



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-816-8129  
8 a.m. to 5 p.m. EST Mon. - Fri.

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## CAPECITABINE RELATED COMPOUND B

Catalog Number: 1090728

Revision Date:

November 16, 2006

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Capecitabine Related Compound B

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

**EMERGENCY OVERVIEW - Reproductive Hazard. As an antineoplastic, this material is a cancer suspect agent.**

**Adverse Effects:** This compound is an intermediate metabolite of capecitabine. Adverse effects of capecitabine may include abdominal or stomach pain; unusual tiredness or weakness; diarrhea; blood disorders; blistering, redness, swelling, numbness, pain, or tingling in palms of hands or bottoms of feet; yellow eye or skin; fever or chills; cough or hoarseness; lower back or side pain; painful or difficult urination; pain, redness, swelling, or sores in mouth and on lips; constipation; loss of appetite; nausea; vomiting; weight loss; dizziness; dry mouth; fainting; increase in heart rate; lightheadedness; rapid breathing; increased thirst; heartburn; red, sore eyes; headache; trouble sleeping; skin rash or itching; and loss of hair. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Overdose effects of capecitabine may include unusual bleeding or bruising and many of the adverse effects listed above.

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization and cancer.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material, dihydropyrimidine dehydrogenase (DPD) deficiency, impaired liver or kidney function, bone marrow depression, chickenpox, herpes zoster, and infection.

**Cross Sensitivity:** Persons sensitive to fluorouracil may be sensitive to this material also.

**Target Organs:** Cardiovascular system, central nervous system, bone marrow

**For additional information on toxicity, see Section 11.**

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### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Capecitabine Related Compound B

**Formula:** C<sub>9</sub>H<sub>11</sub>FN<sub>2</sub>O<sub>5</sub>

**Synonym:** Doxifluridine, 5-DFUR

**Chemical Name:** 5'-Deoxy-5-fluorouridine

**CAS:** 3094-09-5

**RTECS Number:** YU7526000

**Chemical Family:** Pyrimidine analog

**Therapeutic Category:** Antineoplastic

**Composition:** Pure Material

### SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** May cause irritation. Avoid contact. Flush with copious quantities soap and water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

#### Note to Physicians

**Overdose Treatment:** Overdose treatment of fluorouracil (a related compound) should be symptomatic and supportive and may include the following:

1. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first.
2. Administer activated charcoal as a slurry.
3. Monitor bone marrow toxicity, bleeding tendency, and infection. Septicemia may be a fatal complication.
4. Monitor electrolytes for possible electrolyte depletion due to vomiting and diarrhea.
5. Dialysis may be effective in removing this material. [Meditext 2006]

### SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

### SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.

### SECTION 7 - HANDLING AND STORAGE

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors

associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

<b>SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION</b>
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**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety glasses or goggles

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** n/f

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.**

**Appearance and Odor:** White powder

**Odor Threshold:** n/f

**pH:** n/f

**Melting Range:** 186 - 193° C

**Boiling Point:** n/f

**Flash Point:** n/f

**Autoignition Temperature:** n/f

**Evaporation Rate:** n/f

**Upper Flammability Limit:** n/f

**Lower Flammability Limit:** n/f

**Vapor Pressure:** n/f

**Vapor Density:** n/f

**Specific Gravity:** n/f

**Solubility in Water:** n/f

**Fat Solubility:** n/f

**Other Solubility:** n/f

**Partition Coefficient: n-octanol/water:** n/f

**Percent Volatile:** n/f

**Reactivity in Water:** n/f

**Explosive Properties:** n/f

**Oxidizing Properties:** n/f

**Formula:** C<sub>9</sub>H<sub>11</sub>FN<sub>2</sub>O<sub>5</sub>

**Molecular Weight:** 246.20

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### SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** n/f

**Incompatibilities:** Strong oxidizing agents.

**Decomposition Products:** When heated to decomposition material emits toxic fumes of NO<sub>x</sub> and F-. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

### SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: 3390 mg/kg

**Oral Mouse:** LD50: >5000 mg/kg

**Other Toxicity Data:** n/f

**Irritancy Data:** n/f

**Corrosivity:** n/f

**Sensitization Data:** n/f

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** Antimetabolites have been shown to be carcinogenic in animals and may be associated with an increased risk of development of secondary carcinomas when used as antineoplastics in humans.

**Mutagenicity Data:** Capecitabine, a related compound, was not mutagenic in vitro to bacteria in the Ames test or to mammalian cells in the Chinese hamster V79/HPRT gene mutation assay. It was clastogenic in vitro to human peripheral blood lymphocytes but not clastogenic in vivo to mouse bone marrow in the micronucleus test.

**Reproductive and Developmental Effects:** Resorptions and reduced fetal weight occurred in the offspring of pregnant mice administered oral doxifluridine at doses of 50 and 100 mg/kg. Eye defects were increased at the 100 mg dose level.  
Mice given oral capecitabine, a related compound, at doses of 760 mg/kg/day experienced disturbed estrus cycles, which caused a decrease in fertility. In the mice that became pregnant, no fetuses survived at this dose. In males, this dose caused degenerative changes in the testes, including a decrease in the number of spermatocytes and spermatids. Capecitabine caused cleft palate; eye, finger, and/or toe abnormalities; kinky tail; dilation of cerebral ventricles; and embryo death in the offspring of pregnant mice administered 198 mg/kg/day. In pregnant monkeys given capecitabine at a dose of 90 mg/kg/day, fetal death occurred.

### SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** n/f

### SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

### SECTION 14 - TRANSPORT INFORMATION

**Shipping Name:** n/f

**Class:** n/f

**UN Number:** n/f

**Packing Group:** n/f

**Additional Transport Information:** n/f

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<b>SECTION 15 - REGULATORY INFORMATION</b>
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**U.S. Regulatory Information:** n/f**International Regulatory Information:** Hazard code: T  
Risk phrases: R45, R61  
Safety phrases: S36/37/39, S61

<b>SECTION 16 - OTHER INFORMATION</b>
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**Revision:** 16-Nov-06**Previous Revision Date:** 02-Aug-06