SECTION 1. IDENTIFICATION

Product Name: E.E.S. 400® Film-Coated Tablets
Product Use: A macrolide antibiotic.
How Supplied: Pink oval tablets imprinted with the two letter designation, EE
Manufacturer and Distributor:
Carnegie Pharmaceuticals LLC
600, Delran pkwy,
Delran, New Jersey, 08075
USA
Emergency: (732) 783-7011 or call 911
Information: (732) 783-7011

SECTION 2. HAZARD(S) IDENTIFICATION

Emergency Overview

GHS-US Classification

Respiratory sensitization (Category 1), H334

Skin sensitization (Category 1), H317

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

GHS-US Labeling

Pictogram

Signal word Danger
Hazard statement(s)
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statement(s)
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P321 Specific treatment (see supplemental first aid instructions on this label).
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 Wash contaminated clothing before reuse.
P501 Dispose of contents/ container to an approved waste disposal plant.

OSHA Hazards

DANGER
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.

Other hazards

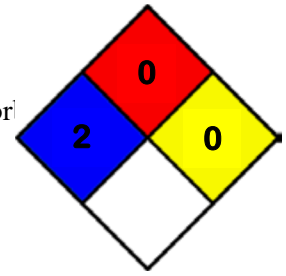
Limited test data available for hazard assessment; handle with caution.
Minimal risk expected when handled in tablet form.

HMIS Classification

Health hazard: 2 - Moderate Hazard - Temporary or minor injury may occur
Flammability: 0 - Materials that will not burn
Physical hazards: 0 - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

NFPA Rating

Health hazard: 2 - Warning - May be harmful if inhaled or absor
Fire: 0 - Not combustible
Reactivity Hazard: 0 - Not reactive when mixed with water



Potential Health Effects

Acute

Ingestion: Ingestion of this material may cause effects similar to those seen in clinical use including: nausea, vomiting, abdominal pain, diarrhea, anorexia, hepatitis, and hepatic dysfunction.

Inhalation: Aerosol generation from dust this product may be irritating to respiratory tract. May cause hypersensitivity reactions in susceptible individuals.

Skin Contact: Contact of this material with the skin may cause irritation. May cause

hypersensitivity reactions in susceptible individuals.

Eye Contact: Contact of this material with the eye may cause serious eye damage/eye irritation Category 2B.

Chronic

Chronic exposure may cause possible hypersensitization or hepatitis.

FOR MORE TOXICOLOGY INFORMATION REFER TO SECTION 11

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Hazardous (Y/N)	Amount Per Tablet	CAS Number
Erythromycin Ethylsuccinate	Y	470mg	1264-62-6
Confectioner's Sugar	Y	Proprietary	57-50-1
Corn Starch	Y	Proprietary	9005-25-8
FD&C Red No. 40	N	Proprietary	25956-17-6
Magnesium Stearate	Y	Proprietary	557-04-0
Polacrilin Potassium	N	Proprietary	39394-76-8
Sodium Citrate	N	Proprietary	6132-04-3
Opadry Pink	N	Proprietary	Not assigned

FOR EXPOSURE LIMITS SEE SECTION 8

SECTION 4. FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Eye: Eye irritation. Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get immediate medical attention.

Skin: Immediately flush the skin with plenty of water while removing contaminated clothing and shoes. Get immediate medical attention. Wash contaminated clothing before reuse.

Inhalation: Remove exposed person from source of exposure to fresh air. If not breathing, clear airway and start cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion: Get immediate medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth with water.

Overdose: Treatment of overdose should be symptomatic and supportive.
Perform gastric lavage. Administer activated charcoal as a slurry.

Monitor vital signs. Monitor ECG. Monitor fluid and electrolyte status. Monitor liver enzymes. Monitor pancreatic enzyme levels.
For allergic or anaphylactoid reactions, open airway and administer antihistamines, corticosteroids, and/or epinephrine.

For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis.
Hemodialysis is unlikely to be of benefit.
(Meditext); (PDR).

SECTION 5. FIRE FIGHTING MEASURES

Conditions of flammability: Not flammable or combustible.

Suitable Extinguishing Media: Use water spray, dry chemical, alcohol-resistant foam, or carbon dioxide.

Fire Fighting Procedures: Do not flush down sewers or other drainage systems. Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full protective clothing.

