

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Capecitabine Tablets USP</b>	
<b>Other means of identification</b>		
<b>Product code</b>	The 150 mg tablet is pink to speckled pink, modified oval, film-coated tablet, debossed with "54 242" on one side, and plain on the other. The 500 mg tablet is pink to speckled pink, modified oval, film coated tablet, debossed with "54 706" on one side, and plain on the other.	
<b>Recommended use</b>	Indicated for Adjuvant Colon Cancer, Metastatic Colorectal Cancer and Metastatic Breast Cancer	
<b>Recommended restrictions</b>	For use in men only.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	West-Ward Pharmaceuticals Corporation	
<b>Address</b>	1809 Wilson Road Columbus, OH 43228 US	
<b>Telephone</b>	(614) 276-4000	
<b>E-mail</b>	Not available.	
<b>Emergency phone number</b>	(614) 276-4000	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Carcinogenicity	Category 1B
	Reproductive toxicity	Category 1B
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Causes skin irritation. Causes serious eye irritation. May cause cancer. May damage fertility or the unborn child.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. Take off contaminated clothing and wash before reuse.	
<b>Storage</b>	Store locked up. Store at 20° to 25°C (68° to 77°F). [see USP Controlled Room Temperature].	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

## 3. Composition/information on ingredients

### Mixtures

Chemical name	CAS number	%
5'-deoxy-5-fluoro-N-[(pentyl-oxo) carbonyl]-cytidine	154361-50-9	0.71

**Composition comments** Refer to Physician's Desk Reference for common components present at <1% All concentrations are in percent by weight. The components are not hazardous or are below required disclosure limits.

#### 4. First-aid measures

##### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

##### Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

##### Eye contact

Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

##### Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

##### Most important symptoms/effects, acute and delayed

Most common side effects include: diarrhea, hand and foot syndrome, nausea, vomiting, abdominal pain, tiredness, weakness, and increased amounts of red blood cell breakdown products (bilirubin) in the blood.

##### Indication of immediate medical attention and special treatment needed

Maintain an open airway and assist ventilation if necessary. Treat coma, seizures, hypotension, and arrhythmias if they occur. Treat nausea and vomiting with metoclopramide and fluid loss caused by gastroenteritis with intravenous crystalloid fluids. Bone marrow depression should be treated with the assistance of an experienced hematologist or oncologist. Extravasation: Immediately stop the infusion and withdraw as much fluid as possible by negative pressure on the syringe. For decontamination administer activated charcoal orally if conditions are appropriate. Gastric lavage is not necessary after small to moderate ingestions if activated charcoal can be given promptly. Because of the rapid intracellular incorporation of these agents, dialysis and other extracorporeal removal procedures are generally not effective.

##### General information

If exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

#### 5. Fire-fighting measures

##### Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

##### Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

##### Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

##### Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

##### Fire fighting equipment/instructions

Use water spray to cool unopened containers.

##### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

##### General fire hazards

No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

##### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**

Minimize dust generation and accumulation. Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage****Precautions for safe handling**

Obtain special instructions before use. Care should be exercised in the handling of this product. Avoid cutting or crushing. Procedures for the proper handling and disposal of this drug should be considered. Do not handle until all safety precautions have been read and understood. Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

Store locked up. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

**8. Exposure controls/personal protection****Occupational exposure limits****US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Components	Type	Value	Form
Dust	PEL	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.

**US. OSHA Table Z-3 (29 CFR 1910.1000)**

Components	Type	Value	Form
Dust	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

**ACGIH**

Components	Type	Value
5'-deoxy-5-fluoro-N-[(pentyl oxy) carbonyl]-cytidine (CAS 154361-50-9)	TWA	0.01 mg/m <sup>3</sup>

**US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
Dust	TWA	3 mg/m <sup>3</sup>	Respirable particles.
		10 mg/m <sup>3</sup>	Inhalable particles.

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

Ventilation should be matched to conditions.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin protection****Hand protection**

For consumer use, no unusual precautions are necessary. The practice of double gloving is supported by research that indicates that many glove materials vary in drug permeability even within lots; therefore, double gloving is recommended.

<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
<b>Respiratory protection</b>	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Pink.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	26 mg/mL at 20°C
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Thermal decomposition can produce Carbon oxides, Nitrogen oxides, Hydrogen fluoride.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Mechanical processing may generate dust. Dust may irritate respiratory system.
<b>Skin contact</b>	May cause skin irritation. Mechanical processing may generate dust. Dust or powder may irritate the skin.
<b>Eye contact</b>	May cause eye irritation. Dust may irritate the eyes.
<b>Ingestion</b>	May irritate and cause stomach pain, vomiting and diarrhea. May cause damage to organs through prolonged or repeated exposure by ingestion.

**Symptoms related to the physical, chemical and toxicological characteristics** Most common side effects include: diarrhea, hand and foot syndrome, nausea, vomiting, abdominal pain, tiredness, weakness, and increased amounts of red blood cell breakdown products (bilirubin) in the blood.

### Information on toxicological effects

**Acute toxicity** Ingestion of large quantities may cause nausea and vomiting. May cause severe diarrhea.

**Skin corrosion/irritation** Mechanical processing may generate dust. Dust or powder may irritate the skin.

**Serious eye damage/eye irritation** May cause eye irritation.

### Respiratory or skin sensitization

**Respiratory sensitization** No sensitizing effects known.

**Skin sensitization** Persons sensitive to fluorouracil may be sensitive to this material also.

**Germ cell mutagenicity** Contains a component that is clastogenic in human lymphocytes.

**Carcinogenicity** May cause cancer. 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.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### NTP Report on Carcinogens

Not listed.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

**Reproductive toxicity** Pregnancy Category D. May damage fertility or the unborn child. 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.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Due to lack of data the classification is not possible.

**Aspiration hazard** Not likely, due to the form of the product.

**Chronic effects** Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

**Further information** See package insert.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
5'-deoxy-5-fluoro-N-[(pentyloxy) carbonyl]-cytidine (CAS 154361-50-9)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	LC50	Oncorhynchus mykiss > 867 mg/l, 96 Hours
<b>Persistence and degradability</b>	Not readily biodegradable.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	The product is slightly soluble in water.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

### 15. Regulatory information

<b>US federal regulations</b>	<p>This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&amp;D or drug use.</p> <p>Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.</p> <p>OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).</p> <p>FDA: Capecitabine Tablets USP, 150mg and 500mg, is an approved prescription medication.</p>
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	03-May-2016
<b>Revision date</b>	-
<b>Version #</b>	01
<b>HMIS® ratings</b>	Health: 2* Flammability: 0 Physical hazard: 0

**References**

- 1) Capecitabine Tablets, Package Insert, West-Ward Pharmaceuticals Corporation, Columbus, Ohio
- 2) PDR – Physicians Desk Reference.
- 3) Ariel Websight. Regulatory and ChemExpert Database.

**Disclaimer**

West-Ward Pharmaceuticals Corporation cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.