

**XELODA(R) Tablets (500 mg)**

Version 1.5                      Revision Date: 01-28-2020                      Date of last issue: 06-10-2017  
Date of first issue: 08-04-2015

**SECTION 1. IDENTIFICATION**

Product name                      : XELODA(R) Tablets (500 mg)  
Product code                      : 00010073476  
Common name(s), syno-        : XELODA Film Coated Tablets 500mg  
nym(s) of the substance        XELODA F.C. Tablets 500mg

**Manufacturer or supplier's details**

Company name of supplier       : Genentech, Inc.  
Address                            : DNA Way 1  
    94080 South San Francisco  
    CA  
    USA  
Telephone                         : 001-(650) 225-1000  
E-mail address                    : info.sds@roche.com  
Emergency telephone            :  
Emergency telephone num-       : US Chemtrec phone                      (800)-424-9300  
ber

**Recommended use of the chemical and restrictions on use**


Recommended use                : Formulated pharmaceutical active substance  
Restrictions on use               : For professional users only.

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Germ cell mutagenicity         : Category 2  
Carcinogenicity                 : Category 1B  
Reproductive toxicity         : Category 1B

**GHS label elements**

Hazard pictograms              : 

Signal Word                      : Danger  
Hazard Statements               : H341 Suspected of causing genetic defects.  
    H350 May cause cancer.  
    H360FD May damage fertility. May damage the unborn child.  
Precautionary Statements     : **Prevention:**  
    P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Capecitabine	154361-50-9	78.4
D-Glucose, 4-O-.beta.-D-galactopyranosyl-	63-42-3	8.2
Cellulose	9004-34-6	3.8
Croscarmellose sodium	74811-65-7	3.1
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3	2.3
non hazardous compounds	Not Assigned	1.96
Octadecanoic acid, magnesium salt (2:1)	557-04-0	1.4
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	<= 0.84

**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.

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- Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Suspected of causing genetic defects.  
May cause cancer.  
May damage fertility. May damage the unborn child.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Hydrogen fluoride  
Nitrogen oxides (NOx)  
Carbon monoxide
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for : Keep in suitable, closed containers for disposal.

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containment and cleaning up

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : to 25 °C  
Protect against light.  
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Blister packages

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Capecitabine	154361-50-9	IOEL	0.01 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL

# SAFETY DATA SHEET

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		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3 (Titanium dioxide)	ACGIH

**Engineering measures** : No data available

### Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees mandatory

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : pink

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Odor	:	Not applicable
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	241 - 243 °F / 116 - 117 °C
Boiling point/boiling range	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.

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Incompatible materials : No data available

Hazardous decomposition products : No data available

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**Acute oral toxicity : Acute toxicity estimate: 3,133 mg/kg  
Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method**Components:****Capecitabine:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

**Octadecanoic acid, magnesium salt (2:1):**

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**

Acute oral toxicity : LD50 (Rat): &gt; 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): &gt; 10,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Capecitabine:**

Remarks : No data available

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**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Suspected of causing genetic defects.

**Components:**

**Capecitabine:**

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
		Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 487 Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: positive
Germ cell mutagenicity - Assessment	:	In vitro tests showed mutagenic effects

**Carcinogenicity**

May cause cancer.

**Components:**

**Capecitabine:**

Species	:	laboratory animal
Result	:	Presumed to have carcinogenic potential for humans
Carcinogenicity - Assessment	:	Presumed to have carcinogenic potential for humans

**Cellulose:**

Remarks	:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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<b>IARC</b>	Group 2B: Possibly carcinogenic to humans Titanium oxide (TiO2)	13463-67-7
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<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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<b>NTP</b>	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### Capecitabine:

Effects on fertility : Species: Mouse, females  
Application Route: Oral  
Dose: 760 mg/kg bw/day  
Symptoms: Effects on mating performance, Effects on fertility.  
Result: female reproductive effects

Species: Mouse, males  
Application Route: Oral  
Dose: 760 mg/kg bw/day  
Symptoms: Testicular effects  
Target Organs: Testis, Epididymis, spermatocytes

Effects on fetal development : Test Type: reproductive and developmental toxicity study  
Species: Mouse  
Result: Teratogenic effects.

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

Presumed human reproductive toxicant

### STOT-single exposure

Not classified based on available information.

### Components:

#### Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

### STOT-repeated exposure

Not classified based on available information.

