

Safety Data Sheet

For TMB Substrate

IDENTIFICATION

Supplier: Affinity Biologicals Inc.
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Emergency Telephone: 905-304-9896 (EST 8:30 a.m. – 5:00 p.m.)
After hours contact your local poison control centre

Product Name: TMB Substrate

Catalogue Number: TMB Substrate component for FVIII-AG-RUO, FIX-AG-RUO, TAFI-AG, FXI-AG, FIX-AG and FVIII-AG

Product use: Visulize™ FVIII-AG-RUO: For *In vitro* research use only
Visulize™ FIX-AG-RUO: For *In vitro* research use only
Visulize™ TAFI-AG: For *In vitro* research use only
Visulize™ FXI-AG: For *In vitro* research use only
VisuLize™ FIX-AG: For *In vitro* diagnostic use
VisuLize™ FVIII-AG: For *In vitro* diagnostic use

HAZARDS IDENTIFICATION

The health risk is low. Product is harmful if swallowed (Xn; R22). Irritating to the eyes (R 36). May cause long-term adverse effects in the aquatic environment (N;R51/53).

COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient: 3,3',5,5'-Tetramethylbenzidine (TMB*) (<0.05% w/w)

CAS registry number: 54827-17-7

LD₅₀ (species and route): Not available

LC₅₀ (species and route): Not available

*Concentration is so low, that it does not affect the classification of the product.

Hazardous Ingredient: Citric acid monohydrate (<5% w/w)

CAS registry number: 5949-29-1

LD₅₀ (species and route): Not available

LC₅₀ (species and route): Not available

FIRST AID MEASURES

Eye Contact: Flush thoroughly with water or physiological salt water, lifting the upper and lower lids occasionally, until no evidence of chemical remains (~15 minutes). Remember to remove contact lenses. If irritation persists: seek medical advice.

Skin Contact: Remove contaminated clothing and wash with water and soap.

Inhalation: Inhalation or aspiration unlikely; however in the event, go to fresh air. Keep at rest. If any adverse reaction (i.e. queasiness/discomfort) occurs seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. Keep under surveillance. If any adverse reaction (i.e. queasiness/discomfort) occurs seek medical advice.

FIRE FIGHTING MEASURES

Conditions of flammability: Not combustible; aqueous solution

Means of extinction - suitable: Use extinguishing media appropriate for surrounding fire conditions

Means of extinction – not suitable: Not available

Protective Equipment: When extinguishing fires use breathing apparatus with an independent source of air

Upper flammable limit: Not available

Lower flammable limit: Not available

Flash Point and method of determination: Not available

Auto-ignition temperature: Not available

Hazardous combustion products: Not available

Explosion data-sensitivity to mechanical impact: Not available

Explosion data-sensitivity to static charge: Not available

Special risks in a fire situation: When heated to dryness the product may form hazardous decomposition products.

ACCIDENTAL RELEASE MEASURES

Personal precautions: Provide for sufficient ventilation/respiratory protection

Waste disposal: Do not empty into drains. If large amounts of the product contaminate sewages, inform appropriate authorities in accordance with local regulations.

Procedure to be followed in case of leak or spill: Wear protective equipment. Provide for sufficient ventilation/respiratory protection. Absorb spilled liquid and place spillage in a plastic container.

HANDLING AND STORAGE

Handling procedures and equipment: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage requirements: Store at 2-8°C when not in use. Keep container closed.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Specific engineering controls to be used: Avoid contact with skin and eyes

Personal protective equipment to be used:

Eye: Wear safety goggles when risk of splashes;

Skin: Wear gloves of plastic or rubber when risk of contact (Breakthrough time: 3 hours)

Respiratory: None

PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Odour & appearance: Clear, odourless

Odour threshold: Not available

Specific gravity: Not available

Vapour Pressure: Not available

Vapour density: Not available

Evaporation rate: Not available

Boiling point: ~100°C

Freezing point: Not available

pH: Not available

Coefficient of water/oil distribution: Not available

Density (g/ml) at 20°C: ~1

Solubility in Water: Completely soluble in water

STABILITY AND REACTIVITY

Conditions under which the product is chemically unstable: Product is stable

Incompatibilities: None known

Conditions of reactivity: None known

Hazardous decomposition products: None known

TOXICOLOGICAL INFORMATION

Route of entry: May be absorbed through ingestion

Effects of acute exposure to product:

Eye: May give irritation

Skin: May give irritation

Inhalation: Inhalation is not possible when used as recommended

Ingestion: May give irritation of gastrointestinal tract

Effects of chronic exposure to product: Has shown a possible mutagenic effect in experimental animals (mice)

Exposure limits: Not available

Irritancy of product: see above

Sensitization to product: Not available

Carcinogenicity: Not available

Reproductive toxicity: Not available

Teratogenicity: Not available

Mutagenicity: see above

Name of toxicologically synergistic products: Not available

ECOLOGICAL INFORMATION

Ecotoxicity: TMB is toxic to aquatic organisms. Effect values (EC₅₀): 1-10mg/l

Mobility in soil: No available or applicable data.

Persistence and degradability: TMB is not readily biodegradable. May cause long-term adverse effects in the aquatic environment.

Bioaccumulative potential: Log K_{ow} of TMB is 4.11 (is expected to accumulate)

Other: avoid emptying into waters or drains

DISPOSAL CONSIDERATIONS

Waste Disposal: Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-code: 16 05 08

TRANSPORT INFORMATION

Special shipping information: None required

REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the SDS contains all the information required by the *Controlled Products Regulations*.

Classification according to EEC directives: Supplier has concluded that the mixture is not to be classified according to EC (67/548 or 199/45) and CLP (1272/2008).

Risk-phrases, Safety phrases, Danger symbol and danger designation:

R 22: Harmful if swallowed.

R 36: Irritating to eyes.

R 51/53: Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

EC₅₀: Effect Concentration 50%

LC₅₀: Lethal Concentration 50%

LD₅₀: Lethal Dose 50%

OTHER INFORMATION

The above statements are provided for informational use only and are believed to be correct. Affinity Biologicals Inc. shall not in any event be liable for incidental, consequential, third party or special damages of any kind resulting from any handling, use or failure of the products or above information.

Prepared at Affinity Biologicals by the Quality Assurance department using SDS data from supplier of raw material. Address any questions to Affinity Biologicals at (800) 903-6020.

Date of preparation of the SDS: March 5, 2018.