information available

SENSITIVE MATERIAL

Data Sheet is subject to frequent change. Please check the SurModics website www.surmodics.com for the latest version.

15-May-2015

Product Code: PNPS
SmartDoc # 7587.0
2. Other hazards
Other hazards not contributing to the classification: None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethanolamine</td>
<td>(CAS No) 111-42-2 (EC no) 203-868-0 (EC index no) 603-071-00-1</td>
<td>7-13</td>
<td>Acute Tox. 4 (Oral), H302 STOT RE 2, H373 Skin Irrit. 2, H315 Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>(CAS No) 7647-01-0 (EC no) 231-509-7 (EC index no) 017-002-00-2</td>
<td>0.1-1</td>
<td>Press. Gas Acute Tox. 3 (Inhalation), H331 Skin Corr. 1A, H314</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. If respiratory symptoms persist, obtain medical attention.

First-aid measures after skin contact: IF ON SKIN (or clothing), remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation persists, call a physician.

First-aid measures after eye contact: IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Get medical advice/attention.

First-aid measures after ingestion: IF SWALLOWED: Do not induce vomiting. Get medical advice/attention if you feel unwell.

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

Symptoms/injuries: Causes skin irritation. Causes serious eye damage. May cause damage to organs (Damage to kidneys and liver).

Symptoms/injuries after inhalation: May cause respiratory irritation.

Symptoms/injuries after skin contact: Causes skin irritation.

Symptoms/injuries after eye contact: Causes serious eye damage.

Symptoms/injuries after ingestion: May cause gastrointestinal irritation.

Chronic symptoms: Suspected of causing cancer. May cause damage to target organs.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media


5.2. Special hazards arising from the substance or mixture

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
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**SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

**General measures**

Do not enter fire area without proper protective equipment, including respiratory protection.

#### 6.1.1. For non-emergency personnel

**Protective equipment**

Wear Protective equipment as described in Section B.

**Emergency procedures**

Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

**Protective equipment**

Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

**For containment**

Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal.

**Methods for cleaning up**

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

### 6.4. Reference to other sections

No additional information available

**SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Do not handle until all safety precautions have been read and understood. Use appropriate personal protection equipment (PPE). Keep away from sources of ignition - No smoking. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions**

Keep the container tightly closed. Store in a dry, cool and well-ventilated place. Store away from light. Avoid elevated temperatures.

**Storage temperature**

2 - 8 °C

#### 7.3. Specific end use(s)

No additional information available

**SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

<table>
<thead>
<tr>
<th>Substance</th>
<th>ACGIH TWA (mg/m³)</th>
<th>NIOSH REL (TWA) (mg/m³)</th>
<th>OSHA PEL (TWA) (mg/m³)</th>
<th>OSHA PEL (TWA) (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethanolamine (111-42-2)</td>
<td></td>
<td>1 mg/m³ inhalable fraction and vapor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - ACGIH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - NIOSH</td>
<td></td>
<td>15 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - OSHA</td>
<td></td>
<td>15 mg/m³ vacated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - OSHA</td>
<td></td>
<td>3 ppm vacated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrogen chloride (7647-01-0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - ACGIH</td>
<td>ACGIH Ceiling (ppm)</td>
<td>2 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - OSHA</td>
<td>OSHA PEL (Ceiling) (mg/m³)</td>
<td>7 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA - OSHA</td>
<td>OSHA PEL (Ceiling) (ppm)</td>
<td>5 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 8.2. Exposure controls

**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.

**Personal protective equipment**

Gloves. Wear chemical goggles and face shield in combination. Wear labcoat with full coverage clothing.

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**Hand protection**
- Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl.

**Eye protection**
- Chemical goggles and face shield must be worn in combination.

**Skin and body protection**
- Lab coat. Wear suitable protective clothing. Wear long sleeves

**Respiratory protection**
- Where vapor, mist, or dust exceed PELs or other applicable OELs, use respiratory equipment. Respirator equipment should meet EN136/EN140 standards for approved respiratory protective equipment.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

- **Physical state**: Liquid
- **Colour**: Clear. Light yellow.
- **Odour**: Odorless.
- **Odour threshold**: No data available
- **pH**: 9.7 - 10.5
- **Relative evaporation rate (butylacetate=1)**: No data available
- **Melting point**: No data available
- **Freezing point**: No data available
- **Boiling point**: No data available
- **Flash point**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Flammability (solid, gas)**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density at 20 °C**: No data available
- **Relative density**: No data available
- **Solubility**: Water: 100 %
- **Log Pow**: No data available
- **Viscosity, kinematic**: No data available
- **Viscosity, dynamic**: No data available
- **Explosive properties**: Product is not explosive.
- **Oxidising properties**: Not an Oxidizer.
- **Explosive limits**: No data available

#### 9.2. Other information
- No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity
- No dangerous reactions known under normal conditions of use.

