

## MATERIAL SAFETY DATA SHEET

### 1. Identification

**Product identifier** Capecitabine tablets

#### Other means of identification

**Synonyms** None identified

**Recommended use** Indicated for Adjuvant Colon Cancer, Metastatic Colorectal Cancer and Metastatic Breast Cancer

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

**Company name** Reliance Life Sciences Pvt. Ltd.

**Address** Dhirubhai Ambani Life Sciences Center (DALC),  
R-282, TTC Area of MIDC, Thane – Belapur Road,  
Rabale, Navi Mumbai – 400701,  
Maharashtra, India.

**Emergency phone number** + 91-22-6767 8000

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### 2. Hazard(s) identification

#### 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 Reproductive toxicity (Category 1B) - H360D May damage the unborn child.

3.7 Reproductive toxicity (Category 1B) - H360F May damage fertility.

#### Label elements



**Signal word** Danger

#### Precautionary statement

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.

#### Other Hazards

Note 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.

### 3. Composition/information on ingredients

Components	CAS number	Quantity
Capecitabine	154361-50-9	500 mg/ 150 mg
Anhydrous lactose	63-42-3	Q.s.
Microcrystalline cellulose	9004-34-6	Q.s.
Croscarmellose sodium	74811-65-7	Q.s.
Hypromellose	9004-65-3	Q.s.
Magnesium stearate	557-04-0	Q.s.

### 4. First-aid measures

**Immediate medical attention needed.** Yes.

**Eye Contact** Rinse immediately with tap water for 20 minutes – open eyelids forcibly.

Consult a physician if irritation persists.

**Skin Contact** Remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents.

Consult a physician if irritation persists.

**Inhalation** Remove the casualty to fresh air and keep him/her calm.  
Get medical treatment.

<b>Ingestion</b>	Summon a physician immediately.  Let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times
<b>Most important symptoms/effects acute and delayed</b>	No information available.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.  In case of accidental exposure, keep a sample of urine in order to determine the content of fluoro-b-alanine

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water spray jet, dry powder, foam, carbon dioxide
<b>Flash point (Liquid)</b>	Not applicable
<b>Specific hazards arising from the substance or mixture</b>	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.
<b>Advice for firefighters</b>	Precipitate gases/vapours/mists with water spray.
<b>Protection of fire-fighters</b>	Use self-contained breathing apparatus.  Avoid skin contact.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Ensure adequate ventilation.  Keep people away and stay on the upwind side.
<b>Environmental precautions</b>	Do not allow to enter drains or waterways.

If the substance reaches waters or the sewer system, inform the competent authority.

The solvent should be held back due to environmental protection.

**Methods and material  
for containment and  
cleaning up**

Collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

**7. Handling and storage**

**Precautions for safe  
Handling**

Processing in closed systems, if possible superposed by inert gas (e.g. nitrogen).

Avoid formation and deposition of dust.

**Conditions for safe  
storage including any  
Incompatibilities**

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15°C to 30°C (59° to 86°F).[See USP Controlled Room Temperature].

**8. Exposure controls/personal protection**

**Control parameters**

**Threshold value (USA)  
air**

- ACGIH-TLV: 10 mg/m<sup>3</sup>
- OSHA-PEL: 5 mg/m<sup>3</sup> (respirable fraction)
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust)
- NIOSH-REL: 5 mg/m<sup>3</sup> (respirable fraction)
- NIOSH-REL: 10 mg/m<sup>3</sup> (total dust)

**Threshold value air**

- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m<sup>3</sup> (defined as 8-hour time-weighted average)

**Exposure controls**

**General protective and  
hygiene measures**

- Instruction of employees mandatory.
- Shower after work recommended.

**Hand protection**

- Wear protective gloves (eg made of neoprene, nitrile or butyl rubber)

**Eye protection**

- Wear safety glasses

## 9. Physical and chemical properties

<b>Appearance</b>	500 mg Tablets; film coated, biconvex, oblong, tablets having "C500" debossed on one side and plain on the other side. 150 mg Tablets; film coated, biconvex, oblong, tablets having "C150" debossed on one side and plain on the other side
<b>Color</b>	500 mg (Peach) 150 mg (Light peach)
<b>Partition coefficient</b>	Log P <sub>ow</sub> ~4.5 (n-octanol/water) pH 7.4
<b>Other information</b>	
<b>Molecular weight</b>	359.35 (Capecitabine)
<b>Molecular formula</b>	C <sub>15</sub> H <sub>22</sub> FN <sub>3</sub> O <sub>6</sub> (Capecitabine)

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under conditions mentioned in 7.
<b>Possibility of hazardous reactions</b>	No information available.
<b>Conditions to avoid</b>	No information available.
<b>Incompatible materials</b>	No information available.
<b>Hazardous decomposition</b>	No information available.
<b>Products</b>	

## 11. Toxicological information

### Information on toxicological effects

<b>Acute toxicity</b>	- LD50 > 2'000 mg/kg (oral, rat)
<b>Subchronic toxicity</b>	- High doses may damage proliferating cells (e.g. bone marrow, leucocytes)
<b>Local effects</b>	- No information available
<b>Sensitization</b>	- Slightly sensitizing (several species)
<b>Mutagenicity</b>	-May cause mutations in vitro (clastogenic effect in lymphocytes)

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	-Lymphocyte test; evidence of clastogenicity.
<b>Carcinogenicity</b>	- No information available
<b>Reproductive toxicity</b>	- Suspected to be teratogenic and to lower parental fertility
<b>Note</b>	- Potentially carcinogenic - May cause diarrhea, nausea, vomiting, loss of appetite, irritation of mucous membranes and alteration of the hemopoietic system (leukopenia) in dependance of the dose
<b>Potential Health Effects</b>	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Carcinogenicity: not listed by NTP, IARC or OSHA

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## 12. Ecological information

<b>Ecotoxicity</b>	- 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)
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## Persistence and degradability

<b>Inherent biodegradability</b>	- Inherently biodegradable evidence for prior abiotic primary degradation as a rate-limiting process 29 %, 28 d
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44 %, 56 d

55 %, 84 d

(MITI Test II, OECD No. 302 C)

**Bioaccumulative potential** No information available

**Mobility in soil** - 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)

**Results of PBT and vPvB assessment** No information available

**Other adverse effects** No information available

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### 13. Disposal considerations

Must dispose of in accordance with all local, state, and federal regulations.

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### 14. Transport information

**DOT** Not regulated as dangerous goods.

**IATA** Not regulated as dangerous goods.

**IMDG** Not regulated as dangerous goods.

**Transport in bulk** Not applicable.

**according to Annex II  
of MARPOL 73/78 and  
the IBC code.**

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### 15. Regulatory information

**Safety, health and environmental  
regulations/legislation  
specific for the substance  
or mixture**



**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 and to local officials.

- State and local regulations vary and may impose additional reporting requirements.

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

**Sources of data** Information from published literature.

**Issue Date** 06 Jul 2020

**Version** 02

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 information from published literature.