

**Product Name:** Biaxin Granules for Oral Suspension  
**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 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:** 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**

**Product Name:**  
**Issued:**

**Biaxin Granules for Oral Suspension**  
**Jun-06-2013**

## 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.
Sucrose 57-50-1	70-90	Present		Not Hazardous*	No data available
Maltodextrin 9050-36-6	1-10	Present		Not Hazardous*	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	Present		Not Hazardous*	No data available
Fruit Flavor	1-5	NA		Not Hazardous*	No data available
Potassium Sorbate 24634-61-5	0.1-1	Present	Xi, R36/38	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Silica, Amorphous 112926-00-8	0.1-1	NA		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

**Product Name:** **Biaxin Granules for Oral Suspension**  
**Issued:** **Jun-06-2013**

## **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.

**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**

**Product Name:** Biaxin Granules for Oral Suspension  
**Issued:** Jun-06-2013

**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:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Sucrose 57-50-1	Not Applicable	None
Maltodextrin 9050-36-6	Not Applicable	None
Clarithromycin 81103-11-9	1 mg/m <sup>3</sup>	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

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Sucrose 57-50-1	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	
Silica, Amorphous 112926-00-8	10 mg/m <sup>3</sup>				

<b>Chemical Name</b>	<b>The Netherlands</b>	<b>Spain</b>	<b>Switzerland</b>	<b>UK OEL/MEL</b>
Sucrose 57-50-1		10 mg/m <sup>3</sup> (TWA)		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)

**Product Name:** Biaxin Granules for Oral Suspension  
**Issued:** Jun-06-2013

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Titanium Dioxide 13463-67-7		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	30 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)
Silica, Amorphous 112926-00-8			4 mg/m <sup>3</sup> (TWA)	

## 8.2. Exposure controls

<b>Engineering Controls:</b>	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
<b>Respiratory Protection:</b>	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.
<b>Eyes:</b>	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
<b>Gloves:</b>	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
<b>Other PPE Data:</b>	Wear appropriate body coverings if contact may occur.
<b>Environmental Exposure Controls:</b>	Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance:</b>	White to off-white Granules
<b>Odor:</b>	Fruit punch aroma.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	4-5.4 for the reconstituted product.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Highly soluble in: water.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

**Product Name:** Biaxin Granules for Oral Suspension  
**Issued:** Jun-06-2013

## **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:** 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.

**Product Name:** Biaxin Granules for Oral Suspension

**Issued:** Jun-06-2013

**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.

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
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

**Product Name:** Biaxin Granules for Oral Suspension  
**Issued:** Jun-06-2013

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**

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



**Product Name:** Biaxin Granules for Oral Suspension  
**Issued:** Jun-06-2013

## 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	Present	X	X	Not listed.	X
Maltodextrin 9050-36-6	Present	X	X	Not listed.	X
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X
Fruit Flavor	-	-	-	Not listed.	-
Potassium Sorbate 24634-61-5	Present	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	-	Present	X	X	Present	
Maltodextrin 9050-36-6	Present	-	X	X	Present	
Clarithromycin 81103-11-9	-	Present	-	-	-	HSR007090
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	
Fruit Flavor	-	-	-	-	-	
Potassium Sorbate 24634-61-5	Present	-	X	X	Present	HSR002739
Silica, Amorphous 112926-00-8	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:
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

**Product Name:** Biacin Granules for Oral Suspension  
**Issued:** Jun-06-2013

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

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

**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**

**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

**Product Name:**

**Biaxin Granules for Oral Suspension**

**Issued:**

**Jun-06-2013**

**Disclaimer:**

*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*