Combustion Products: Irritating or toxic substances may be emitted upon thermal decomposition. Thermal decomposition products may include Carbon Oxides (CO, CO_2) and Nitrogen Oxides (NOx).

Flash Point: Not found.

Auto-Ignition Temperature: Not found.

Flammability limits:
LEL: Not found.
UEL: Not found.

Minimum explosive concentration for dust: Not found.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid dust formation. Avoid breathing vapors, mist or gas. Environmental

precautions: Do not let product enter drains. REFER TO SECTION 15 FOR SPILL/RELEASE REPORTING INFORMATION.

Spill/Clean-up: Isolate area to restrict unnecessary personnel. Put on suitable protective clothing and equipment. Collect spilled material with paper toweling or other absorbent material. For larger spills of material, use a scoop or shovel to collect spilled material into a labeled container for recovery or disposal. Clean area thoroughly using several washes with detergent and water. Treat product, and contaminated materials (including wash/rinse

liquid) as hazardous waste and place in a suitable container for disposal.

SEE SECTION 8 FOR APPROPRIATE PROTECTIVE CLOTHING/EQUIPMENT TO BE WORN DURING SPILL CLEAN UP.

SECTION 7. HANDLING AND STORAGE

Handling Precautions: Use with adequate ventilation. Avoid crushing tablets. If tablets are crushed, avoid contact with eye, skin and clothing. Minimize aerosol generation and avoid inhalation of material. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use gloves and protective clothing as recommended in Section 8.

Storage Conditions: Store below 86°F (30°C).

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Limits:

Hazardous Material	OEL	Type	Value
Erythromycin Ethylsuccinate	Pfizer	TWA-8	0.1 mg/m^3
Confectioner's Sugar	ACGIH NIOSH REL OSHA OSHA	TWA-8 TWA-10 TWA-10 TWA-8 TWA-8	10 mg/m^3 5 mg/m^3 (respirable fraction) 10 mg/m^3 (total) 5 mg/m^3 (respirable fraction) 15 mg/m^3 (total dust)
Corn Starch	ACGIH	TWA	10 mg/m^3
Magnesium Stearate	ACGIH	TWA-8	10 mg/m^3 (stearates)

Engineering Controls: Local exhaust ventilation may be necessary to control air contaminants to their exposure limits. General room ventilation is adequate unless the process generates aerosol. If aerosol generation is probable, use appropriate ventilation such as a fume hood.

Personal Protective Equipment (PPE)

Eye Protection: Wear chemical safety goggles and face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Have eye-wash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry

	hands.
Respiratory Protection:	Respiratory protection is not required under normal conditions. If exposure limits are exceeded, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Hygiene:	Wash hands, forearms, and face thoroughly after handling compound.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (Physical State, Color, Etc.): Pink oval tablets imprinted with the two letter designation, EE. Odor: Not Available.

Odor Threshold: Not Available. pH:

Not Available.

Melting Point/Freezing Point: Not Available.

Initial Boiling Point And Boiling Range: Not Available. Flash

Point: Not Available.

Evaporation Rate: Not Available. Flammability

(Solid, Gas): Not Available.

Upper/Lower Flammability Or Explosive Limits: Not Available. Vapor

Pressure: Not Available.

Vapor Density: Not Available.

Relative Density: Not Available.

Solubility(ies): Not Available.

Partition Coefficient: N-Octanol/Water: Not Available.

Autoignition Temperature: Not Available.

Decomposition Temperature: Not Available.

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Incompatibilities: Strong oxidizers.

Conditions of Reactivity: Stable.

Hazardous Decomposition Products: Carbon oxides, nitrogen oxides. Hazardous

Polymerization: Not expected to polymerize.

Oxidizing Properties: Not found.

Explosion data relative to mechanical impact: Not expected to be a mechanical explosion hazard.

SECTION 11. TOXICOLOGICAL INFORMATION (for Erythromycin Ethylsuccinate)

Signs and Symptoms of Overexposure: Nausea, vomiting, abdominal pain, diarrhea, taste perversion, yellow eyes or skin, hearing loss, ringing in ears, ototoxicity, fever, cholestasis, blood disorders, superinfection, pseudomembranous colitis, or irregular heart rate.

