

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

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.

Ingestion	Summon a physician immediately. Let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times
Most important symptoms/effects acute and delayed	No information available.
Indication of immediate medical attention and special treatment needed	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

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation. Keep people away and stay on the upwind side.
Environmental precautions	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
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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 ³ - OSHA-PEL: 5 mg/m ³ (respirable fraction) - OSHA-PEL: 15 mg/m ³ (total dust) - NIOSH-REL: 5 mg/m ³ (respirable fraction) - NIOSH-REL: 10 mg/m ³ (total dust)
Threshold value air	- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³ (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

Appearance	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
Color	500 mg (Peach) 150 mg (Light peach)
Partition coefficient	Log P_{ow} ~4.5 (n-octanol/water) pH 7.4
Other information	
Molecular weight	359.35 (Capecitabine)
Molecular formula	<chem>C15H22FN3O6</chem> (Capecitabine)

10. Stability and reactivity

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

11. Toxicological information

Information on toxicological effects

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

	-Lymphocyte test; evidence of clastogenicity.
Carcinogenicity	- No information available
Reproductive toxicity	- Suspected to be teratogenic and to lower parental fertility
Note	<ul style="list-style-type: none">- 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
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Inhalation, Ingestion, Skin contact, Eye contact- Carcinogenicity: not listed by NTP, IARC or OSHA

12. Ecological information

Ecotoxicity	<ul style="list-style-type: none">- 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

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)

Bioaccumulative potential No information available

Mobility in soil - medium adsorption to activated sludge, medium mobility
(water activated sludge, 3 h)
 $K_d = 272 \text{ l/kg}$ (activated sludge)
(Adsorption to activated sludge in biodegradability test)

Results of PBT and No information available

vPvB assessment

Other adverse No information available
effects

13. Disposal considerations

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

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.

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.

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

Sources of data Information from published literature.

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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.