

XELODA(R) Tablets (500 mg)Version
1.6Revision Date:
10-20-2021Date of last issue: 01-28-2020
Date of first issue: 08-04-2015**SECTION 1. IDENTIFICATION**

Product name : XELODA(R) Tablets (500 mg)

Product code : 00010073476

Common name(s),
synonym(s) of the substance : XELODA Film Coated Tablets 500mg
XELODA F.C. Tablets 500mg**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone : US Chemtrec phone (800)-424-9300
number**Recommended use of the chemical and restrictions on use**

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (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:**

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P201 Obtain special instructions before use.
 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 ₂)	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.

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- Remove contact lenses.
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
Carbon oxides
- 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

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respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

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

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				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
		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 particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	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 (Titanium dioxide)	10 mg/m3	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Capecitabine	Surface waters	0.2 µg/l
	Remarks: Based on chronic data	

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

In case of contact through splashing:
Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : pink

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

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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

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.

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 method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Capecitabine:

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Cellulose:

Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

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Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Titanium oxide (TiO₂):Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Titanium oxide (TiO₂):**Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified based on available information.

Components:**Capecitabine:**

Remarks : No data available

Titanium oxide (TiO₂):Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Titanium oxide (TiO₂):**Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

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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.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO₂) 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP 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.

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Capecitabine:

- Effects on fertility : Species: Mouse, females
Application Route: Oral

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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

Octadecanoic acid, magnesium salt (2:1):

No data available

Experience with human exposure

Components:

Capecitabine:

General Information : Target Organs: Gastro-intestinal system

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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
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 |

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 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): > 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 (TiO₂):

 Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
 Exposure time: 96 h
 Test Type: static test

 LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
 Exposure time: 96 h
 Test Type: semi-static test
 Method: OECD Test Guideline 203

 Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
 Exposure time: 48 h
 Test Type: static test
 Method: OECD Test Guideline 202

 Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
 Exposure time: 72 h
 Test Type: static test
 Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l

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Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Capecitabine:

Biodegradability : Concentration: 30 mg/l
Result: Inherently biodegradable.
Biodegradation: 29 %
Exposure time: 28 d
Method: OECD Test Guideline 302C
GLP: no

Concentration: 30 mg/l
Biodegradation: 44 %
Exposure time: 56 d
Method: OECD Test Guideline 302C
GLP: no

Concentration: 30 mg/l
Biodegradation: 55 %
Exposure time: 84 d
Method: OECD Test Guideline 302C
GLP: no

Result: 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

Titanium oxide (TiO2):

Biodegradability : Remarks: Not applicable

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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

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107

Titanium dioxide:

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

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.

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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

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

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

This material does not contain any components with a section 302 EHS TPQ.

- SARA 311/312 Hazards** : Germ cell mutagenicity
Carcinogenicity
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SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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 SOCOMI 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations
Massachusetts Right To Know

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

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), which is/are known to the State of California to cause cancer. For more information go to 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:

AIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

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Capecitabine

Croscarmellose sodium

non hazardous compounds

- 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 : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

SAFETY DATA SHEET

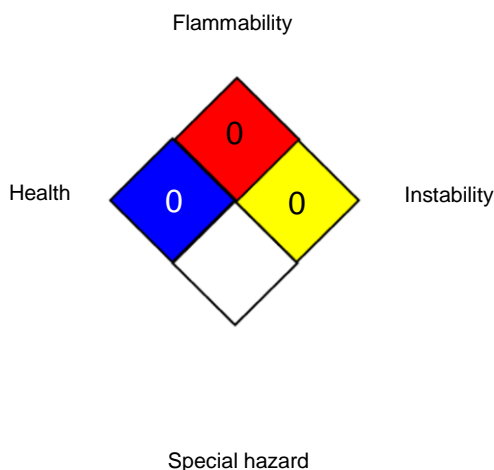
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NFPA 704:



HMIS® IV:

HEALTH	*	1
FLAMMABILITY	0	
PHYSICAL HAZARD	0	

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

AIIIC - Australian Inventory of Industrial Chemicals; 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 Effect Loading Rate; NTP - National Toxicology

XELODA(R) Tablets (500 mg)

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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; TECl - Thailand Existing Chemicals 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 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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