

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Erythromycin Pledgets USP, 2%

**Synonyms:** (3R\*,4S\*,5S\*,6R\*,7R\*,9R\*,11R\*,12R\*,13S\*,14R\*)-4-[(2,6-Dideoxy-3-C-methyl- 3-O-methyl-alpha-L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13- hexamethyl-6-[[[3,4,6-trideoxy-3-(dimethylamino)-beta-D-xylo-hexopyranosyl]oxy] oxacyclotetradecane-2,10-dione

**National Drug Code (NDC):** 61748-202-60

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com


**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Flammable liquid Category 2

**Health Hazards:** May be harmful if swallowed Category 5



**Symbol(s):** 

**Signal Word:** Danger.

**Hazard Statement(s):** H225 Highly flammable liquid and vapour.  
H303 May be harmful if swallowed.

**Precautionary Statement(s):** P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion – proof electrical/ ventilating/ lighting/ equipment.  
P242 Use only non – sparking tools.  
P243 Take precautionary measures against static discharge.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
+  
P361  
+  
P353
- P311 Call a POISON CENTER/doctor if you feel unwell.
- P370 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary.  
+  
P378
- P403 Store in a well-ventilated place. Keep cool.  
+  
P235
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazards Not Otherwise Classified:** None.  
**Supplementary Information:** None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(3R*,4S*,5S*,6R*,7R*,9R*,11R*,12R*,13S*,14R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-beta-D-xylohexopyranosyl]oxy]oxacyclotetradecane-2,10-dione	114-07-8	Erythromycin	C <sub>37</sub> H <sub>67</sub> NO <sub>13</sub>	733.94	2%

\*The formula contains 20 mg Erythromycin in a base of alcohol (68.5%) (denatured with *tert*-butyl alcohol and denatonium benzoate), Propylene Glycol and Citric Acid to adjust pH.

### 4. First Aid Measures

**Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

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**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Individuals sensitive to erythromycin or other materials in its chemical class may develop allergic reactions. Serious allergic reactions, including anaphylaxis, have been reported. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted; liver effects, effects on hearing, skin rash; gastrointestinal disturbances (vomiting, abdominal pain, diarrhea, anorexia, nausea); unusual tiredness or weakness; yellow eyes or skin; sore mouth or tongue; white patches in mouth or on tongue; irregular heartbeat.

**Medical Conditions Aggravated by Exposure:** No data available.

**Notes to Physician:** Treat supportively and symptomatically.

### 5. Firefighting Measures

**Suitable Extinguishing Media:** Use extinguishing media for type of surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.

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### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** None known.

**Other Specific Hazards:** This product is flammable; it can be readily ignited under ambient conditions. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides and hydrogen chloride).

**Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Soak up spills and leaks with standard absorbent materials. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

**Specific End Use:** Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Erythromycin	WEEL: 3 mg/m <sup>3</sup> TWA 0.1 mg/m <sup>3</sup> TWA

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

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<b>Respiratory Protection:</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Eyes Protection:</b>	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Clear, colorless liquid.
<b>Odor:</b>	Rubbing alcohol odor.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	8.0 – 10.5.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	Refluxes 80°C (176°F).
<b>Flash Point:</b>	13 - 16°C (55.4 - 60.8°F) – for alcohol.
<b>Evaporation Rate:</b>	0.19.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.

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**Conditions to Avoid (e.g., static discharge, shock, or vibration):** Avoid heat, light and contact with incompatible chemicals.

**Incompatible Materials:** This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

**Hazardous Decomposition Products:** If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g. carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides, and hydrogen chloride).

### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion:** May be harmful if swallowed.

**Skin Contact:** May be harmful if absorbed through the skin. May cause irritation.

**Eye Contact:** May cause eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

#### **Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Erythromycin	Rat	Oral	LD <sub>50</sub>	4,600 mg/kg
Erythromycin	Mouse	Oral	LD <sub>50</sub>	2,580 mg/kg

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

**Eye Irritation:** No data available.

**Sensitization:** No data available.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** No data available.

**Reproductive Effects:** No data available.

**Carcinogenicity:** No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

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International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

### 12. Ecological Information

#### Ecotoxicity

##### **Aquatic:**

Compound	Species	Test Type	Dose
Erythromycin	Whiteleg shrimp ( <i>Penaeus vannamei</i> )	EC <sub>50</sub>	0.0227 mg/l, 48 hours
Erythromycin	Striped bass ( <i>Morone saxatilis</i> )	LC <sub>50</sub>	266-457 mg/l, 96 hours

**Terrestrial:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** No data available.

**Mobility in Soil:** No data available.

**Mobility in Environment:** No data available.

**Other Adverse Effects:** No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

**UN Number:** UN3077 (Erythromycin)

UN1170 (Alcohol)

**UN Proper Shipping Name:** Environmentally hazardous substance, solid, n.o.s.  
(Erythromycin)

Ethyl alcohol (Alcohol)

**Transport Hazard Class(es):** 9 (Erythromycin)

3 (Alcohol)

**Packing Group:** III (Erythromycin)

II (Alcohol)

**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):**

Not regulated as a dangerous good.

**15. Regulatory Information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):**

This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance and Reportable Quantity:**

Not listed.

**SARA 313:**

Not listed.

**SARA 302:**

Not listed.

**State Regulations**

**Massachusetts:**

Not listed.

**New Jersey:**

Not listed.

**Pennsylvania:**

Not listed.

**California Proposition 65:**

Not listed.

**16. Other Information**

**Revision Date:** 08/18/2015

**Revision Number:** 0

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