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	SAP-10062274	
Synonyms	- XENICAL Capsules (hard) 120 mg - Tetrahydrolipstatin	 *1

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

Use	- as pharmaceutical active substance for medical treatment of obesity	*1

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300

1 referring to: Orlistat

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification: no classification and labelling according to GHS

Other hazards

Note: - no information available

SECTION 3: Composition/information on ingredients

Characterization	Orlistat with other inactive ingredients hard-gelatin capsule containing pellets of powder	
Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Orlistat 96829-58-2	~ 37.95 %	- Combustible dust (No category), USH003
Microcrystalline cellulose 9004-34-6	29.6 %	
Povidone K30 9003-39-8	3.8 %	
Sodium lauryl sulfate 151-21-3	2.3 %	- Flammable solids (Category 2), H228 - Acute toxicity (Category 3), H311 - Acute toxicity (Category 4), H302 - Skin corrosion/irritation (Category 2), H315 - Serious eye damage/eye irritation (Category 2A), H319 - Specific target organ toxicity - Single exposure (Category 3), H335
Sodium starch glycolate 9063-38-1	2.3 %	

For the full text of the H-phrases mentioned in this Section, see Section 16.

***1** referring to: Orlistat

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse with tap water for 10 minutes - open eyelids forcibly
Skin contact	- when in contact with the skin, clean with soap and water
Inhalation	- in the event of symptoms get medical treatment

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

Note	- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	-	adapt extinguishing media to surrounding fire conditions
Flash point (liquid)		not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	-	substance is hazardous for water: contain fire-fighting wastewater

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	-	no special precautions required

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	-	take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials	-	stainless steel, aluminium, enamel, glass	*1

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	-	15 - 30 °C	
	-	keep containers tightly closed	
	-	protected from light and humidity	
Validity	-	see expiry date on the label	
Packaging materials	-	tightly closing; material: stainless steel (lined with polyethylene bag)	*1
	-	polyethylene bag in metal drum	
	-	blister packages	

1 referring to: Orlistat

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m3	*2
	- OSHA-PEL: 5 mg/m3 (respirable dust fraction)	*2
	- OSHA-PEL: 15 mg/m3 (total dust)	*2
	- NIOSH-REL: 5 mg/m3 (respirable dust fraction)	*2
	- NIOSH-REL: 10 mg/m3 (total dust)	*2
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m3	*1

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 during normal operations
Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses

1 referring to: Orlistat
2 referring to: Microcrystalline cellulose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	dark blue turquois	
Form	hard gelatin capsules	
Solubility	< 10 mg/l, water (23 °C)	*1
	350’000 mg/l, ethanol (23 °C)	*1
	600’000 mg/l, methanol	*1
	350’000 mg/l, chloroform (23 °C)	*1
	300’000 mg/l, n-hexane	*1
	600’000 mg/l, diethyl ether (23 °C)	*1
	350’000 mg/l, tetrahydrofuran	*1
Partition coefficient	log $P_{ow} \geq 3$ (octanol/buffer) pH 7.45	*1
Melting temperature	42 to 46 °C	*1

9.2. Other information

Note	- no information available

1 referring to: Orlistat

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available	

10.2. Chemical stability

Stability	- decomposition upon heating	*1

10.3. Possibility of hazardous reactions

Note	- no information available	

10.4. Conditions to avoid

Conditions to avoid	- light	*1
	- humidity	*1
	- heat	*1

10.5. Incompatible materials

Materials to avoid	- acids, oxidizing agents, bases	*1

10.6. Hazardous decomposition products

Note	- no information available	

1 referring to: Orlistat

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD_{50} > 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	- reduces fat absorption by inhibiting pancreatic lipase	*1
	- oral overdose may cause diarrhoea especially upon simultaneous uptake of fat	*1
	- no toxic effects have been observed during occupational handling	*1

Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA
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.

1 referring to: Orlistat

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- 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)	*1
	- 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)	*1
	- barely inhibitory on aerobic bacterial respiration (activated sludge) NOEC (3 h) 50 mg/l (nominal concentration) (OECD No. 209)	*1
	- barely toxic for earthworms (Lumbricus terrestris) LC_{50} (28 days) ~ 907 mg/kg	*1
	- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 10 mg/l (FDA Technical Assistance Document No. 4.02)	*1

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable ~ 18 %, 29 days (FDA Technical Assistance Document No. 3.11)	*1

12.3. Bioaccumulative potential

Note	- no information available

12.4. Mobility in soil

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) *1

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

1 referring to: Orlistat

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues
- observe local/national regulations regarding waste disposal
- medicines should not be disposed of via wastewater
- return to supplier or hand over to authorized disposal company
- 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.

SECTION 14: Transport information

IATA	Class	UN/ID	PG		PI	Label	Mark
	9	3077	III		956/956	9	EHS

IMDG	Class	UN	PG	EmS	PI	Label	Mark
	9	3077	III	F-A S-F	P002/IBC08	9	marine pollutant

RID/ADR	Class	UN	PG	Haz.no	PI	Label	Mark	Classif. code
	9	3077	III	90	P002/IBC08	9	EHS	M7

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

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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 enter a waterway or into soil, or 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

Full text of H-Statements referred to under section 3

H228	Flammable solid.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
USH003	May form combustible dust concentrations in the air

Note
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation
- changes from previous version in sections 2, 3, 16

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.