

Safety Data Sheet

LIFELINE CELL TECHNOLOGY SAFETY DATA SHEET

SECTION 1 – PRODUCT AND COMPANY INFORMATION

Product Name: Human BTEC Diseased CF
Product Number: FC-0103
Company Address: Lifeline Cell Technology
8415 Progress Drive, Suite T
Frederick, MD 21701
Technical Phone: (877) 845-7787
Fax: (301) 845-2405
Emergency Phone: (877) 845-7787
Product use: Cell/Tissue culture

SECTION 2 – HAZARDS IDENTIFICATION

Hazard Identification: Dimethyl Sulfoxide (approximately 10%)

GHS Classification

Flammable liquids (Category 4), H227

GHS Label elements including precautionary statements:

Pictograms: None
Signal word: Warning

Hazard statements

H227 Combustible liquid
H280 Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. –No smoking
P280 Wear protective gloves/protective clothing/eye protection/face protection
P370+P378 In case of fire use dry sand, dry chemical or alcohol-resistant foam for extinction.
P403+P235 Store in a well ventilated place. Keep cool.
P501 Dispose of contents/container to an approved waste disposal plant

Hazards not covered by GHS: This product contains raw material of human source. The human cells in this product have been tested and found to be negative for Hepatitis B, Hepatitis C, HIV-1 and HIV-2 by FDA approved methods. These tests cannot offer complete assurance of the absence of these or other infectious agents.

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SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

| | | | |
|------------------------------|--------------------|-------------|-----------|
| Principal Components: | Water | CAS number: | 7732-18-5 |
| | Dimethyl Sulfoxide | CAS number: | 67-68-5 |
| | Fetal Bovine Serum | CAS number: | N/A |

Composition: The subject product is a cell suspension in a nutrient chemical solution with Fetal Bovine Serum, and Dimethyl Sulfoxide (DMSO) in purified water. With the exception of 5-15% Fetal Bovine Serum, 5-15% DMSO and purified water, all other ingredients are in concentrations of less than 1%.

Synonym: BTEC

SECTION 4 – FIRST AID MEASURES

Potential Health Effects:

Eye: May cause irritation of the eye.

Skin: May cause skin irritation.

Ingestion: May be harmful if swallowed.

Inhalation: May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.

First aid measures:

Oral Exposure: If swallowed, rinse out mouth with water provided person is conscious. Call a physician.

Dermal Exposure: In case of contact with skin, flush with copious amounts of water for at least 15 minutes. Should irritation occur, call a physician.

Eye Exposure: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

SECTION 5 – FIRE FIGHTING MEASURES

General Fire hazard: For small fires, use media such as “alcohol” foam, dry chemical or carbon dioxide. For large fires, apply water from as far away as possible. Use large quantities (flooding) of water applied as a mist or spray; solid streams of water may be ineffective. Cool all affected containers with flooding quantities of water.

Extinguishing media: Use media appropriate for fire conditions.

Advice for Firefighters: Wear self-contained breathing apparatus if necessary.

Hazardous decomposition products from the mixture: Carbon oxides and Sulfur oxides

Further information: Use water spray to cool unopened containers.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions and Protective Equipment: Avoid breathing vapors, mist or gas. Remove all sources of ignition. Beware of vapours accumulating to form explosive concentrations. Vapour can accumulate in low areas. Refer to section 8 for appropriate personal protection.

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Environmental Precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods for Clean Up: Absorb liquid with disposable laboratory towel or other absorbent material and then place in a closed container for disposal. Wash spill site after liquid cleanup is complete with cleansers appropriate for the spill site surface material.

SECTION 7 – HANDLING AND STORAGE

Precautions for Handling: Refer to section 8 for appropriate personal protection. Avoid contact with eyes, skin or clothing. Product may cause allergic reaction in sensitized individuals. Do not pipet by mouth.

Storage: Keep container tightly closed. Store at ultralow temperature, -150°C or below. Protect from light.

SECTION 8 – EXPOSURE CONTROLS AND PERSONAL PROTECTION

Components with workplace control parameters:

| Component | CAS# | Value | Control Parameters | Basis |
|--------------------|---------|-------|---|---|
| Dimethyl Sulfoxide | 67-68-5 | TWA | 250.000 ppm 0.800000 mg/m ³ | USA. Workplace Environmental Exposure Levels (WEEL) |

Engineering Controls: Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of the workday.

Ventilation: Area ventilation is generally adequate.

Personal Protective Equipment:

Respiratory: Respirator is not required.
Hand: Chemical resistant gloves required.
Eye: Safety glasses or goggles required.
Clothing: Laboratory coat recommended.

General Hygiene Measures: Wash hands thoroughly after handling.

SECTION 9 – PHYSICAL / CHEMICAL PROPERTIES

Appearance: Frozen, pale yellow to tan liquid

Upper/lower flammability or Explosive limits: No data available

Odor: Faint earthy or musky odor

Vapor pressure: No data available

Odor threshold: No data available

Vapor density: No data available

pH: No data available

Relative density: No data available

Freezing point: No data available

Solubility: Soluble in water

Boiling point: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability: Not flammable

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Upper/lower flammability or explosive limits: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Viscosity: No data available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: No data available
Chemical stability: Stable under recommended storage and usage conditions.
Possible hazardous reactions: No data available
Conditions to be avoided: Heat, sparks and flames.
Incompatible materials: Acid chlorides, Phosphorus halides, Strong acids, Strong oxidizing agents, Strong reducing agents
Hazardous decomposition products: Carbon oxides and Sulfur oxides may be released in a fire.