Acute Effects: Oral LD50 (rat) = 9272 mg/kg. oral LD50 (mouse) = 2929 mg/kg. iv LD50 (mouse) = 426 mg/kg.

Ingestion: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, abdominal pain, diarrhea, anorexia, hepatitis, and hepatic dysfunction.

Inhalation: Aerosol generation from dust this product may be irritating to respiratory tract.

May cause hypersensitivity reactions in susceptible individuals.

Skin Contact: Contact of this material with the skin may cause irritation. May cause hypersensitivity reactions in susceptible individuals.

Eye Contact: Contact of this material with the eye may cause serious eye damage/eye irritation Category 2B.

Target Organ Effects: None.

Medical Conditions Aggravated by Exposure: Liver or kidney impairment. Cardiac arrhythmias. Sjögren's syndrome. Myasthenia gravis. Porphyria. Hearing disorders.

Chronic Effects:

Carcinogenicity: This product is not listed as a carcinogen by: ACHIG: No; NTP: No; IARC: No; OSHA: No. Long-term oral dietary studies conducted with erythromycin stearate in rats up to 400 mg/kg/day and in mice up to about 500 mg/kg/day (approximately 1 to 2 fold of the maximum human dose on a body surface area basis) did not

provide evidence of tumorigenicity.

Genotoxicity: Not expected to be genotoxic under occupational exposure conditions.
Erythromycin stearate did not show genotoxic potential in the Ames, and mouse lymphoma assays or induce chromosomal aberrations in CHO cells.

Mutagenicity: Not expected to be mutagenic under occupational exposure conditions.
Teratogenicity: Pregnancy Category B
There is no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base by oral gavage at 350 mg/kg/day (approximately twice the maximum recommended human dose on a body surface area) prior to and during mating, during gestation, and through weaning. No evidence of teratogenicity or embryotoxicity was observed when erythromycin base was given by oral gavage to pregnant rats and mice at 700 mg/kg/day and to pregnant rabbits at 125 mg/kg/day (approximately 1 to 3 times the maximum recommended human dose).

Reproductive Effects: There was no apparent effect on male or female fertility in rats treated with erythromycin base by oral gavage at 700 mg/kg/day (approximately 3 times the maximum human dose on a body surface area basis).

Other: Labor and Delivery - The effect of erythromycin on labor and delivery is unknown.
Nursing Mothers - Erythromycin is excreted in human milk. Caution should be exercised when erythromycin is administered to a nursing woman.

SECTION 12. ECOLOGICAL INFORMATION

No data is available on the degradability of this product. Releases to the environment should be avoided.

SECTION 13. DISPOSAL CONSIDERATIONS

Incineration at an approved facility is recommended. Federal, State, and Local environmental regulations and site conditions may affect proper disposal options.

SECTION 14. TRANSPORT INFORMATION

DOT (US)
Not regulated

IMDG

Not regulated

IATA
Not regulated

SECTION 15. REGULATORY INFORMATION

U.S. Federal Regulations
Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): The reportable quantity (RQ) for this material is not known. If appropriate, immediately report to the National Response Center (800/424-8802) as required by U.S. Federal Law. Also contact appropriate state and local regulatory agencies.

Toxic Substances Control Act (TSCA): The following components of this product are included on the TSCA inventory:

Confectioner's Sugar
Corn Starch
FD&C Red No. 40
Magnesium Stearate

Clean Water Act (CWA): Not found.

Clean Air Act (CAA): Not found.

OSHA Hazards: DANGER
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 311/312 Hazards: None.

State Regulations

California Prop. 65 Components
This product contains chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

International Regulations
Canadian Environmental Protection Act: Not Listed.
Canadian Workplace Hazardous Materials Information System (WHMIS):

WHMIS hazard class: Class D, Division 2, Subdivision A

The following components of this product are included on WHMIS:

Confectioner's Sugar Corn Starch
Sodium Citrate

European Inventory of Existing Chemicals (EINECS):
The following components of this product are included on EINECS:

Erythromycin Ethylsuccinate Corn Starch
FD&C Red No. 40

EU Symbol: Xn

EU Indication of danger: Harmful

EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases: S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

SECTION 16. OTHER INFORMATION

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the approved therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

Federal law prohibits dispensing without prescription. See package insert for approved medical use.

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