Safety Data Sheet

XENICAL® Capsules 120 mg

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

1.1. Product identifier

Product name	XENICAL® Capsules 120 mg
Product code	SAP-10062274

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

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

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Roche Products Pty Limited Level 8, 30-34 Hickson Road Millers Point NSW 2000 Australia Phone 0061-2-9454-9624 Fax 0061-2-9971-7401 E-Mail info.sds@roche.com	Local representation:

1.4. Emergency telephone number

Emergency telephone number	Phone	0061-2-9454-9624

1 referring to: Orlistat

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification	no classification and labelling according to GHS	
Australian Remark	- Poisons Schedule - Schedule 4	*1
	- NON-HAZARDOUS SUBSTANCE. DANGEROUS GOODS.	
	- Listed on the Australian Inventory of Chemical Substances (AICS)	*2
	- Listed on the Australian Inventory of Chemical Substances (AICS)	*3
	- Listed on the Australian Inventory of Chemical Substances (AICS)	*4
	- Listed on the Australian Inventory of Chemical Substances (AICS)	*5

2.3. Other hazards

Note - no information available

1 referring to: Orlistat
2 referring to: Cellulose
3 referring to: Povidone K30
4 referring to: Sodium carboxymethyl starch
5 referring to: Sodium lauryl sulfate

SECTION 3: Composition/information on ingredients

Characterization: Orlistat with other inactive ingredients
hard-gelatin capsule containing pellets of powder

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

UN number: 3077

Ingredient	Concentration	GHS-Classification (pure ingredient)
Orlistat 96829-58-2	37.95 %	
Microcrystalline cellulose 9004-34-6	29.6 %	
Povidone K30 9003-39-8	3.8 %	
Sodium carboxymethyl starch 9063-38-1	2.3 %	
Sodium lauryl sulfate 151-21-3	2.3 %	- Flammable solids (Category 2), H228 - Acute toxicity (Category 4), H332 - Acute toxicity (Category 4), H302 - Skin corrosion/irritation (Category 2), H315 - Serious eye damage/eye irritation (Category 1), H318 - Specific target organ toxicity - Single exposure (Category 3), H335

For the full text of the 'Hazard statements' 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 20 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

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) - polyethylene bag in metal drum - blister packages	*1

1 referring to: Orlistat

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m3	*1

8.2. Exposure controls

Respiratory protection	- 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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour	dark blue turquoise	
Form	hard gelatin capsules	
Solubility	< 10 mg/l, water (23 °C) 350’000 mg/l, ethanol (23 °C) 600’000 mg/l, methanol 350’000 mg/l, chloroform (23 °C) 300’000 mg/l, n-hexane 600’000 mg/l, diethyl ether (23 °C) 350’000 mg/l, tetrahydrofuran	*1 *1 *1 *1 *1 *1 *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
Chronic toxicity	- NOEL 125 mg/kg/d (oral, rat; 12 months)	*1
Local effects	- eye: non-irritant (rabbit)	*1
Sensitization	- no information available	
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
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
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

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 authorised disposal company
- unused medicines should be returned to a pharmacy for disposal

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

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

Technical name Orlistat mixture

SECTION 15: Regulatory information

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

Water hazard class (Germany)	2: hazardous for water (according to annex 4 of directive VwVwS of 17.05.1999)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H228	Flammable solid.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

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

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.