### Components:

#### Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Capecitabine:

No data available

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No data available

**Experience with human exposure****Components:****Capecitabine:**

General Information : Target Organs: Gastro-intestinal system  
Symptoms: Diarrhea, Vomiting, constipation, decrease in appetite

Target Organs: Bone marrow  
Symptoms: decreased activity

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Capecitabine:**

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  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: average measured concentration

Toxicity to algae/aquatic plants : EbC50 (Selenastrum capricornutum (green algae)): 58 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

ErC50 (Selenastrum capricornutum (green algae)): 200 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 14 mg/l  
Exposure time: 72 h

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Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (Daphnia magna (Water flea)): > 112 mg/l  
Exposure time: 21 d

Method: OECD Test Guideline 211

GLP: yes

Remarks: average measured concentration

NOEC (Daphnia magna (Water flea)): 112 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

GLP: yes

Remarks: average measured concentration

Toxicity to microorganisms : EC50 (activated sludge): &gt; 1,000 mg/l

Test Type: Respiration inhibition

Method: OECD Test Guideline 209

GLP: yes

Remarks: Barely inhibitory on aerobic bacterial respiration

**Cellulose:****Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

**Octadecanoic acid, magnesium salt (2:1):****Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Titanium oxide (TiO<sub>2</sub>):**Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 48 hToxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l  
Exposure time: 720 h**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

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Biodegradability

: Concentration: 30 mg/l  
Result: Inherently biodegradable.  
Biodegradation: 29 %  
Exposure time: 28 d  
Method: OECD Test Guideline 302C  
GLP: noConcentration: 30 mg/l  
Biodegradation: 44 %  
Exposure time: 56 d  
Method: OECD Test Guideline 302C  
GLP: noConcentration: 30 mg/l  
Biodegradation: 55 %  
Exposure time: 84 d  
Method: OECD Test Guideline 302C  
GLP: noResult: Not readily biodegradable.  
Biodegradation: 92.6 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
GLP: yes  
Remarks: The 10 day time window criterion is not fulfilled.Physico-chemical removability : Method: OECD Test Guideline 302C  
Remarks: Not abiotically degradable**Bioaccumulative potential****Components:****Capecitabine:**Partition coefficient: n-octanol/water : log Pow: ca. 4.5  
pH: 7.4**Cellulose:**

Partition coefficient: n-octanol/water : Remarks: No data available

**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n-octanol/water : log Pow: 0.8  
Method: OECD Test Guideline 107**Titanium oxide (TiO<sub>2</sub>):**

Partition coefficient: n-octanol/water : Remarks: No data available

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**Mobility in soil**

**Components:**

**Capecitabine:**

Distribution among environmental compartments : Medium: Sludge  
Kd: 272 ml/g

**Other adverse effects**

**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life.

**Components:**

**Capecitabine:**

Results of PBT and vPvB assessment : This substance is not considered to be very persistent and very bioaccumulating (vPvB).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life.

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

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**UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know**

**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**

Components	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : Germ cell mutagenicity  
 Carcinogenicity  
 Reproductive toxicity

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations**

**Massachusetts Right To Know**

Capecitabine	154361-50-9
Cellulose	9004-34-6

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**Pennsylvania Right To Know**

Capecitabine	154361-50-9
D-Glucose, 4-O-.beta.-D-galactopyranosyl-	63-42-3
Cellulose	9004-34-6
Croscarmellose sodium	74811-65-7

**Maine Chemicals of High Concern**

Capecitabine	154361-50-9
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**Vermont Chemicals of High Concern**

Capecitabine	154361-50-9
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**Washington Chemicals of High Concern**

Capecitabine	154361-50-9
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**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO<sub>2</sub>), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Octadecanoic acid, magnesium salt (2:1)	557-04-0

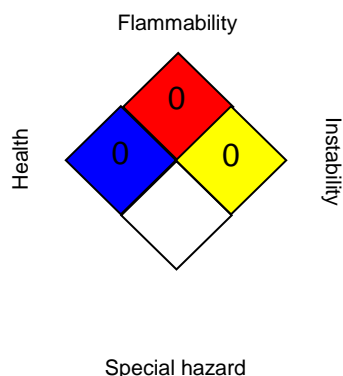
**The ingredients of this product are reported in the following inventories:**

- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
  - Capecitabine
  - Croscarmellose sodium
  - non hazardous compounds
- AICS : Not in compliance with the inventory
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Substance(s) not listed on TSCA inventory

**TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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<b>HEALTH</b>	*	<b>1</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable



# SAFETY DATA SHEET

## **XELODA(R) Tablets (500 mg)**

Version  
1.5

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Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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