



SAFETY DATA SHEET

Section 1: Identification	
Material	Capecitabine Tablets USP 150 mg & 500 mg
Recommended use	Pharmaceutical Product
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Health Hazards	Contains a cytotoxic agent. exposure by all routes of exposure must be avoided. In the workplace, exposure to dusts from product via inhalation and skin contact may cause irritation. Eye contact from dusts can cause mechanical irritation. In therapeutic use, the most common adverse effects reported have included diarrhea, hand-and-foot syndrome, nausea, vomiting, abdominal pain, fatigue/weakness, and excess bilirubin in blood. Therapeutic use can cause bleeding, and bone marrow depression and severe, possibly life-threatening gastrointestinal, liver and cardiovascular effects. Can cause harm to fetus during pregnancy. May cause adverse effects on fertility, based on animal data. This material has shown potential mutagenic effects. These effects may be possible as a result of workplace exposure.
Flammability Hazards	This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon, iron, magnesium, titanium and nitrogen oxides and hydrogen fluoride).
Reactivity Hazards	This product is not reactive
Environmental Hazards	The active ingredient is acutely toxic to algae and chronically toxic to fish. Release of this product to the environment may cause harm to aquatic or terrestrial organisms.
Emergency	Emergency responders must wear personal protective equipment suitable



Recommendations	for the situation to which they are responding
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Capecitabine	154361-50-9
Lactose Anhydrous	63-42-3
Croscarmellose Sodium	74811-65-7
Hypromellose	9004-65-3
Microcrystalline cellulose	9004-34-6
Magnesium Stearate	557-04-0
Opadry Pink	NA
Section 4: First-Aid Measures	
Description of First AID measures	Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.
Skin Exposure:	If skin contact with this product occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.
Eye Exposure	If dusts of this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing
Inhalation	If dusts are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur
Ingestion	If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention



Medical Conditions Aggravated by Exposure	In therapeutic use, pre-existing coronary artery disease, dihydropyrimidine dehydrogenase (DPD) deficiency, Hand-and-Foot Syndrome, hyperbilirubinemia, liver disease, renal impairment, neutropenia or thrombocytopenia may be aggravated. Persons who may have hypersensitivity reactions to this product or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure
Indication of immediate medical attention and special treatment	Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. Although no clinical experience using dialysis as a treatment for acute oral exposure has been reported, dialysis may be of benefit in reducing circulating concentrations of 5'-DFUR, a low-molecular-weight metabolite of the parent compound. Capecitabine-induced diarrhea may respond to standard anti-diarrheal therapy (e.g., loperamide). Patients with severe diarrhea should be closely monitored and given fluid and electrolyte replacement for dehydration as indicated.
Section 5: Fire-Fighting Measures	
Fire extinguishing media	Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product
Unsuitable fire extinguishing media	None known.
Special Hazards arising from the substance	This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, iron, magnesium, sulfur, titanium and nitrogen oxides and hydrogen fluoride).
Explosion Sensitivity to Mechanical Impact	Not applicable
Explosion Sensitivity to Static Discharge	Not sensitive
Special protective actions for Fire-Fighters	Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other



	environmentally sensitive areas.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Avoid generating airborne dusts of this material during spill response procedures as described below.
Protective Equipment Small Spills/Spills in Hoods	Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean incidental spills (e.g. a single container).
Large Spills	For large spills (e.g., a pallet of containers), proper protective equipment, including double nitrile or appropriate gloves, and protective clothing (i.e., disposable Tyvek coveralls). When there is any danger of airborne dusts being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.
Methods for Clean-up and containment Cleanup of Small Spills	Pick-up or wipe-up spilled tablets with damp absorbent sheets to prevent generation of dusts. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water
Large Spills	Restrict access to the spill areas. Gently wet down area and carefully sweep up spilled product, avoiding the generation of airborne dusts. The dispersion of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water
All Spills	Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal



	regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.
Environmental Precautions	Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect
Section 7: Handling and Storage	
Precautions for safe handling	<p>This product contains a cytotoxic agent. All work practices must be designed to reduce Human exposure to the lowest level. All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation.</p> <p>Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this material. Minimize all exposures to this product. Avoid generation of dusts. Areas in which this product is used should be wiped down, so that particulates do not accumulate. Good hygiene practices must be in place for workers handling this material, including change facilities and a work place clothing program. Workers whose clothing may have become contaminated should change into uncontaminated clothing before leaving the work premises.</p> <p>Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Contaminated clothing is required to remain in the work place for cleaning.</p>
Conditions for safe storage	Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F). Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure



	containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
Specified End use(s)	This product is a human pharmaceutical
Protective Practices during maintenance of contaminated Equipment	When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.
Section 8: Exposure Controls/Personal Protection	
Exposure Limits/Control parameters Ventilation and Engineering Controls	General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately
Protective Equipment	The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR 1910.132), equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02, Z94.3-M1982, Industrial Eye and Face Protectors and CSA Standard Z195-02, Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.
Respiratory Protection	Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection



	authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-face piece pressure/demand SCBA or a full face piece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).
Eye Protection	Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations
Hand Protection	Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary, refer to appropriate regulations.
Skin Protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.
Special Note	Any contaminated protective clothing or gloves should be changed immediately and disposed of properly. Hands and wrists should be washed immediately after removing contaminated gloves

Section 9: Physical and Chemical Properties

Physical Form	Tablets
Colour	150 mg – Light peach 500 mg - Peach
Description	Capecitabine tablets USP, 150 mg are light peach colored, capsule shaped, biconvex film coated tablets debossed with '6' on one side and 'H' on the other side. They are supplied as follows: Bottle of 60 tablets NDC 31722-774-60 Capecitabine tablets USP, 500 mg are peach colored, oval shaped, biconvex film coated tablets debossed with '3' on one side and 'H' on the other side. They are supplied as follows: Bottle of 60 tablets NDC 31722-775-60 Bottle of 120 tablets NDC 31722-775-12

Section 10: Stability and Reactivity

Chemical stability	Stable under normal conditions
Decomposition	Products of thermal decomposition may include carbon, iron, magnesium,

Products combustion	sulfur, titanium and nitrogen oxides and hydrogen fluoride
Hydrolysis	None known
Materials with which substance is incompatible	Incompatible with strong oxidizing agents, and strong acids
Possibility of hazardous reaction/polymerization	Will not occur
Conditions to avoid	Exposure to or contact with extreme temperatures, incompatible chemicals
Section 11: Toxicological Information	
Acute toxicity	Not classified based on available information.
Health Effects or Risks From Exposure	
Acute oral toxicity	Acute toxicity estimate: 3,133 mg/kg Method: Calculation method
Acute dermal toxicity	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute oral toxicity	LD50 Oral (Rat): > 2,000 mg/kg
Section 12: Ecological Information	
Toxicity to fish	LC50 (Oncorhynchus mykiss (rainbow trout)): > 867 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: yes NOEC (Oncorhynchus mykiss (rainbow trout)): 867 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: yes
Toxicity to daphnia and other aquatic invertebrates	EC50 (Daphnia magna (Water flea)): > 850 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 GLP: yes Remarks: average measured concentration NOEC (Daphnia magna (Water flea)): 500 mg/l



	<p>Exposure time: 48 h</p> <p>Method: OECD Test Guideline 202</p> <p>GLP: yes</p> <p>Remarks: average measured concentration</p>
Toxicity to microorganisms	<p>EC50 (activated sludge): > 1,000 mg/l</p> <p>Test Type: Respiration inhibition</p> <p>Method: OECD Test Guideline 209</p> <p>GLP: yes</p> <p>Remarks: Barely inhibitory on aerobic bacterial respiration</p>
Section 13: Disposal Considerations	
Waste from residues	<p>The product should not be allowed to enter drains, water courses or the soil.</p> <p>Do not contaminate ponds, waterways or ditches with chemical or used container.</p> <p>Send to a licensed waste management company.</p>
Contaminated packaging	<p>Empty remaining contents.</p> <p>Dispose of as unused product.</p> <p>Empty containers should be taken to an approved waste handling site for recycling or disposal.</p> <p>Do not re-use empty containers.</p>
Section 14: Transport Information	
<p>UNRTDG</p> <p>Not regulated as a dangerous good</p> <p>IATA-DGR</p> <p>Not regulated as a dangerous good</p> <p>IMDG-Code</p> <p>Not regulated as a dangerous good</p> <p>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</p> <p>Not applicable</p> <p>Domestic regulation</p>	



49 CFR

Not regulated as a dangerous good

Section 15: Regulatory Information

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Germ cell mutagenicity

Carcinogenicity

Reproductive toxicity

Section 16: Other Information

Issue Date : 24-04-2024

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.