

Product Name: Biaxin XL Filmtab 500 mg Tablets
Issued: Aug-08-2011



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Biaxin XL Filmtab 500 mg Tablets
Synonyms: Biaxin XL Extended Release tablets; Clarithromycin Extended Release tablets, 500 mg; Biaxin CR 500 mg; MONOZECLAR 500 mg
List Number: 3165; 10061

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064
USA
Customer Service Telephone: 1-800-255-5162 (US and Canada only)
E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

General Note Abbott Laboratories
Serious eye damage/eye irritation Category 2
Reproductive toxicity Category 2
None

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xi - Irritant
Risk Phrases: R36 - Irritating to eyes
R63 - Possible risk of harm to the unborn child

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Warning

Hazard Statements: H319 - Causes serious eye irritation
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Clarithromycin 81103-11-9	40-60	NA	Xn, R22; Xi, R36; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302)	No data available
Lactose 63-42-3	15-30	200-559-2		Not classified	No data available
Hydroxypropyl Methylcellulose 9004-65-3	15-30	NA		Not classified	No data available
Talc, Nonasbestos Containing 14807-96-6	1-5	238-877-9		Not classified	No data available
Magnesium Stearate 557-04-0	1-5	209-150-3		Not classified	No data available
Propylene Glycol 57-55-6	0.1-1	200-338-0		Not classified	No data available
Titanium Dioxide 13463-67-7	0.1-1	236-675-5		Not classified	No data available

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

Section 4. First aid measures

4.1 Description of first aid measures

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Clinical data suggests the following: gastrointestinal upset, diarrhea, nausea, abdominal pain, pruritus, headaches, skin irritation, metallic taste, abnormal liver function, abnormal kidney function.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: gastrointestinal system, liver, kidneys. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

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6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Abbott EEL	Skin Notation
Clarithromycin 81103-11-9	1 mg/m ³	None
Lactose 63-42-3	Not Applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None
Propylene Glycol 57-55-6	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				
Propylene Glycol 57-55-6				150 ppm (TWA) 470 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	VME: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (VLA-ED)	2 mg/m ³ (MAK)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)
Propylene Glycol 57-55-6				450 ppm (STEL) 1422 mg/m ³ (STEL) 30 mg/m ³ (STEL) 150 ppm (TWA) 474 mg/m ³ (TWA) 10 mg/m ³ (TWA)
Titanium Dioxide 13463-67-7		10 mg/m ³ (VLA-ED)	3 mg/m ³ (MAK)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls:	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Other PPE Data:	Wear appropriate body coverings if contact may occur.
Environmental Exposure Controls:	Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Pale Yellow Ovaloid tablet
Odor:	Slight vanillin odor.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient: n-octanol/water	Not determined.

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Autoignition Temp. (°C): Not determined.
Decomposition temperature (°C): Not Determined
Viscosity (centipoise): Not determined.
Explosion Severity: Not determined.
Oxidizer Properties: Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Not determined.

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Clarithromycin 81103-11-9	LD50 >=	1230	mg/kg	Rats Mice
Lactose 63-42-3	LD50 >	5000	mg/kg	Mice Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals

Acute Toxicity - Dermal: Data for component (s) given below.

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Chemical Name	Acute Test	Value	Units	Species
Propylene Glycol 57-55-6	LD50 =	20,800	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Macrolide antibiotics are reported to be mild eye irritants.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Clarithromycin 81103-11-9	Liver Kidney Eyes Gastrointestinal Tract	Monkeys	100	mg/kg	Oral	28 days
		Dogs	100			1 Month
		Rats	600			30 days
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

Reproductive Effects: In animals adverse reproductive effects include: fetal abnormalities, fetal toxicity.
 Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Clarithromycin 81103-11-9	Mice	1000	mg/kg	Oral	During Gestation
	Rats	160			

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Clarithromycin 81103-11-9	Negative	Negative	Negative	Negative
Magnesium Stearate 557-04-0	No Data.	Negative	No Data.	No Data.

Aspiration hazard: Not determined

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Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- | | |
|------------------------------------|----------------|
| 14.1. UN Number: | Not applicable |
| 14.2. Proper shipping name: | Not applicable |
| 14.3. Hazard class: | Not applicable |
| 14.4. Packing group: | Not applicable |
| 14.5. Environmental hazard: | Not applicable |
| 14.6. Special Provisions: | Not applicable |

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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Lactose 63-42-3	200-559-2	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Talc, Nonasbestos Containing 14807-96-6	238-877-9	X	X	Not listed.	X
Magnesium Stearate 557-04-0	209-150-3	X	X	Not listed.	X
Propylene Glycol 57-55-6	200-338-0	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	236-675-5	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Clarithromycin 81103-11-9	-	8-(4)-1126	-	-	-	HSR007090
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Hydroxypropyl Methylcellulose 9004-65-3	(8)-196	-	X	X	KE-05368	
Talc, Nonasbestos Containing 14807-96-6	(1)-468	-	X	X	KE-32773	
Magnesium Stearate 557-04-0	(2)-611	-	X	X	KE-26390	
Propylene Glycol 57-55-6	(2)-234	2-(8)-321 2-(8)-323	X	X	KE-29267	
Titanium Dioxide 13463-67-7	(5)-5225 (1)-558	-	X	X	KE-33900	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Clarithromycin	40-60	Not Listed	Not Listed	Not Listed
Lactose	15-30	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	15-30	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	1-5	Not Listed	Not Listed	Not Listed
Magnesium Stearate	1-5	Not Listed	Not Listed	Not Listed

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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Propylene Glycol	0.1-1	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Clarithromycin	40-60	No	Not Applicable	Not applicable
Lactose	15-30	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	15-30	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	1-5	No	Not Applicable	Not applicable
Magnesium Stearate	1-5	No	Not Applicable	Not applicable
Propylene Glycol	0.1-1	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: Not Applicable
RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Chemical Name	Percent	Proposition 65 Listed Materials
Clarithromycin	40-60	Developmental toxicity, initial date 5/1/97

WHMIS Hazard Class: Exempt.

NFPA Rating:
 Health: 1
 Fire: 1
 Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R36 - Irritating to eyes, R63 - Possible risk of harm to the unborn child

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed, H319 - Causes serious eye irritation, H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Global Occupational Toxicology (D-03QW)

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Supersedes the SDS dated: Aug-08-2002

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