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Product Name	Capecitabine Tablets USP 150 mg and 500 mg	

1. Product Information

Product Name: Capecitabine Tablets USP 150 mg and 500 mg

2. Composition/Information on Ingredients

C.A.S. No : 154361-50-9
Molecular Formula : $C_{15}H_{22}FN_3O_6$
Molecular Weight : 359.35.
Chemical Name : 5'-deoxy-5-fluoro-N-[(pentoxo) carbonyl]-cytidine.

3. Hazards Identification

Exposure: Inhalation, Ingestion, Skin contact, Eye contact

Target Organs: eye, skin, mucous membranes, gastrointestinal system

Acute Effects: May cause eye irritation., May cause skin irritation., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

Chronic Effects: May cause skin irritation.

Carcinogenicity: formulation not listed by NTP, IARC or OSHA

GHS Classification Health Hazards:

3.5 Germ cell mutagenicity (Category 2)

H341 Suspected of causing genetic defects.

3.6 Carcinogenicity (Category 1B)

H350 May cause cancer.

3.7 D Reproductive toxicity (Category 1B)

H360D May damage the unborn child.

3.7 F Reproductive toxicity (Category 1B)


H360F May damage fertility.

Signalword: Danger

Label:

Precautionary statements:

- P201 Obtain special instructions before use.
- P260 Do not breathe dust
- P281 Use personal protective equipment as required.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.

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Additional Health Information - Some components of this product are considered potential reproductive effectors at high dosage. Refer to Section 11 (Toxicological information) for additional information on this product.

- The most common dose-dependent adverse effects associated with therapeutic treatments include diarrhea, nausea, vomiting, sores in mouth and throat, abdominal pain, constipation, loss of appetite, dehydration, rash and dry, itchy or discolored skin.
- Additional effects may include nail problems, hair loss, tiredness, weakness, dizziness, headache, fever, chest, back, joint and muscle pain, trouble sleeping, taste problems and palms of the hands or soles of the feet tingle, become painful or swollen.
- Cytostatics in general have to be classified as potentially carcinogenic, teratogenic and mutagenic. During handling any occupational exposure as well as environmental contamination have to be avoided.

4. First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.


Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. Emergency Overview

Major Health Hazards: No major health hazards are known.

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6. Fire Fighting Measures

- Suitable extinguishing media** - Water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid)** - Not applicable
- Specific hazards**
- Very high probability of ignition of dust whirled up
 - Formation of toxic and corrosive combustion gases (hydrogen fluoride, nitrogen oxides) possible
 - Consider danger for the environment: dike spilled liquid
- Protection of fire-fighters**
- Precipitate gases/vapours/mists with water spray
 - Use self-contained breathing apparatus
 - Avoid skin contact

7. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.


Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

8. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

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9. Exposure Controls/Personal Protection

- Threshold value (USA) air
- ACGIH-TLV: 10 mg/m³
 - OSHA-PEL: 15 mg/m³ (total dust)
 - OSHA-PEL: 5 mg/m³ (respirable fraction)
 - NIOSH-REL: 10 mg/m³ (total dust)
 - NIOSH-REL: 5 mg/m³ (respirable fraction)
- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ (defined as 8-hour time-weighted average)
- Personal protective equipment**
- Hand protection
- Protective gloves (eg made of neoprene, nitrile or butyl rubber)
- Eye protection
- Safety glasses
- General protective and hygiene measures
- Instruction of employees mandatory
 - Shower after work recommended

10. Physical Properties

150 mg : Light peach to peach colored, oblong shaped biconvex film coated tablets, debossed with "C" on one side and "150" on other side.

500 mg: Light peach to peach colored, oblong shaped biconvex film coated tablets, debossed with "C" on one side and "500" on other side.

11. Stability and Reactivity

Stability: Stable under normal conditions of use.


Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

12. Toxicological Information

- Acute toxicity
- LD50 > 2'000 mg/kg (oral, rat)
 - LD50 > 2'000 mg/kg (oral, rat)
- Sensitization
- Slightly sensitizing (several species)
- Subchronic toxicity
- High doses may damage proliferating cells (e.g. bone marrow, leucocytes)
- Mutagenicity
- May cause mutations in vitro (clastogenic effect in lymphocytes) lymphocyte test; evidence of clastogenicity
- Reproductive toxicity
- Suspected to be teratogenic and to lower parental fertility
- Note
- May cause diarrhea, nausea, vomiting, loss of appetite, irritation of mucous membranes and alteration of the hemopoietic system (leukopenia) in dependance of the dose
 - Cytostatics are potentially carcinogenic


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13. Ecological Information

Inherent biodegradability	- inherently biodegradable evidence for prior abiotic primary degradation as a rate-limiting process 29 %, 28 d 44 %, 56 d 55 %, 84 d (MITI Test II, OECD No. 302 C)
Ecotoxicity	- barely toxic for algae (<i>Selenastrum capricornutum</i>) EbC50 (72 h) 58 mg/l ErC50 (72 h) 200 mg/l NOEC (72 h) 14 mg/l (OECD No. 201) barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC50 (48 h) > 850 mg/l NOEC (48 h) 500 mg/l - barely toxic for fish (rainbow trout) LC50 (96 h) > 867 mg/l NOEC (96 h) 867 mg/l - barely inhibitory on aerobic bacterial respiration EC50 > 1000 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)
Mobility	- medium adsorption to activated sludge, medium mobility (water-activated sludge, 3 h) Kd = 272 l/kg (activated sludge) (Adsorption to activated sludge in biodegradability test)

14. Disposal Considerations

Waste from residues	- Observe local/national regulations regarding waste disposal - Incinerate in qualified installation with flue gas scrubbing - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.
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15. Transport Information


Note : Not classified by transport regulations, proper shipping name non-regulated

16. Regulatory Information

TSCA Status - FDA Exemption - not on inventory
 Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
 - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
 - State and local regulations vary and may impose additional reporting requirements

17. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

	Prepared by	Checked by
Sign	<i>C.R.</i>	
Date	12/03/2015	12/03/2015