

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

**Erythromycin Base Dihydrate**  
**Jun-06-2016**



## **SAFETY DATA SHEET**

### **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

#### **1.1. Product identifier**

**Product Name:** Erythromycin Base Dihydrate

**Synonyms:** Erythromycin Base, ABP: Erythromycin Base, USP: Erythromycin Base, USP (ABP): Erythromycin Base, Monohydrate: Erythromycin Base, USP, Dihydrate: Ery Base Dihydrate: Erythromycin Base Dihydrate, USP: Erythromycin Base Dihydrate, USP/EP: Erythromycin Base: Ery Base

**Registration Number(s)** 01-2120065789-37-0000

**List Number:** 5126: 5218: 5293: 5305: 5333: 5890: 5619: 5617

**Drug Code Number:** 27978: 27978: 40335: 66839: 61966: 27901: 38335: 49076: 27906: 27979: 27964: 27909: 79147: 48227: 78873: 45356

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

**Recommended use:** Pharmaceuticals  
Process Intermediate

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

**Supplier:** AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
+1-847-932-7900

**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**

**Serious eye damage/eye irritation** Category 2

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

**Indication of danger:** Xi - Irritant

**Risk Phrases:** R36 - Irritating to eyes

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

**Erythromycin Base Dihydrate**  
**Jun-06-2016**

## 2.2. Label elements



**Signal Word:** Warning

**Hazard Statements:** H319 - Causes serious eye irritation

**EU Specific Hazard Statements** May form combustible dust concentrations in air.

**Precautionary Statements**  
P264 - Wash face, hands and any exposed skin thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention

## 2.3. Other hazards

Not determined

## **SECTION 3: Composition/information on ingredients**

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Erythromycin Base 114-07-8	98-100	Present	Xi, R36	Eye Irrit. 2 (H319)	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.

**Product Name:** Erythromycin Base Dihydrate  
**Issued:** Jun-06-2016

**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. Available information support the following: vomiting, abdominal pain, diarrhea, anorexia, nausea

**Medical Conditions Aggravated by Exposure** None known from occupational exposure. 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.

#### **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**

**Product Name:** Erythromycin Base Dihydrate  
**Issued:** Jun-06-2016

Store according to label instructions.

### 7.3. Specific end use(s)

**Recommended use:** Pharmaceuticals  
Process Intermediate

## **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

#### **Exposure limits:**

Chemical Name	Employee Exposure Limit	Skin Notation
Erythromycin Base 114-07-8	3 mg/m <sup>3</sup>	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 to light yellow Crystalline Powder

**Odor:** Odorless.

**Odor Threshold:** Not determined

**pH:** 8-10.5 as a saturated aqueous solution

**Boiling Pt. @ 760 mm Hg (°C):** Not determined

**Melting/Freezing Point (°C):** 133-138

**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):** Freely soluble in: alcohol, chloroform, ether. Slightly soluble in: water.

<b>Product Name:</b>	<b>Erythromycin Base Dihydrate</b>
<b>Issued:</b>	<b>Jun-06-2016</b>
<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

## **9.2. Other information**

<b>Maximum Pressure Rise (bar):</b>	10.4
<b>Max. rate of pressure rise (bar/sec):</b>	1328
<b>Kst Value (bar.m/s):</b>	360
<b>Min. Ignition Energy-Cloud (mJ):</b>	3-5
<b>Min. Ignit. Temp. Dust Cloud (°C):</b>	320-340

## **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:** None under normal processing

### **10.4. Conditions to avoid**

Not determined

### **10.5. Incompatible materials**

Oxidizing agents, Acids

### **10.6. Hazardous decomposition products**

Carbon oxides, Nitrogen oxides (NOx)

## **SECTION 11: Toxicological information**

### **11.1. Information on toxicological effects**

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

<b>Oral:</b>	Yes
<b>Dermal:</b>	Yes
<b>Inhalation:</b>	Yes

**Product Name:** Erythromycin Base Dihydrate  
**Issued:** Jun-06-2016

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

Chemical Name	Acute Test	Value	Units	Species
Erythromycin Base 114-07-8	LD50 =	3000-9272	mg/kg	Rats Mice Hamsters

**Acute Toxicity - Dermal:** Not determined

**Acute Toxicity - Inhalation:** Not determined

**Corrosivity** Not determined

**Dermal Irritation:** Not determined

**Eye irritation** May be an eye irritant.

**Sensitization** May produce allergic response in individuals sensitive to erythromycins.

**Toxicokinetics/Metabolism:** Not determined

**Target Organ Effects** Not determined

**Reproductive Effects** Not determined

**Carcinogenicity** Not determined

**Mutagenicity:** Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Erythromycin Base 114-07-8	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

Not determined

### 12.2. Persistence and degradability

Not determined

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined

**Product Name:** Erythromycin Base Dihydrate  
**Issued:** Jun-06-2016

### 12.5. Results of PBT and 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** Not applicable

according to Annex II of  
MARPOL 73/78 and the IBC

**Code:**

## **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
Erythromycin Base 114-07-8	Present	-	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Erythromycin Base 114-07-8	-	Present	X	X	Present	HSR003860

#### **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

**Product Name:** Erythromycin Base Dihydrate  
**Issued:** Jun-06-2016

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	Weight-%	NTP:	IARC:	ACGIH:
Erythromycin Base	98-100	Not listed	Not listed	Not listed

**SARA 313 Information**

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Erythromycin Base	98-100	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.

**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:**  
R36 - Irritating to eyes

**Full text of H-Statements referred to under sections 2 and 3**  
H319 - Causes serious eye irritation

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

**Issued:** Jun-06-2016

**Supersedes the SDS dated:** Jan-30-2013



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