MATERIAL SAFETY DATA SHEET

Cat# 1741-100, -1000 Capecitabine **MSDS DATE: Mar 12, 2012**

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: **Capecitabine**

PRODUCT CODES: **Cat# 1741-100, -1000**

MANUFACTURER: **BioVision, Inc.**
ADDRESS: **155 S. Milpitas Boulevard, Milpitas, CA 95035**

EMERGENCY PHONE: **858-373-8066**
CHEMTREC PHONE:
OTHER CALLS: **408-493-1800**
FAX PHONE: **408-493-1801**

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Description	Volume	Safety Information
Capecitabine	Solid	1741-100: 100 mg 1741-1000: 1 g	See below

SECTION 3: HAZARDS IDENTIFICATION

Product Name/Chemical Name	CAS Number	EC-No.	MW	Chemical Formula
Capecitabine	154361-50-9	--	359.35	$C_{15}H_{22}FN_3O_6$

Capecitabine:
Emergency Overview
OSHA Hazards: Target organ effect, Toxic by ingestion, Toxic by inhalation, Irritant, Teratogen
Target Organs: Gastrointestinal tract, Blood, Reproductive system, Bone marrow
GHS Classification:
Acute toxicity, Oral (Category 3)
Acute toxicity, Inhalation (Category 3)
Skin irritation (Category 2)
Eye irritation (Category 2B)
Carcinogenicity (1B)
Reproductive toxicity (Category 1B)
Acute aquatic toxicity (Category 2)
Chronic aquatic toxicity (Category 2)

GHS Label elements, including precautionary statements
Pictogram:

Signal word: Danger
Hazard statement(s):
H301 Toxic if swallowed.
H315 Causes skin irritation.
H320 Causes eye irritation.
H331 Toxic if inhaled.
H350 May cause cancer.
H360 May damage fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statement(s):
P264 Wash hands thoroughly after handling.
P273 Avoid release to the environment.
P281 Use personal protective equipment as required.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P330 Rinse mouth.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P391 Collect spillage.
P404+P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.
P501 Dispose of contents/container to an approved waste disposal plant.

HMIS Classification
Health hazard: 2
Flammability: 1
Physical hazards: 0

NFPA Rating
- **Health Hazard:** 2
- **Fire**: 1
- **Reactivity Hazard**: 0

Potential Health Effects
- **Inhalation:** Toxic if inhaled. May cause respiratory tract irritation.
- **Skin:** May be harmful if absorbed through skin. Causes skin irritation.
- **Eyes:** Causes eye irritation.
- **Ingestion:** Toxic if swallowed.

SECTION 4: FIRST AID MEASURES

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In case of skin contact: Wash off with soap and plenty of water. Consult a physician.
In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5: FIRE-FIGHTING MEASURES

Condition of flammability: Not flammable or combustible.
Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.
Hazardous combustion products: Hazardous combustion products formed under fire conditions— no data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, gas, or dust. Ensure adequate ventilation. Evacuate personnel to safe areas.
Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
Methods for cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection. Take precautionary measures against electrostatic charging.
Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: -20 °C

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.
Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Capecitabine
Appearance:	White to off-white solid
pH:	No data available

Water Solubility:	2 mg/ml with slight warming
Other Solubility:	DMSO (100 mg/ml), EtOH (10 mg/ml)
Specific Gravity (g/ml):	No data available
Boiling Point (°C):	No data available
Melting Point (°C):	115-120 ^{o}C (239-248 ^{o}F)
Flash Point (°C):	No data available
Ignition Temperature (°C):	No data available
Density	No data available

SECTION 10: STABILITY AND REACTIVITY

Property	Capecitabine
Chemical stability	Stable under recommended storage conditions
Conditions to avoid:	No data available
Materials to avoid:	Strong oxidizing agents, Strong acids
Hazardous decomposition products:	Carbon oxides, nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Capecitabine:
Acute toxicity: LD50 Oral – rat – >2000 mg/kg
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitization: no data available
Germ cell mutagenicity: no data available
Mutagenicity: May cause mutations in vitro (clastogenic effect in lymphocytes)→ lymphocyte test: evidence of clastogenicity
Subchronic toxicity: High doses may damage proliferating cells (e.g. bone marrow, leukocytes.)

