

My5-FU Sample Stabilizer Pack / My5-FU Sample Stabilizer Vial

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 11-July-17

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

1.1. Product identifier

Product form : Mixture
Product name : My5-FU Sample Stabilizer Pack / My5-FU Sample Stabilizer Vial
Product code : 5FU-STB / 5FU-STB-V

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

1.2.1. Relevant identified uses

Industrial/Professional Use : For professional use only
Use of the substance/mixture : In Vitro Diagnostic Medical Device

1.2.2. Uses advised against

Not for human use

1.3. Details of the supplier of the safety data sheet

Manufacturer

Saladax Biomedical, Inc.
116 Research Dr.
18015 Bethlehem, PA
T 610-419-6731
techsupport@saladax.com
www.saladax.com

European Authorized Representative

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands
T +31 70 345 8570

1.4. Emergency telephone number

Emergency number : CHEMTREC 1-800-424-9300 (US or Canada); 1-703-527-3887 (International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 3 H226
Acute toxicity (oral), Category 4 H302
Acute toxicity (dermal) Category 4 H312
Acute toxicity (inhalation) Category 4 H332
Specific target organ toxicity (single exposure) Category 1 H370

Adverse physicochemical, human health and environmental effects

None known.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02



GHS07



GHS08

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H226 - Flammable liquid and vapour
H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled
H370 - Causes damage to organs

Precautionary statements (CLP) :

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P243 - Take precautionary measures against static discharge
P260 - Do not breathe fume/mist/vapours/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink, or smoke when using this product
P280 - Wear protective gloves, clothing, and eye protection

2.3. Other hazards

No additional information available.

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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]
Methanol	(CAS No) 67-56-1 (EC no) 200-659-6;200-659 (EC index no) 603-001-00-X	30	Flam. Liq. 2, H225 Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:vapour), H331 STOT SE 1, H370

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). Call a POISON CENTER or doctor/physician.
- First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
- First-aid measures after skin contact : Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician. Wash with plenty of soap and water. Wash contaminated clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell.

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

- Symptoms/injuries : Methanol in high concentration may cause blindness and effects on the central nervous system and optic nerve. Death in extreme cases. Repeated or prolonged exposure to high levels may affect the liver and kidneys.
- Symptoms/injuries after inhalation : Danger of serious damage to health by prolonged exposure through inhalation. Harmful if inhaled.
- Symptoms/injuries after skin contact : Repeated exposure to this material can result in absorption through skin causing significant health hazard. Harmful in contact with skin
- Symptoms/injuries after eye contact : Irritating to eyes.
- Symptoms/injuries after ingestion : Harmful if swallowed. The swallowing of even a small amount of methanol can cause blindness or lead to death. The following may result in the case of a low dosage: nausea, headache, stomach-ache, vomiting and impaired vision (blurred vision, photophobia). There is furthermore risk of damage to liver, kidneys and heart. Effects may be delayed and manifest within 18 to 48 hours. Stinging sensation. Headache. Disorientation. Dizziness. Unconsciousness. Contains ethanol; constant ingestion of ethanol can lead to cirrhosis of the liver.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Flammable liquid and vapour.
- Explosion hazard : May form flammable/explosive vapour-air mixture.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection. Avoid breathing dust/fume/gas/mist/vapours/spray.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Handle empty containers with care because residual vapours are flammable.
Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. No open flames. No smoking. Take precautionary measures against static discharge. Use only non-sparking tools. Use only outdoors or in a well-ventilated area. Do not breathe fume, mist, spray, vapours.
Hygiene measures : Do not eat, drink or smoke when using this product. Wash face, hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof ventilating, electrical, lighting, equipment.
Storage conditions : Keep only in the original container in a cool, well ventilated place away from incompatible materials and heat sources. Keep container tightly closed.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Methanol (67-56-1)		
EU	IOELV TWA (mg/m ³)	260 mg/m ³
EU	IOELV TWA (ppm)	200 ppm

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8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure. Safety glasses. Gloves. Protective clothing.
Hand protection	: Wear protective gloves (to European standard EN 374 or equivalent).
Eye protection	: Chemical goggles or safety glasses. Chemical goggles should be consistent with EN166 or equivalent.
Respiratory protection	: Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. In fine dispersion/spraying/misting: In case of insufficient ventilation, wear suitable respiratory equipment.



Other information	: Do not eat, drink or smoke during use.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Clear, colorless liquid.
Odour	: Alcohol odour.
Odour threshold	: No data available
pH	: Neutral
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: -20 °C
Freezing point	: No data available
Boiling point	: 83 °C
Flash point	: 35 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Flammable liquid and vapour
Vapour pressure	: 100 mm Hg
Relative vapour density at 20 °C	: 0.95 g/mL
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

VOC content	: 30 %
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SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Flammable liquid and vapour. May form flammable/explosive vapour-air mixture.

10.3. Possibility of hazardous reactions

Product will not undergo polymerization.

10.4. Conditions to avoid

Extremely high or low temperatures. Open flame. Overheating. Heat. Sparks. Direct sunlight.

