

**1. Product and Company Identification**

Product name	Xenical(R) Capsules (120 mg)
Product code	0341762
Use	- Xenical(R) is a lipase inhibitor for obesity management that acts by inhibiting the absorption of dietary fats.
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America  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. Hazard identification****Emergency Overview**

Form	capsules
Color	dark blue
Potential Health Effects	- 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
GHS Classification	no classification and labelling according to GHS
Additional Health Information	- Pre-existing gastrointestinal system conditions, gallbladder problems, and other disorders involving the Target Organs of this product may be aggravated by exposures to this product. - It is advisable for nursing mothers to exercise caution regarding exposure.

## Xenical(R) Capsules (120 mg)

- The Sodium Lauryl Sulfate component of this product is a skin sensitizer; subsequent exposure to very small amounts may cause allergic reaction in susceptible individuals.

\*1 referring to: Orlistat

### 3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Orlistat CAS: 96829-58-2	~ 50 %
Microcrystalline cellulose CAS: 9004-34-6	~ 39 %
Povidone CAS: 9003-39-8	~ 5 %
Sodium Lauryl Sulfate CAS: 151-21-3	~ 3 %
Modified Food Starch CAS: 9005-84-9	~ 3 %

### 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

### 6. Accidental release measures

Personal precautions	- ensure adequate ventilation
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## Xenical(R) Capsules (120 mg)

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|--------------------------|--|
| Environmental protection | - avoid release to the environment   |
| Methods for cleaning up  | - Scoop or shovel spilled material into a suitable labeled open head drum<br>- Secure the drum cover and move the container to a safe holding area<br>- Clean spill area thoroughly<br>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.<br>- 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<br>- room temperature<br>- store in a dry place<br>- 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 <sup>3</sup>                           | *2 |
|                           | - OSHA-PEL: 5 mg/m <sup>3</sup> (respirable dust fraction)  | *2 |
|                           | - OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)               | *2 |
|                           | - NIOSH-REL: 5 mg/m <sup>3</sup> (respirable dust fraction) | *2 |
|                           | - NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)              | *2 |

- |                             |  |    |
|-----------------------------|--|----|
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 3.0 mg/m <sup>3</sup> | *1 |
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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.<br>- respiratory protection not necessary |
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| Hand protection | - protective gloves |
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| Eye protection | - safety glasses |
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- |                 |                       |
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| Body protection | - protective clothing |
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- |                  |                            |
|------------------|----------------------------|
| *1 referring to: | Orlistat                   |
| *2 referring to: | Microcrystalline cellulose |

## Xenical(R) Capsules (120 mg)

### 9. Physical and chemical properties

Color	dark blue
Form	capsules
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	- LD <sub>50</sub> > 5'000 mg/kg (oral, rat)	*1
Local effects	- eye: non-irritant (rabbit)	*1
Chronic toxicity	- NOEL 125 mg/kg/d (oral, rat; 12 months)	*1
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	*1
Carcinogenicity	- not carcinogenic	*1
Reproductive toxicity	- not teratogenic, not embryotoxic (several species)	*1
Note	- elimination half-life after systemic application and high doses approx. 4-5 hours (i.v., 125 mg/kg/d, dog, 2 weeks) - no toxic effects have been observed during occupational handling	*1 *1
*1 referring to:	Orlistat	

### 12. Ecological information

Ready biodegradability	- not readily biodegradable ~ 18 %, 29 days (FDA Technical Assistance Document No. 3.11)	*1
Inherent biodegradability	- not inherently biodegradable 12 % biodegradation, 28 d ≥98 % elimination, 1 d (Zahn-Wellens test, OECD No. 302 B)	*1
	- not anaerobically biodegradable 12 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*1

