

**1. Product and Company Identification**

Product name	XELODA(R) Tablets (500 mg)	
Product code	03 4118 5	
Use	- Xeloda is a pharmacological product used in the treatment of colorectal and breast cancer.	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

2. Hazards identification**Emergency Overview**

Form	tablets
Color	peach
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Inhalation, Ingestion, Skin contact, Eye contact- Target Organs: skin, eyes, mucous membranes, gastrointestinal system- Acute Effects: May cause eye irritation., May cause skin irritation., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.- Chronic Effects: May cause skin irritation.- Carcinogenicity: formulation not listed by NTP, IARC or OSHA
Additional Health Information	<ul style="list-style-type: none">- Some components of this product are considered potential reproductive effectors at high dosage. Refer to Section 11 (Toxicological information) for additional information on this product.- The most common dose-dependent adverse effects associated with therapeutic treatments include diarrhea, nausea, vomiting, sores in mouth and throat, abdominal pain, constipation, loss of appetite, dehydration, rash, dry, itchy or discolored skin.

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Note

- additional effects may include nail problems, hair loss, tiredness, weakness, dizziness, headache, fever, chest, back, joint and muscle pain, trouble sleeping, taste problems, and palms of the hands or soles of the feet tingle, become painful or swollen.
- Hand-and-Foot Syndrome can occur when taking Xeloda. In time, it is possible that one's fingerprints may be erased due to the skin peeling off the palms of one's hands.

3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Capecitabine CAS: 154361-50-9	~ 81 %
Microcrystalline cellulose CAS: 9004-34-6	~ 4 %
Magnesium stearate CAS: 557-04-0	~ 1 %

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

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6. Accidental release measures

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|--------------------------|--|
| Personal precautions | - ensure adequate ventilation |
| Environmental protection | - avoid release to the environment |
| Methods for cleaning up | - Scoop or shovel spilled material into a suitable labeled open head drum
- Secure the drum cover and move the container to a safe holding area
- Clean spill area thoroughly
- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.
- Check area for residual material and repeat clean up if detected |

7. Handling and storage

Handling

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| Technical measures | - local exhaust ventilation necessary |
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Storage

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| Storage conditions | - keep containers tightly closed
- room temperature
- store in a dry place
- protected from light |
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8. Exposure controls/Personal protection

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| Engineering Measures | - see 7. |
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|---------------------------|---|
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ * |
| | - OSHA-PEL: 5 mg/m ³ (respirable dust fraction) * |
| | - OSHA-PEL: 15 mg/m ³ (total dust) * |
| | - NIOSH-REL: 5 mg/m ³ (respirable dust fraction) * |
| | - NIOSH-REL: 10 mg/m ³ (total dust) * |

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|-----------------------------|---|
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³ (defined as 8-hour time-weighted average) * |
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Personal protective equipment

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|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary |
| Hand protection | - protective gloves |
| Eye protection | - safety glasses |

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Body protection - protective clothing

*1 referring to: Microcrystalline cellulose

*2 referring to: Capecitabine

9. Physical and chemical properties

Color peach

Form tablets

Solubility soluble, water

10. Stability and reactivity

Stability - stable under the conditions mentioned in chapter 7

Conditions to avoid - high temperatures

Materials to avoid - strong acids, oxidizing agents

Note - Hazardous Polymerization: Will not occur.

11. Toxicological information

Acute toxicity - LD₅₀ > 2'000 mg/kg (oral, rat) *3
- LD₅₀ > 2'000 mg/kg (oral, rat) *2

Sensitization - slightly sensitizing (several species) *2

Subchronic toxicity - high doses may damage proliferating cells (e.g. bone marrow, leucocytes) *2

Mutagenicity - no indication for mutagenicity (various in vivo and in vitro test systems) *2
- may cause mutations in vitro (clastogenic effect in lymphocytes) *2
- lymphocyte test; evidence of clastogenicity *2

Reproduction toxicity - suspected to be teratogenic and to lower parental fertility *2
- decreased weight of testis and epididymis, decrease and degeneration of spermatocytes and spermatids (760 mg/kg/d; oral, mouse, male) *2
- reduced mating ability and fertility rate (760 mg/kg/d; oral, mouse, female) *2

Note - may cause diarrhea, nausea, vomiting, loss of appetite, irritation of mucous membranes and alteration of the hemopoietic system (leukopenia) in dependence of the dose *2
- cytostatics are potentially carcinogenic *2

*2 referring to: Capecitabine

*3 referring to: Magnesium stearate

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12. Ecological information

Inherent biodegradability	- inherently biodegradable	*1
Ecotoxicity	- barely toxic for fish (rainbow trout) LC ₅₀ (96 h) > 867 mg/l NOEC (96 h) 867 mg/l	*2
	- barely toxic for planktonic crustaceans (Daphnia magna) EC ₅₀ (48 h) > 850 mg/l NOEC (48 h) 500 mg/l	*2
	- barely inhibitory on aerobic bacterial respiration EC ₅₀ > 1000 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*2
*1 referring to:	Microcrystalline cellulose	
*2 referring to:	Capecitabine	

13. Disposal considerations

Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - 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.
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	- not regulated under RCRA

14. Transport information

Note	- not classified by transport regulations, proper shipping name non-regulated
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15. Regulatory information

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 (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements.

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16. Other information

Edition documentation - changes from previous version in sections 2, 9, 13

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.