

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

Full text of H-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazardous ingredients :

Diethanolamine

Hazard statements (CLP) :

H315 - Causes skin irritation
 H318 - Causes serious eye damage
 H351 - Suspected of causing cancer
 H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (CLP) :

P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P260 - Do not breathe vapours, fume, mist
 P264 - Wash hands, forearms and face thoroughly after handling
 P280 - Wear eye protection, protective clothing, face shield, protective gloves
 P302+P352 - IF ON SKIN: Wash with plenty of water
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

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if present and easy to do. Continue rinsing
P310 - Immediately call a doctor
P314 - Get medical advice/attention if you feel unwell
P321 - Specific treatment (see first aid instructions on this label)
P332+P313 - If skin irritation occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P405 - Store locked up
P501 - Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste

2.3. 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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Diethanolamine	(CAS No) 111-42-2 (EC no) 203-868-0 (EC index no) 603-071-00-1	7 - 13	Acute Tox. 4 (Oral), H302 STOT RE 2, H373 Skin Irrit. 2, H315 Eye Dam. 1, H318
Hydrogen chloride	(CAS No) 7647-01-0 (EC no) 231-595-7 (EC index no) 017-002-00-2	0.1 - 1	Press. Gas Acute Tox. 3 (Inhalation), H331 Skin Corr. 1A, H314

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

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

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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Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No specific emergency measures are required other than good laboratory hygiene and safety practices.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

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

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

Diethanolamine (111-42-2)		
USA - ACGIH	ACGIH TWA (mg/m ³)	1 mg/m ³ inhalable fraction and vapor
USA - NIOSH	NIOSH REL (TWA) (mg/m ³)	15 mg/m ³
USA - OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ vacated
USA - OSHA	OSHA PEL (TWA) (ppm)	3 ppm vacated
Hydrogen chloride (7647-01-0)		
USA - ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA - OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA - OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

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

Diethanolamine (111-42-2)	
LD50 oral rat	620 µl/kg
LD50 dermal rabbit	7640 µl/kg
Hydrogen chloride (7647-01-0)	
LD50 oral rat	238 (238 - 277) mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 inhalation rat (mg/l)	1.68 mg/l 1h

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

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (ADN) : Not applicable

Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

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

Carriage prohibited (ADN) : No

Not subject to ADN : No

14.6.5. Rail transport

Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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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:

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

Classification according to Regulation (EC) 1272/2008	Classification procedure
Skin Irrit. 2 H315	Calculation method
Eye Dam. 1 H318	Calculation method
Carc. 2 H351	Calculation method
STOT RE 2 H373	Calculation method

Surmodics Custom SDS EU (REACH Annex II)

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