

Merz Pharmaceuticals, LLC

MATERIAL SAFETY DATA SHEET

NFPA Rating Health 1 Flammability 3 Reactivity 0 Special 0

TELEPHONE CONTACTS

Phone: (336) 856-2003

SECTION 1: PRODUCT IDENTIFICATION

Compound Name: ERYGEL® (2% Erythromycin)
Product Type: Prescription Gel Acne Treatment
Distributor's Name: Merz Pharmaceuticals, LLC
Address: 4215 Tudor Lane
Greensboro, NC 27410
Preparation Date: March 3, 2003

SECTION 2: COMPOSITION/HAZARDOUS INGREDIENT INFORMATION

Chemical Name	CAS Number	Percent (By Weight)	Exposure Limits in Air	
			OSHA PEL	ACGIH TLV
Ethyl Alcohol	64-17-5	92.0%	1000 ppm	1880 mg/m ³
Erythromycin	114-07-8	2.3%	N/A	N/A

SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview: ERYGEL® may cause moderate to severe irritation to eyes. Do not allow contact with eyes. Product is flammable. Keep away from flames or other ignition sources.

Potential Health Effects:

Eye Contact: Contact with the eyes may result in moderate to severe irritation.
Skin Contact: Prolonged contact with skin may result in mild to moderate irritation.
Inhalation: Not likely to occur under normal conditions of use.
Ingestion: May cause irritation, nausea, and vomiting if swallowed.
Chronic Effects: Long term 2 year oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity.

SECTION 4: FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes, if irritation persists, obtain medical attention.
Skin Contact: If irritation develops, wash skin thoroughly with soap and water and contact a healthcare professional.
Inhalation: Not likely to occur under normal conditions of use.
Ingestion: Contact a healthcare professional or poison control center immediately.

SECTION 5: FIRE FIGHTING MEASURES

Flash Point and Method: 55°F (Seta Flash Cup)
Flammable Limits: Not determined
Auto ignition Temperature: 860°F – 869°F
Fire-Extinguishing Materials: Use extinguishing media suitable for materials supporting combustion such as water fog, CO₂, foam, or dry chemical.
Fire Fighting Procedures: Use self-contained breathing apparatus in enclosed or confined spaces or as otherwise needed.
Unusual Fire and Explosion Hazards: Product is flammable. Keep away from flames or other ignition

sources.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Sweep up or take up with absorbent material and wash with water. If large quantities are spilled, flush spill area with water.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid unintentional contact with skin surfaces. Do not allow contact with eyes. Wash thoroughly after handling. Observe all labeling precautions and protective equipment recommendations.

Storage: Store in a cool, dry location out of direct sunlight. Keep container closed when not in use.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls: None necessary for normal product handling.

Respiratory Protection: None necessary for normal product handling.

Eye Protection: None necessary for normal product handling. Avoid eye contact.

Protective Clothing: None necessary for normal product handling. Clinicians repeatedly applying the product to patients should wear gloves when handling ERYGEL®.

Hygienic Work Practices: Wash hands thoroughly after handling. No eating, drinking, or smoking in area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Vapor Density (Air = 1): No data on this product

Boiling Point: 80°C (Ethyl Alcohol)

Solubility in water: Dispersible

Specific Gravity: No data on this product

pH: No data on this product

Vapor Pressure (mm of Hg at 20EC): 30 mm @ 25°C (Ethyl Alcohol)

Appearance and Odor: Clear viscous colorless gel

SECTION 10: STABILITY AND REACTIVITY

General: This product is stable and hazardous polymerization will not occur.

Incompatible Materials & Conditions to Avoid: Store away from oxidizers and heat. Store below 30°C.

Hazardous Decomposition: Carbon Dioxide and or Carbon Monoxide.

SECTION 11: TOXICOLOGICAL INFORMATION

Oral: The oral LD₅₀ for ERYGEL®, based on its alcohol content, can be calculated to be between 7.06 and 10.6 g/Kg when tested in rats.

Skin: During clinical trials the evidence of adverse reactions was as follows: burning/stinging (5.0%), itching (1.0%), erythema (0.5%), rash (0.5%), and skin tenderness (0.5%).

Ocular: ERYGEL®, based on its alcohol content, may result in moderate to severe irritation to eyes.

Sensitization: ERYGEL® is contraindicated in individuals who have shown hypersensitivity to any of its components.

Reproduction: There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (at levels up to 0.25% of diet) prior to and during mating, during gestation, and through wearing of two successive litters. Because animal reproduction studies are not always predictable of human response, this drug should be

used in pregnancy only if clearly needed. Erythromycin has been reported to cross the placental barrier in humans, but fetal plasma levels are generally low.

Carcinogenic/Mutagenic: Long term 2 year oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats feed erythromycin (base) at levels up to 0.25% of diet.

SECTION 12: ECOLOGICAL INFORMATION

Persistence and Degradability: Readily and rapidly degradable.

Aquatic Toxicity: No data available on this product.

SECTION 13: DISPOSAL CONSIDERATIONS

For small amounts of ERYGEL[®], discard as ordinary trash. For large quantities, contact Merz Pharmaceuticals, LLC for information on disposal options.

SECTION 14: TRANSPORT INFORMATION

ID 8000 Consumer Commodity, containing flammable solution ORM-D.

UN 1993 Flammable Liquid N.O.S. (Ethyl Alcohol Solution), Class 3, Pkg Group III.

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):

Components of this product are listed on the TSCA Inventory.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

This product contains no components subject to reporting or notification requirements.

SARA Title III (Superfund Amendments and Reauthorization Act):

311/312 Hazard Categories: Immediate Health, Fire

313 Reportable Ingredients: None

California Proposition 65:

This product contains no components known to the State of California to cause cancer or reproductive effects.

WHMIS (Workplace Hazardous Materials Information System - Canada):

Not regulated.

SECTION 16: OTHER INFORMATION

Revision Summary: November 6, 2002; Supersedes June 10, 2001

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