SECTION 11 – TOXICOLOGICAL INFORMATION

Likely routes of exposure: Ingestion, skin, eye contact.

Acute toxicity (Dimethyl Sulfoxide)

Oral LD50: LD50 Oral – Rat – 14,500 mg/kg
Inhalation LC50: LC50 Inhalation – Rat – 4 hrs – 40,250 ppm
Dermal LD50: LD50 Dermal Rabbit - > 5,000 mg/kg
Other: No data available

Chronic toxicity: No data available

Skin corrosion: No data available
Eye damage: No data available
Sensitization (Respiration or Skin): No data available
Specific target organ toxicity – single exposure: No data available
Specific target organ toxicity – repeated exposure: No data available
Aspiration hazard: No data available

Germ cell mutagenicity:

Dimethyl Sulfoxide: Mouse, lymphocyte, cytogenetic analysis, mutation in mammalian somatic cells
Rat: Cytogenetic analysis
Mouse: DNA damage

Carcinogenicity:

Dimethyl Sulfoxide: Rat – Oral
Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors

Dimethyl Sulfoxide: Mouse – Oral

Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Leukaemia Skin and Appendages: Other: Tumors

NTP: not listed
IARC: not listed
ACGIH: not listed
OSHA: not listed

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Reproductive toxicity:

Dimethyl Sulfoxide: Reproductive toxicity – Rat – Intraperitoneal

Effects on fertility: Abortion. Post-implantation mortality (e.g. dead and/or reabsorbed implants per total number of implants).

Dimethyl Sulfoxide: Reproductive toxicity – Rat – Subcutaneous

Effects on fertility: Post-implantation mortality (e.g. dead and/or reabsorbed implants per total number of implants per corpora lutea). Effects on fertility: Litter size (e.g. number of fetuses per liter; measured before birth).

Dimethyl Sulfoxide: Reproductive toxicity – Mouse – Oral

Effects on fertility: Pre-implantation mortality (e.g. reduction in number of implants per female; number of implants per corpora lutea). Effects on embryo or fetus: Fetotoxicity (except death, e.g. stunted fetus). Specific developmental abnormalities: Musculoskeletal system.

Additional Information:

Dimethyl Sulfoxide: RTECS: PV6210000

Effects due to ingestion may include: Nausea, Fatigue, Headache

Eyes – Eye disease – Based on Human Evidence

SECTION 12 – ECOLOGICAL INFORMATION

Toxicity to Fish: LC50 Pimephales promelas (fathead minnow) 34,000 mg/L – 96 h (Dimethyl Sulfoxide)

LC50 Oncorhynchus mykiss (rainbow trout) 35,000 mg/L – 96 h (Dimethyl Sulfoxide)

Toxicity to other aquatic

Invertebrates: EC50 Daphnia magna (water flea) 24,600 mg/L – 48 h (Dimethyl Sulfoxide), (OECD Guideline 202)

Toxicity to algae: EC50 Pseudokirchneriella subcapitata (green algae) 17,000 mg/L – 72 h (Dimethyl Sulfoxide), (OECD Guideline 201)

Persistence/Degradability: Dimethyl Sulfoxide: Result: 31% - According to the results of tests of biodegradability a component of this product (Dimethyl Sulfoxide) is not readily biodegradable (OECD Guideline 301D).

Bioaccumulation Potential: No data available

Mobility in Soil: No data available. Expected to be mobile in soil due to high solubility in water.

SECTION 13 – DISPOSAL CONSIDERATIONS

RCRA hazardous waste code: Not listed as a hazardous waste.

Appropriate disposal containers: No specific restrictions on waste container type.

Appropriate Method of Disposal: Clean up and dispose of waste in accordance with all federal, state and local environmental regulations.

SECTION 14 – TRANSPORT INFORMATION

UN number: N/A

Proper Shipping Name: None.

DOT: Non-hazardous for transport.

IMDG: Non-hazardous for transport.

IATA: Non-hazardous for transport.

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SECTION 15 – REGULATORY INFORMATION

SARA 302 Components: No chemicals in this product are subject to SARA Title III, Section 302.

SARA 313 Components: This product does not contain chemical components with known CAS numbers that exceed the threshold (De Minimus) reporting levels established by SARA Title III, Section 313.

SARA 311/312: Fire hazard, Chronic health hazard

Massachusetts Right to Know Components: No components are subject to Massachusetts Right to Know Act.

Pennsylvania Right to Know Components:

| | | |
|--------------------|-------------|-----------|
| Water | CAS number: | 7732-18-5 |
| Dimethyl Sulfoxide | CAS number: | 67-68-5 |
| Fetal Bovine Serum | CAS number: | N/A |

New Jersey Right to Know Components:

| | | |
|--------------------|-------------|---------|
| Dimethyl Sulfoxide | CAS number: | 67-68-5 |
| Fetal Bovine Serum | CAS number: | N/A |

California Prop. 65 Components: This product does not contain any chemicals known to the state of California to cause cancer, birth defects or other reproductive harm.

SECTION 16 – OTHER INFORMATION

Preparation information:

Prepared by: Quality Department
Date Prepared: April 28, 2021
Replaced Version date: August 2, 2018

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