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10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Fumes, Carbon monoxide, Carbon dioxide, May release flammable gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed. Dermal: Harmful in contact with skin. Inhalation: Harmful if inhaled.

Methanol (67-56-1)	
LC50 inhalation rat (mg/l)	130.7 mg/l/4h (lit. ECHA)
LD50 oral rat (mg/kg)	1187 - 2769 mg/kg
LD50 dermal rabbit (mg/kg)	15800 mg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
Specific target organ toxicity (single exposure) : Causes damage to organs.

Specific target organ toxicity (repeated exposure) : Not classified (Based on available data, the classification criteria are not met)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

Potential Adverse human health effects and symptoms : Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

My5-FU Sample Stabilizer Pack / My5-FU Sample Stabilizer Vial	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

My5-FU Sample Stabilizer Pack / My5-FU Sample Stabilizer Vial	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

My5-FU Sample Stabilizer Pack / My5-FU Sample Stabilizer Vial	
Mobility in soil	This material is soluble in water.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Additional information : Handle empty containers with care because residual vapours are flammable.

Ecology - waste materials : Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: 1993
UN-No. (IMDG)	: 1993
UN-No. (IATA)	: 1993
UN-No. (ADN)	: 1993
UN-No. (RID)	: 1993

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: FLAMMABLE LIQUID, N.O.S.
Proper Shipping Name (IMDG)	: FLAMMABLE LIQUID, N.O.S.
Proper Shipping Name (IATA)	: Flammable liquid, n.o.s.
Proper Shipping Name (ADN)	: FLAMMABLE LIQUID, N.O.S.
Proper Shipping Name (RID)	: FLAMMABLE LIQUID, N.O.S.
Transport document description (ADR)	: UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl alcohol SOLUTION), 3, III, (D/E)
Transport document description (IMDG)	: UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl alcohol SOLUTION), 3, III
Transport document description (IATA)	: UN 1993 Flammable liquid, n.o.s. (Methyl alcohol SOLUTION), 3, III
Transport document description (ADN)	: UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl alcohol SOLUTION), 3, III
Transport document description (RID)	: UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl alcohol SOLUTION), 3, III

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: 3
Danger labels (ADR)	: 3



IMDG

Transport hazard class(es) (IMDG)	: 3
Danger labels (IMDG)	: 3



IATA

Transport hazard class(es) (IATA)	: 3
Hazard labels (IATA)	: 3



ADN

Transport hazard class(es) (ADN)	: 3
Danger labels (ADN)	: 3

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RID

Transport hazard class(es) (RID) : 3

Danger labels (RID) : 3



14.4. Packing group

Packing group (ADR) : III

Packing group (IMDG) : III

Packing group (IATA) : III

Packing group (ADN) : III

Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 274, 601, 640E
Limited quantities (ADR) : 5L
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T4
Portable tank and bulk container special provisions (ADR) : TP1, TP29
Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E

- Transport by sea

Special provisions (IMDG) : 223, 274, 955

Limited quantities (IMDG) : 5 L

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Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P001, LP01
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP1, TP29
EmS-No. (Fire)	: F-E
EmS-No. (Spillage)	: S-E
Stowage category (IMDG)	: A

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y344
PCA limited quantity max net quantity (IATA)	: 10L
PCA packing instructions (IATA)	: 355
PCA max net quantity (IATA)	: 60L
CAO packing instructions (IATA)	: 366
CAO max net quantity (IATA)	: 220L
Special provisions (IATA)	: A3
ERG code (IATA)	: 3L

- Inland waterway transport

Classification code (ADN)	: F1
Special provisions (ADN)	: 274, 601, 640E
Limited quantities (ADN)	: 5 L
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T
Equipment required (ADN)	: PP, EX, A
Ventilation (ADN)	: VE01
Number of blue cones/lights (ADN)	: 0

- Rail transport

Classification code (RID)	: F1
Special provisions (RID)	: 274, 601, 640E
Limited quantities (RID)	: 5L
Excepted quantities (RID)	: E1
Packing instructions (RID)	: P001, IBC03, LP01, R001
Mixed packing provisions (RID)	: MP19
Portable tank and bulk container instructions (RID)	: T4
Portable tank and bulk container special provisions (RID)	: TP1, TP29
Tank codes for RID tanks (RID)	: LGBF
Transport category (RID)	: 3
Special provisions for carriage – Packages (RID)	: W12
Colis express (express parcels) (RID)	: CE4
Hazard identification number (RID)	: 30

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

Not applicable

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 REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

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VOC content : 30 %

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Date of Preparation : 17 July 2017

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Flam. Liq. 2	Flammable liquids Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H331	Toxic if inhaled
H332	Harmful if inhaled
H370	Causes damage to organs
ADR	European regulations concerning the International Transport of Dangerous Goods by Road
RID	European regulations concerning the International Transport of Dangerous Goods by Rail
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADN	European regulations concerning the International Carriage of Dangerous Goods by Inland Waterways

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product