

Product Name: Biaxin Filmtab 500mg
Issued: Jun-06-2013

SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Biaxin Filmtab 500mg
Synonyms: Biaxin 500 mg tablets; Biaxin Filmtabs; Clarithromycin tablets, 500 mg
List Number: 2586; 4325

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: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.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

Acute oral toxicity Category 4

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

Indication of danger: Xn - Harmful

Risk Phrases: R22 - Harmful if swallowed

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/container to an approved waste disposal plant

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	50-70	NA	Xn, R22	Acute Tox. 4 (H302)	No data available
Cellulose Microcrystalline 9004-34-6	10-20	Present		Not Hazardous*	No data available
Croscarmellose Sodium 9000-11-7	1-10	NA		Not Hazardous*	No data available
Kollidon 9003-39-8	1-10	NA		Not Hazardous*	No data available
Propylene Glycol 57-55-6	1-5	Present		Not Hazardous*	No data available
Magnesium Stearate 557-04-0	1-5	Present		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	0.1-1	Present		Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	0.1-1	Present		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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

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Section 4. First aid measures

4.1 Description of first aid measures

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: None known from occupational exposure. Clinical data suggests the following: diarrhea, nausea, vomiting, headaches, abnormal liver function, abnormal kidney function, gastrointestinal upset, taste alterations.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, liver, gastrointestinal system. Hypersensitivity to the material and/or similar materials. Pregnancy.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Additional Information: Clarithromycin : Pseudomembranous colitis has been reported with use of nearly all antibiotics including clarithromycin.

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

Product Name: Biaxin Filmtab 500mg
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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.

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	Employee Exposure Limit	Skin Notation
Clarithromycin 81103-11-9	1 mg/m ³	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Croscarmellose Sodium 9000-11-7	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Propylene Glycol 57-55-6	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Croscarmellose Sodium 9000-11-7	10 mg/m ³ as nuisance dust, 3 mg/m ³ for respirable particulate				

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Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Kollidon 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Propylene Glycol 57-55-6				150 ppm (TWA) 470 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Colloidal Silicon Dioxide 7631-86-9	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate		4 mg/m ³ TWA	6 mg/m ³ (TWA) 2.4 mg/m ³ (TWA) 6 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 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 (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Colloidal Silicon Dioxide 7631-86-9			0.3 mg/m ³ (TWA)	18 mg/m ³ (STEL) 7.2 mg/m ³ (STEL) 18 mg/m ³ (STEL) 6 mg/m ³ (TWA) 2.4 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

Product Name:	Biaxin Filmtab 500mg
Issued:	Jun-06-2013
Appearance:	Pale Yellow Ovaloid tablet
Odor:	Not determined.
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.
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

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Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

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
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Croscarmellose Sodium 9000-11-7	LD50 >	5050	mg/kg	Rats
Kollidon 9003-39-8	LD50 =	100000	mg/kg	Rats
		1040		Rabbits
	LD50 >	40000		Mice
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits
Croscarmellose Sodium 9000-11-7	LD50 >	2000	mg/kg	Rabbits
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
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats
Croscarmellose Sodium 9000-11-7	LC 50 >	0.13	mg/L, 4 hour	Rats
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats
Colloidal Silicon Dioxide 7631-86-9	LC 50 >	200	mg/L, 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

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

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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
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities, fetal toxicity. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity
 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
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

Aspiration hazard: Not determined

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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	0.1-1	5000	Brachydanio rerio	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	0.1-1	7600	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	0.1-1	440	Unicellular Green Algae	72 Hours

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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
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

Product Name:
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International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Croscarmellose Sodium 9000-11-7	-	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Propylene Glycol 57-55-6	Present	X	X	Not listed.	X
Magnesium Stearate 557-04-0	Present	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Clarithromycin 81103-11-9	-	Present	-	-	-	HSR007090
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Croscarmellose Sodium 9000-11-7	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Propylene Glycol 57-55-6	Present	Present	X	X	Present	
Magnesium Stearate 557-04-0	Present	-	X	X	Present	
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	
Colloidal Silicon Dioxide 7631-86-9	Present	-	X	X	Present	

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	50-70	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	10-20	Not Listed	Not Listed	Not Listed
Croscarmellose Sodium	1-10	Not Listed	Not Listed	Not Listed
Kollidon	1-10	Not Listed	Not Listed	Not Listed
Propylene Glycol	1-5	Not Listed	Not Listed	Not Listed
Magnesium Stearate	1-5	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	Not Listed	Not Listed	Not Listed
Colloidal Silicon 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	50-70	No	Not Applicable	Not applicable

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Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Cellulose Microcrystalline	10-20	No	Not Applicable	Not applicable
Croscarmellose Sodium	1-10	No	Not Applicable	Not applicable
Kollidon	1-10	No	Not Applicable	Not applicable
Propylene Glycol	1-5	No	Not Applicable	Not applicable
Magnesium Stearate	1-5	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	No	Not Applicable	Not applicable
Colloidal Silicon Dioxide	0.1-1	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not a hazardous waste.

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	50-70	Developmental toxicity, initial date 5/1/97

WHMIS Hazard Class: Not determined.

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: R22 - Harmful if swallowed
Document Authored By: Global Occupational Toxicology (D-03QC)
Issued: Jun-06-2013
Supersedes the SDS dated: Aug-08-2011

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