

Safety Data Sheet

XELODA(R) Tablets (500 mg)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name XELODA(R) Tablets (500 mg)
Product code SAP-10073476
Synonyms - XELODA Film Coated Tablets 500 mg
- XELODA F.C. Tablets 500 mg

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance (cytostatic)

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

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SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

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 Reproductive toxicity (Category 1B)
H360D May damage the unborn child.
- 3.7 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.

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.

SECTION 3: Composition/information on ingredients

Characterization

pharmaceutical active substance in the group of fluorinated cytosines

*1

Ingredients

Concentration

**GHS-Classification
(pure ingredient)**

Capecitabine
154361-50-9

~ 81 %

- Combustible dust (No category), USH003
- Germ cell mutagenicity (Category 2), H341
- Carcinogenicity (Category 1B), H350
- Reproductive toxicity (Category 1B), H360D
- Reproductive toxicity (Category 1B), H360F

Microcrystalline cellulose
9004-34-6

~ 4 %

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Magnesium stearate ~ 1 %
557-04-0

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.

*1 referring to: Capecitabine

SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|--------------|---|
| Eye contact | <ul style="list-style-type: none">- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly- consult a physician if irritation persists |
| Skin contact | <ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents- consult a physician if skin irritation persists |
| Inhalation | <ul style="list-style-type: none">- remove the casualty to fresh air and keep him/her calm- get medical treatment |
| Ingestion | <ul style="list-style-type: none">- summon a physician immediately- let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times |

4.2. Most important symptoms and effects, both acute and delayed

Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician

- treat symptomatically
- in case of accidental exposure, keep a sample of urine in order to determine the content of fluoro- β -alanine

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

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

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5.3. Advice for firefighters

- Protection of fire-fighters
- precipitate gases/vapours/mists with water spray
 - use self-contained breathing apparatus
 - avoid skin contact

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Personal precautions
- ensure adequate ventilation
 - keep people away and stay on the upwind side

6.2. Environmental precautions

- Environmental protection
- 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

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up
- collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Technical measures
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
 - avoid formation and deposition of dust

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions
- below 30 °C
 - protected from light and humidity
- Validity
- 3 years, ≤30 °C, see "best use before" date stated on the label

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- Threshold value (USA) air
- ACGIH-TLV: 10 mg/m³ *2
 - OSHA-PEL: 15 mg/m³ (total dust) *2
 - OSHA-PEL: 5 mg/m³ (respirable fraction) *2
 - NIOSH-REL: 10 mg/m³ (total dust) *2
 - NIOSH-REL: 5 mg/m³ (respirable fraction) *2

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Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ (defined as 8-hour time-weighted average) *1

8.2. Exposure controls

General protective and hygiene measures - instruction of employees mandatory
- shower after work recommended

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

Eye protection - safety glasses

*1 referring to: Capecitabine

*2 referring to: Microcrystalline cellulose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color country-specific

Form oblong, biconvex tablet

Solubility 26'000 mg/l, water (20 °C) *1
207'000 mg/l, ethanol (20 °C) *1

Partition coefficient log P_{ow} ~ 4.5 (n-octanol/water) pH 7.4 *1

Melting temperature 116 to 117 °C *1

9.2. Other information

Note - no information available

*1 referring to: Capecitabine

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

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10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀ > 2'000 mg/kg (oral, rat)	*1
	- LD ₅₀ > 2'000 mg/kg (oral, rat)	*3
Subchronic toxicity	- high doses may damage proliferating cells (e.g. bone marrow, leucocytes)	*1
Local effects	- no information available	
Sensitization	- slightly sensitizing (several species)	*1
Mutagenicity	- may cause mutations in vitro (clastogenic effect in lymphocytes)	*1
	- lymphocyte test; evidence of clastogenicity	*1
Carcinogenicity	- no information available	
Reproductive toxicity	- suspected to be teratogenic and to lower parental fertility	*1
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
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	*1
	- cytostatics are potentially carcinogenic	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA	

*1 referring to: Capecitabine

*3 referring to: Magnesium stearate

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SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for algae (<i>Selenastrum capricornutum</i>) EbC ₅₀ (72 h) 58 mg/l ErC ₅₀ (72 h) 200 mg/l NOEC (72 h) 14 mg/l (OECD No. 201)	*1
	- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC ₅₀ (48 h) > 850 mg/l NOEC (48 h) 500 mg/l	*1
	- barely toxic for fish (rainbow trout) LC ₅₀ (96 h) > 867 mg/l NOEC (96 h) 867 mg/l	*1
	- barely inhibitory on aerobic bacterial respiration EC ₅₀ > 1000 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*1

12.2. 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)	*1
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12.3. Bioaccumulative potential

Note	- no information available
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12.4. Mobility in soil

Mobility	- medium adsorption to activated sludge, medium mobility (water-activated sludge, 3 h) K _d = 272 l/kg (activated sludge) (Adsorption to activated sludge in biodegradability test)	*1
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12.5. Results of PBT and vPvB assessment

Note	- no information available
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12.6. Other adverse effects

Note	- no information available
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*1 referring to: Capecitabine

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues
- return to supplier or hand over to authorized disposal company
 - 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.

SECTION 14: Transport information

- Note
- not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. 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.

SECTION 16: Other information

- Safety-lab number
- BS-6606 *1
 - BS-8569 *1

Full text of H-Statements referred to under section 3

- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- H360D May damage the unborn child.
- H360F May damage fertility.
- USH003 May form combustible dust concentrations in the air

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- Note
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
- Edition documentation
- changes from previous version in sections 15
- *1 referring to: Capecitabine

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.