SECTION 1. IDENTIFICATION

Product name : XELODA(R) Tablets (150 mg)
Product code : 00010075152
Common name(s), synonym(s) of the substance : XELODA Film Coated Tablets 150 mg
                                      XELODA F.C. Tablets 150 mg
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 number : US Chemtrec phone (800)-424-9300

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:
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

Version 1.3  Revision Date: 10-20-2021  Date of last issue: 01-28-2020

Date of first issue: 02-02-2017

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capecitabine</td>
<td>154361-50-9</td>
<td>77.1</td>
</tr>
<tr>
<td>D-Glucose, 4-O-beta-D- galactopyranosyl</td>
<td>63-42-3</td>
<td>8.0</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>3.7</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>3.1</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>3.1</td>
</tr>
<tr>
<td>Cellulose, 2-hydroxypropyl methyl ether</td>
<td>9004-65-3</td>
<td>2.3</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.4</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt;= 1.3</td>
</tr>
</tbody>
</table>

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 : Immediately flush eye(s) with plenty of water.
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.  
Rinse mouth with water.  

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 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capecitabine</td>
<td>154361-50-9</td>
<td>IOEL</td>
<td>0.01 mg/m3</td>
<td>Roche Industrial</td>
</tr>
</tbody>
</table>
## SAFETY DATA SHEET

### XELODA(R) Tablets (150 mg)

<table>
<thead>
<tr>
<th>Hygiene Committee (RIHC)</th>
<th>TWA</th>
<th>TWA (Respirable)</th>
<th>TWA (total)</th>
<th>TWA (total dust)</th>
<th>TWA (respirable fraction)</th>
<th>TWA (Total dust)</th>
<th>TWA (Total dust)</th>
<th>TWA (Total dust)</th>
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</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>TWA (total dust)</td>
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</tr>
<tr>
<td>Octadecanoic acid,</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>TWA</td>
<td>3 mg/m³</td>
<td>TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>TWA (Total dust)</td>
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<tr>
<td>magnesium salt (2:1)</td>
<td></td>
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</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA</td>
<td>15 mg/m³</td>
<td>TWA (total dust)</td>
<td>10 mg/m³</td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>TWA (Titanium dioxide)</td>
</tr>
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</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC):**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capecitabine</td>
<td>Surface waters</td>
<td>0.2 µg/l</td>
<td>Based on chronic data</td>
</tr>
</tbody>
</table>

**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
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 : No data available
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) :
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>10-20-2021</td>
<td>01-28-2020</td>
</tr>
</tbody>
</table>

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

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: 3,185 mg/kg Method: Calculation method
Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist 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

Octadecanoic acid, magnesium salt (2:1):
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 425
Acute 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

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.
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

Components:

Capecitabine:
Effects on fertility:
Species: Mouse, females
Application Route: Oral
Dose: 760 mg/kg bw/day
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:
Species: Mouse
Test Type: reproductive and developmental toxicity study
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
- 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to algae/aquatic</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>XELODA(R) Tablets (150 mg)</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 112 mg/l</td>
<td>EC50 (activated sludge): &gt; 1,000 mg/l</td>
<td></td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 1,000 mg/l</td>
<td>LC50 (Daphnia magna (Water flea)): &gt; 1,000 mg/l</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 48 h</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100</td>
</tr>
<tr>
<td></td>
<td>GLP: yes</td>
<td>GLP: yes</td>
<td></td>
<td>GLP: yes</td>
<td>GLP: yes</td>
<td></td>
</tr>
</tbody>
</table>

**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
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

| plants mg/l |
| Exposure time: 72 h |
| Test Type: static test |
| Method: OECD Test Guideline 201 |

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

XELODA(R) Tablets (150 mg)

Version 
1.3

Revision Date: 
10-20-2021

Date of last issue: 01-28-2020

Date of first issue: 02-02-2017

Biodegradability
Remarks: Not applicable

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
: An environmental hazard cannot be excluded in the event of
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, Reproductive toxicity
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 SOCMI 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
Titanium oxide (TiO2) 13463-67-7

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
non hazardous compounds Not Assigned
Titanium oxide (TiO2) 13463-67-7

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
Titanium oxide (TiO2) 13463-67-7

The ingredients of this product are reported in the following inventories:
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

Version 1.3
Revision Date: 10-20-2021
Date of last issue: 01-28-2020
Date of first issue: 02-02-2017

AIIC : Not in compliance with the inventory

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

XELODA(R) Tablets (150 mg)

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

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

AIIC - 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
SAFETY DATA SHEET

XELODA(R) Tablets (150 mg)

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; TECI - 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

Revision Date : 10-20-2021

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.

US / Z8 / 2010