

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

**6,11-Di-O-Methyl Erythromycin A**  
**Nov-14-2011**



## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** 6,11-Di-O-Methyl Erythromycin A  
**Synonyms:** Clarithromycin Related Compound A

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

**Recommended use:** Process Intermediate

#### **1.3 Details of the supplier of the safety data sheet**

**Supplier:** Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064  
USA  
**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**

**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**



**Signal Word:** Warning  
**Hazard Statements:** H302 - Harmful if swallowed

**Product Name:** 6,11-Di-O-Methyl Erythromycin A  
**Issued:** Nov-14-2011

**Precautionary Statements:** 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.
6,11-Di-O-Methyl Erythromycin A	90 - 100%	NA	Xn, R22	Acute Tox. 4 (H302)	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: 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

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**Issued:** Nov-14-2011

**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**

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:** Process Intermediate

## **Section 8. Exposure controls/personal protection**

### **8.1. Control parameters**

**Product Name:** 6,11-Di-O-Methyl Erythromycin A  
**Issued:** Nov-14-2011

**Exposure limits:**

Chemical Name	Abbott EEL	Skin Notation
6,11-Di-O-Methyl Erythromycin A	Not Applicable	None

**8.2. Exposure controls**

**Engineering Controls:** Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

**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:** White Powder

**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):** Soluble in: hot dimethylformamide, methanol, hot 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

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## 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

Carbon oxides, Nitrogen oxides (NOx)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

#### **Routes of Exposure:**

**Oral:** Unlikely  
**Dermal:** Yes  
**Inhalation:** Yes

**Acute Toxicity - Oral:** Data for similar material given below.

Chemical Name	Acute Test	Value	Units	Species
6,11-Di-O-Methyl Erythromycin A	LD50 >=	1230	mg/kg, for a similar material	Rats Mice

**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 similar material given below.

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Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
6,11-Di-O-Methyl Erythromycin A	Liver	Monkeys	100	mg/kg, for a similar material	Oral	28 days
	Kidney	Dogs	100			1 Month
	Eyes Gastrointestinal Tract	Rats	600			30 days

**Reproductive Effects:** Similar Material : In animals adverse reproductive effects include: fetal abnormalities. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity  
Data given for similar material below.

Chemical Name	Species	Dosage	Units	Route	Duration
6,11-Di-O-Methyl Erythromycin A	Mice	1000	ppm, for similar material	Oral	During Gestation
	Rats	160			

**Carcinogenicity:** Not determined.

**Mutagenicity:** Similar material was tested negative in other mutagenicity bioassays.

**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

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.

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**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
6,11-Di-O-Methyl Erythromycin A	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
6,11-Di-O-Methyl Erythromycin A	-	-	-	-	-	

#### **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:**

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Chemical Name	Percent	NTP:	IARC:	ACGIH:
6,11-Di-O-Methyl Erythromycin A	90 - 100%	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):
6,11-Di-O-Methyl Erythromycin A	90 - 100%	No	Not Applicable	Not applicable

**Immediate Health:** Yes  
**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.

**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

**Full text of H-Statements referred to under sections 2 and 3**  
H302 - Harmful if swallowed

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

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**Disclaimer:**

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