Material Safety Data Sheet

Xenical(R) Capsules (120 mg)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	Xenical(R) Capsules (120 mg)
Product code	0341762

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use	-	Xenical(R) is a lipase inhibitor for obesity management that acts by inhibiting the absorption of dietary fats.

1.3. Details of the supplier of the safety data sheet

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

Local representation:

1.4. Emergency telephone number

Emergency telephone number	US emergency phone: (800)-827-6243

SECTION 2: Hazards 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

Other hazards

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. - 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.

SECTION 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 %

SECTION 4: First aid measures

4.1. Description of 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

4.2. Most important symptoms and effects, both acute and delayed

Note	-	no information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	-	water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)		not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	-	Toxic emissions may be given off in a fire

5.3. Advice for firefighters

Protection of fire-fighters	-	use self-contained breathing apparatus
Special method of fire-fighting	-	cool endangered containers with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	-	ensure adequate ventilation

6.2. Environmental precautions

Environmental protection	-	avoid release to the environment

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	- local exhaust ventilation necessary

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Note	- no information available	
Threshold value (USA) air	- ACGIH-TLV: 10 mg/m3	*1
	- OSHA-PEL: 5 mg/m3 (respirable dust fraction)	*1
	- OSHA-PEL: 15 mg/m3 (total dust)	*1
	- NIOSH-REL: 5 mg/m3 (respirable dust fraction)	*1
	- NIOSH-REL: 10 mg/m3 (total dust)	*1
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m3	*2

8.2. Exposure controls

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
Body protection	- protective clothing

*1	referring to:	Microcrystalline cellulose
*2	referring to:	Orlistat

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	dark blue
Form	capsules

Solubility		soluble, water

9.2. Other information

Note	-	no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	-	no information available

10.2. Chemical stability

Stability	-	stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Conditions to avoid	-	high temperatures

10.5. Incompatible materials

Materials to avoid	-	strong acids, oxidizing agents

10.6. Hazardous decomposition products

Note	-	Hazardous Polymerization: Will not occur.

SECTION 11: Toxicological information

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

*2 referring to: Orlistat

SECTION 12: Ecological information

Ecotoxicity	- moderately toxic for fish, test performed using solubilisers (rainbow trout) LC_{50} (96 h) > 18.5 mg/l NOEC (96 h) 18.5 mg/l (FDA Technical Assistance Document No. 4.11)	*2
	- strongly toxic for planktonic crustaceans, test performed using solubilisers (Daphnia magna) EC_{50} (48 h) 6.92 mg/l NOEC (48 h) 1.95 mg/l (FDA Technical Assistance Document No. 4.08)	*2
	- barely toxic for algae, test performed with water accommodated fractions (Selenastrum capricornutum) EC_{50} (10 d) > 1.92 mg/l (saturation concentration) NOEC (10 d) 1.92 mg/l (saturation concentration) (FDA Technical Assistance Document No. 4.01)	*2
	- barely inhibitory on aerobic bacterial respiration (activated sludge) NOEC (3 h) 50 mg/l (nominal concentration) (OECD No. 209)	*2
	- barely toxic for earthworms (Lumbricus terrestris) LC_{50} (28 days) ~ 907 mg/kg	*2
	- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 10 mg/l (FDA Technical Assistance Document No. 4.02)	*2
Ready biodegradability	- not readily biodegradable ~ 18 %, 29 days (FDA Technical Assistance Document No. 3.11)	*2
Inherent biodegradability	- not inherently biodegradable 12 % biodegradation, 28 d ≥ 98 % elimination, 1 d (Zahn-Wellens test, OECD No. 302 B)	*2
	- not anaerobically biodegradable 12 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*2
	- not inherently biodegradable < 10 %, 1 d < 10 %, 16 d < 10 %, 28 d (flask shaking test Roche Basel, inherent biodegradation)	*3
	- inherently biodegradable	*1

12.3. Bioaccumulative potential

Note	- no information available	

12.4. Mobility in soil

Note	- no information available	

Mobility	- low mobility (Soil-Water, 25 °C) K_{OC} = 100605 (silty loam) K_{OC} = 176577 (clay loam) K_{OC} = 7010 (loam) (FDA Technical Assistance Document No. 3.08) *2 - strong adsorption (water-activated sludge, 1 d, ~22 °C) K_d = 500000 l/kg (Zahn-Wellens test, OECD No. 302 B) *2

12.5. Results of PBT and vPvB assessment

Note	- no information available

12.6. Other adverse effects

Note	- no information available

*1	referring to:	Microcrystalline cellulose
*2	referring to:	Orlistat
*3	referring to:	POVIDONE K 30

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.

SECTION 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	Orlistat

SECTION 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.

SECTION 16: Other information

Edition documentation	- changes from previous version in sections 8, 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.