Carcinogenicity:

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: no data available
Teratogenicity: no data available
Specific target organ toxicity – single exposure (GHS): no data available
Specific target organ toxicity – repeated exposure (GHS): no data available
Aspiration hazard: no data available
Potential Health Effects
Inhalation: Toxic if inhaled. May cause respiratory tract irritation.
Skin: May be harmful if absorbed through skin. Causes skin irritation.
Eyes: Causes eye irritation.
Ingestion: Toxic if swallowed.
Signs and Symptoms of Exposure: Exposure may cause diarrhea, nausea, vomiting, loss of appetite, irritation of mucous membranes, and alteration of hematopoietic system (leukopenia) in dependence of the dose. Cytostatics are potentially carcinogenic.
Synergistic effects: no data available
Additional information: RTECS: not available

SECTION 12: ECOLOGICAL INFORMATION

Capecitabine:
Persistence and degradability: Inherently biodegradable: evidence for prior abiotic primary degradation as a rate-limiting process→ 29%, 28 days; 44%, 56 days; 55%, 84 days
Toxicity: Strongly toxic for algae (Selenastrum capricornutum): EbC_{50} (72 h) 0.58 mg/l; ErC_{50} (72) 2.0 mg/l; NOEC (72 h) 0.14 mg/l
Barely toxic for planktonic crustaceans (Daphnia magna): EC_{50} (48 h) > 850 mg/l; NOEC (48 h) 500 mg/l
Barely toxic to fish (rainbow trout): LC_{50} (96 h) >867 mg/l; NOEC (96 h) 867
Barely inhibitory on aerobic bacterial respiration: EC_{50} > 1000 mg/l
Bioaccumulative potential: Slow degradation, probably ester hydrolysis (30 mg/l; HPLC): $t_{1/2}$ ~21 d, ~22 ^{o}C, pH ~7
Rapid degradation only at very acidic pH (1000 mg/l, water; HPLC): $t_{1/2}$ ≥60 h, ~22 ^{o}C, pH 2; $t_{1/2}$ ~6 h, ~22 ^{o}C, pH 1;): $t_{1/2}$ <2 h, ~22 ^{o}C, pH 0.5; $t_{1/2}$ ~1 h, 30 ^{o}C, pH 0.5
Mobility in soil: Medium adsorption to activated sludge, medium mobility (water-activated sludge, 3 h): K_d = 272 l/kg (activated sludge)
PBT and vPvB assessment: no data available
Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Toxic to aquatic life with long lasting effects.

SECTION 13: DISPOSAL CONSIDERATIONS

Product: Observe all federal, state, and local environmental regulations.
Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Capecitabine:
DOT (US): UN-number: 3077, Class: 9, Packing group: III; Proper shipping name: Environmental hazardous substance, solid, n.o.s. (Capecitabine); Marine pollutant: Yes; Poison inhalation hazard: No
IMDG: UN-number: 3077, Class: 9, Packing group: III; EMS-No: F-A, S-F; Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Capecitabine); Marine pollutant: Yes
IATA: UN-number: 3077, Class: 9, Packing group: III; Proper shipping name: Environmental hazardous substance, solid, n.o.s. (Capecitabine)

SECTION 15: REGULATORY INFORMATION

Capecitabine:
OSHA Hazards: Target organ effect, Toxic by ingestion, Toxic by inhalation, Irritant, Teratogen
DSL Status: This product contains the following components that are not on the Canadian DSL nor NDSL lists.
Capecitabine, CAS-No. 154361-50-9
SARA 302 Components: SARA 302: No chemical in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.
SARA 311/312 Hazards: Acute Health Hazard
Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.
Pennsylvania Right To Know Components: Capecitabine, CAS-No. 154361-50-9
New Jersey Right To Know Components: Capecitabine, CAS-No. 154361-50-9
California Prop. 65 Components: No data available

EU regulations

Component	Risk Phrases	Safety Phrases
Capecitabine	R36/38, R45, R51/53, R61	S22, S36/37/39, S45, S53, S61

SECTION 16: OTHER INFORMATION

OTHER INFORMATION:
PREPARATION INFORMATION:
DISCLAIMER:
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. BioVision, Inc., shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.