

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

abbvie
SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Erythromycin Base

Synonyms: Erythromycin Base USP, High Potency: Erythromycin Base, USP/BP:
Erythromycin Base USP/EP: Erythromycin Base, BP: Erythromycin Base, FMU:
Erythromycin, USP, Base: Erythromycin Base, High Potency: Erythromycin Base,
USP/EP (NC): Ery Base: Erythromycin Base, USP (NC): Erythromycin Base, EP
(NC): Erythromycin Base, USP (APL-FERM)

List Number: 5168: 5210: 5230: 5269: 5306: 5308: 5346: 5565: 5609: 5614: 5924: 6093: 6602:
11652: 10559

Drug Code Number: 15650: 20420: 22097: 25516: 27890: 27891: 27903: 27910: 27912: 27913: 27914:
27915: 27916: 27955: 27980: 39569: 40803: 42037: 49058: 52308: 59126: 60086:
65366: 66839: 68470: 73269: 80767: 85774: 21419: 10054679; 10067677;
105590401; 105590415; 20033818; 20032371; 20032290; 20033920; 20032265
20032267; 20032291; 20032271; 20032264; 20032272

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

Recommended use: Pharmaceuticals
Process Intermediate
Industrial use

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

Product Name: Erythromycin Base
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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

2.2. Label elements



Signal Word: Warning

Hazard Statements: H319 - Causes serious eye irritation

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	99-100	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.

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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. 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

Product Name: Erythromycin Base
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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: Pharmaceuticals
Process Intermediate
Industrial use

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 ³	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

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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 (11.2 grams/l)
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

Volume Resistivity (ohm.m):	1.8 x 10 ¹⁸
Max. rate of pressure rise (bar/sec):	652
Kst Value (bar.m/s):	176
Min. Ignition Energy-Cloud (mJ):	50
Min. Ignit. Temp. Dust Cloud (°C):	430
Min. Explosive Conc. (g/m³):	35

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 (NO_x)

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

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: Data for component (s) given below:

Corrosivity Not determined

Dermal Irritation: Not determined

Eye irritation Major ingredient: May produce mild eye irritation.

Sensitization May produce allergic response in individuals sensitive to erythromycins.

Toxicokinetics/Metabolism: Not determined

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

Reproductive Effects Not determined

Carcinogenicity Data for component (s) given below:

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

Data for component (s) given below:

12.2. Persistence and degradability

Product Name: Erythromycin Base
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Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

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

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	99-100	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	99-100	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: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

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

Product Name: Erythromycin Base
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Full text of H-Statements referred to under sections 2 and 3
H319 - Causes serious eye irritation

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Disclaimer:

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