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	<ul style="list-style-type: none"> <li>- not inherently biodegradable  <ul style="list-style-type: none"> <li>&lt; 10 %, 1 d</li> <li>&lt; 10 %, 16 d</li> <li>&lt; 10 %, 28 d</li> </ul>                     (flask shaking test Roche Basel, inherent biodegradation) <span style="float: right;">*3</span> </li> <li>- inherently biodegradable <span style="float: right;">*2</span></li> </ul>
Ecotoxicity	<ul style="list-style-type: none"> <li>- moderately toxic for fish, test performed using solubilisers (rainbow trout)  <ul style="list-style-type: none"> <li>LC<sub>50</sub> (96 h) &gt; 18.5 mg/l</li> <li>NOEC (96 h) 18.5 mg/l</li> </ul>                     (FDA Technical Assistance Document No. 4.11) <span style="float: right;">*1</span> </li> <li>- strongly toxic for planktonic crustaceans, test performed using solubilisers (Daphnia magna)  <ul style="list-style-type: none"> <li>EC<sub>50</sub> (48 h) 6.92 mg/l</li> <li>NOEC (48 h) 1.95 mg/l</li> </ul>                     (FDA Technical Assistance Document No. 4.08) <span style="float: right;">*1</span> </li> <li>- barely toxic for algae, test performed with water accommodated fractions (Selenastrum capricornutum)  <ul style="list-style-type: none"> <li>EC<sub>50</sub> (10 d) &gt; 1.92 mg/l (saturation concentration)</li> <li>NOEC (10 d) 1.92 mg/l (saturation concentration)</li> </ul>                     (FDA Technical Assistance Document No. 4.01) <span style="float: right;">*1</span> </li> <li>- barely inhibitory on aerobic bacterial respiration (activated sludge)  <ul style="list-style-type: none"> <li>NOEC (3 h) 50 mg/l (nominal concentration)</li> </ul>                     (OECD No. 209) <span style="float: right;">*1</span> </li> <li>- barely toxic for earthworms (Lumbricus terrestris)  <ul style="list-style-type: none"> <li>LC<sub>50</sub> (28 days) ~ 907 mg/kg</li> </ul> <span style="float: right;">*1</span> </li> <li>- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture)  <ul style="list-style-type: none"> <li>NOEC 10 mg/l</li> </ul>                     (FDA Technical Assistance Document No. 4.02) <span style="float: right;">*1</span> </li> </ul>
Mobility	<ul style="list-style-type: none"> <li>- low mobility (Soil-Water, 25 °C)  <ul style="list-style-type: none"> <li>K<sub>oc</sub> = 100605 (silty loam)</li> <li>K<sub>oc</sub> = 176577 (clay loam)</li> <li>K<sub>oc</sub> = 7010 (loam)</li> </ul>                     (FDA Technical Assistance Document No. 3.08) <span style="float: right;">*1</span> </li> <li>- strong adsorption (water-activated sludge, 1 d, ~22 °C)  <ul style="list-style-type: none"> <li>K<sub>d</sub> = 500000 l/kg</li> </ul>                     (Zahn-Wellens test, OECD No. 302 B) <span style="float: right;">*1</span> </li> </ul>
*1 referring to:	Orlistat
*2 referring to:	Microcrystalline cellulose
*3 referring to:	POVIDONE K 30
<b>13. Disposal considerations</b>	
Waste from residues	<ul style="list-style-type: none"> <li>- incinerate in qualified installation with flue gas scrubbing</li> <li>- observe local/national regulations regarding waste disposal</li> <li>- 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.</li> </ul>

## Xenical(R) Capsules (120 mg)

Contaminated packaging - Empty containers must be triple rinsed prior to disposal, recycling or reuse.

### 14. Transport information

DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no
	9	3077	III			9	

DOT Remark: - NON-REGULATED IN NON-BULK PACKAGINGS TRANSPORTED BY MOTOR VEHICLES, RAIL CARS OR AIRCRAFT (49CFR 171.4(c)).

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name Mycophenolate mofetil

### 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.

### 16. Other information

Edition documentation - changes from previous version in sections 2, 13, 14

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.