

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Biaxin Granules for Oral Suspension

Synonyms: Clarithromycin Granules for Oral Suspension; Clarithromycin for Oral Suspension, 125 mg/5 mL; Clarithromycin for Oral Suspension 250 mg/5 mL; Biaxin Granules for Oral Suspension 250 mg/5 mL; Biaxin Granules for Oral Suspension 125 mg/5 mL

List Number: 3163; 3188; A3163; A3188

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
Not classified

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Indication of danger: Not classified

2.2 Label elements

Not classified

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011

Section 2. Hazards identification

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.
Sucrose 57-50-1	70-90	200-334-9		Not classified	No data available
Maltodextrin 9050-36-6	1-10	232-940-4		Not classified	No data available
Clarithromycin 81103-11-9	1-10	NA	Xn, R22	Acute Tox. 4 (H302)	No data available
Titanium Dioxide 13463-67-7	1-5	236-675-5		Not classified	No data available
Fruit Flavor	1-5	NA		Not classified	No data available
Potassium Sorbate 24634-61-5	0.1-1	246-376-1	Xi, R36/38	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Silica, Amorphous 112926-00-8	0.1-1	NA		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

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: gastrointestinal upset, pruritus, lightheadedness and headache, metallic taste, abnormal kidney function, abnormal liver function, rash.

Product Name: **Biaxin Granules for Oral Suspension**
Issued: **Nov-14-2011**

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: gastrointestinal system, liver, kidneys.

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.

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

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Abbott EEL	Skin Notation
Sucrose 57-50-1	Not Applicable	None
Maltodextrin 9050-36-6	Not Applicable	None
Clarithromycin 81103-11-9	1 mg/m ³	None
Titanium Dioxide 13463-67-7	Not Applicable	None
Fruit Flavor	Not Applicable	None
Potassium Sorbate 24634-61-5	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sucrose 57-50-1	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate	VME: 10 mg/m ³		20 mg/m ³ (STEL) 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)	
Silica, Amorphous 112926-00-8	10 mg/m ³				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Sucrose 57-50-1		10 mg/m ³ (VLA-ED)		20 mg/m ³ (STEL) 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)
Silica, Amorphous 112926-00-8			4 mg/m ³ (MAK)	

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.

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Granules
Odor:	Fruit punch aroma.
Odor Threshold:	Not determined
pH:	4-5.4 for the reconstituted product.
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):	Highly soluble in: water.
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 recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011

10.6 Hazardous decomposition products

Not determined.

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Yes

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

Chemical Name	Acute Test	Value	Units	Species
Sucrose 57-50-1	LD50 >	29,700	mg/kg	Rats
Clarithromycin 81103-11-9	LD50 >=	1230	mg/kg	Rats Mice
Potassium Sorbate 24634-61-5	LD50 =	3200	mg/kg	Rats

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

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.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Clarithromycin 81103-11-9	Liver Kidney Eyes Gastrointestinal Tract	Monkeys Dogs Rats	100 100 600	mg/kg	Oral	28 days 1 Month 30 days
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	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 Rats	1000 160	mg/kg	Oral	During Gestation

Carcinogenicity: Data for component(s) given below.

Product Name: Biaxin Granules for Oral Suspension
Issued: Nov-14-2011

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: Not determined.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Clarithromycin 81103-11-9	Negative	Negative	Negative	Negative
Potassium Sorbate 24634-61-5	No Data.	Negative	No Data.	No Data.

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
Potassium Sorbate 24634-61-5	0.1-1	1250	Fish	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Potassium Sorbate 24634-61-5	0.1-1	750	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Potassium Sorbate 24634-61-5	0.1-1	24.1 >100	Unicellular Green Algae Activated sludge	72 Hours 3 hours

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

Product Name: **Biaxin Granules for Oral Suspension**
Issued: **Nov-14-2011**

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Sucrose 57-50-1	200-334-9	X	X	Not listed.	X
Maltodextrin 9050-36-6	232-940-4	X	X	Not listed.	X
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Titanium Dioxide 13463-67-7	236-675-5	X	X	Not listed.	X
Fruit Flavor	-	-	-	Not listed.	-
Potassium Sorbate 24634-61-5	246-376-1	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sucrose 57-50-1	-	8-(4)-345	X	X	KE-17258	

Product Name:
Issued:

Biaxin Granules for Oral Suspension
Nov-14-2011

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Maltodextrin 9050-36-6	(8)-98	-	X	X	KE-22996	
Clarithromycin 81103-11-9	-	8-(4)-1126	-	-	-	HSR007090
Titanium Dioxide 13463-67-7	(5)-5225 (1)-558	-	X	X	KE-33900	
Fruit Flavor	-	-	-	-	-	
Potassium Sorbate 24634-61-5	(2)-2575 (2)-1076	-	X	X	KE-18528	HSR002739
Silica, Amorphous 112926-00-8	(1)-548	-	X	X	KE-32733	

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:
Sucrose	70-90	Not Listed	Not Listed	Not Listed
Maltodextrin	1-10	Not Listed	Not Listed	Not Listed
Clarithromycin	1-10	Not Listed	Not Listed	Not Listed
Titanium Dioxide	1-5	Not Listed	Not Listed	Not Listed
Fruit Flavor	1-5	Not Listed	Not Listed	Not Listed
Potassium Sorbate	0.1-1	Not Listed	Not Listed	Not Listed
Silica, Amorphous	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):
Sucrose	70-90	No	Not Applicable	Not applicable
Maltodextrin	1-10	No	Not Applicable	Not applicable
Clarithromycin	1-10	No	Not Applicable	Not applicable
Titanium Dioxide	1-5	No	Not Applicable	Not applicable
Fruit Flavor	1-5	No	Not Applicable	Not applicable
Potassium Sorbate	0.1-1	No	Not Applicable	Not applicable
Silica, Amorphous	0.1-1	No	Not Applicable	Not applicable

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

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Chemical Name	Percent	Proposition 65 Listed Materials
Clarithromycin	1-10	Developmental toxicity, initial date 5/1/97

Product Name: Biaxin Granules for Oral Suspension

Issued: Nov-14-2011

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 0

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

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Disclaimer:

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