#### 10.2. Chemical stability
- Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of hazardous reactions
- None known.

#### 10.4. Conditions to avoid
- Light. elevated temperatures. Moisture.

#### 10.5. Incompatible materials
- Strong oxidizing agents. Strong acids. some metals.
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10.6. Hazardous decomposition products
Hazardous fumes of nitrous oxides (NOx) and carbon oxides. Phosphorus oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity: Not classified No data available

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50 oral rat</th>
<th>LD50 dermal rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethanolamine (111-42-2)</td>
<td>620 µl/kg</td>
<td>7640 µl/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50 oral rat</th>
<th>LD50 dermal rabbit</th>
<th>LC50 inhalation rat (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen chloride (7647-01-0)</td>
<td>238 (238 - 277) mg/kg</td>
<td>&gt; 5010 mg/kg</td>
<td>1.68 mg/l 1h</td>
</tr>
</tbody>
</table>

Irritation: Irritating to skin. Risk of serious damage to eyes.

pH: 9.7 - 10.5

Corrosivity: Not classified No data available

pH: 9.7 - 10.5

Sensitisation: Not classified No data available

Repeated dose toxicity: Harmful: danger of serious damage to health by prolonged exposure through inhalation. Harmful: danger of serious damage to health by prolonged exposure in contact with skin. Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Carcinogenicity: Not classified No data available

Mutagenicity: Not classified No data available

Toxicity for reproduction: Not classified No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general: No data available.

12.2. Persistence and degradability

BioFX AP-Yellow One Component Microwell Substrate (pNPP) with Stabilizing Pellets
Persistence and degradability: Not established.

Diethanolamine (111-42-2)
Persistence and degradability: Not established.

12.3. Bioaccumulative potential

Diethanolamine (111-42-2)
Bioaccumulative potential: Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

12.6. Other adverse effects
No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods: Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without approval of local, regional and national wastewater authorities.

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN
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### 14.1. UN number
Not hazardous for transport

### 14.2. UN proper shipping name

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Class(es)</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name</td>
<td>ADR: Not applicable</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>IMDG: Not applicable</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>IATA: Not applicable</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>ADN: Not applicable</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>RID: Not applicable</td>
<td>Not applicable</td>
<td></td>
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</table>

### 14.3. Transport hazard class(es)

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Class(es)</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Transport hazard class(es) (ADR)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>Transport hazard class(es) (IMDG)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>Transport hazard class(es) (IATA)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>ADN</td>
<td>Transport hazard class(es) (ADN)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>Transport hazard class(es) (RID)</td>
<td>Not applicable</td>
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### 14.4. Packing group

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>ADR: Not applicable</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>IMDG: Not applicable</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>IATA: Not applicable</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>ADN: Not applicable</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>RID: Not applicable</td>
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</table>

### 14.5. Environmental hazards

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dangerous for the environment</td>
<td>No</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>No</td>
</tr>
<tr>
<td>Other information</td>
<td>No supplementary information available</td>
</tr>
</tbody>
</table>

### 14.6. Special precautions for user

#### 14.6.1. Overland transport
Not applicable

#### 14.6.2. Transport by sea
Not applicable

#### 14.6.3. Air transport
Not applicable

#### 14.6.4. Inland waterway transport

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carriage prohibited (ADN)</td>
<td>No</td>
</tr>
<tr>
<td>Not subject to ADN</td>
<td>No</td>
</tr>
</tbody>
</table>

#### 14.6.5. Rail transport

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carriage prohibited (RID)</td>
<td>No</td>
</tr>
</tbody>
</table>

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable
BioFX® AP-Yellow One Component Microwell Substrate (pNPP) with Stabilizing Pellets
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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions
BioFX AP-Yellow One Component Microwell Substrate (pNPP) with Stabilizing Pellets is not on the REACH Candidate List
Contains no substance on the REACH Candidate List
Contains no REACH Annex XIV substances.

15.1.2. National regulations

All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) inventory

Germany
Water hazard class (WGK) : 1 - low hazard to waters

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:
Revision 0: New SDS Created.

Other information : Author: NMR.

Full text of H- and EUH--phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 3 (Inhalation)</th>
<th>Acute toxicity (inhal.), Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral), Category 4</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation, Category 1</td>
</tr>
<tr>
<td>Press. Gas</td>
<td>Gases under pressure</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation, Category 1A</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation, Category 2</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific target organ toxicity — Repeated exposure, Category 2</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H331</td>
<td>Toxic if inhaled</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

Classification according to Regulation (EC) 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
<th>Calculation procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit. 2 H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1 H318</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Carc. 2 H351</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2 H373</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

Surmodics Custom SDS EU (REACH Annex II)

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