

## SAFETY DATA SHEET

**SDS Identifier:** Erythromycin Topical Gel USP, 2 %

<b>SECTION 1 - IDENTIFICATION</b>	
<b>Product Name</b>	Erythromycin Topical Gel USP, 2 %
<b>Company Identification</b>	<b>Teligent Pharma, Inc.</b>
	105 Lincoln Avenue
	Buena, New Jersey 08310
	<b>Emergency:</b> Call Poison Control Center: 1 – 800 – 222 – 1222 SDS prepared July 2017
<b>SECTION 2 – HAZARD(S) IDENTIFICATION</b>	
Emergency overview: This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communications Standard [29 CFR 1910.1200]: this product is not considered a hazard material when used in a manner which is consistent with the labeled directions.	
<b>Eyes</b>	Will cause irritation to the eyes
<b>Skin</b>	May cause skin irritation. May be absorbed through the skin.
<b>Inhalation</b>	May cause respiratory irritation in some sensitive individuals.
<b>Ingestion</b>	If swallowed may cause gastrointestinal discomfort and diarrhea.
<b>SECTION 3 – COMPOSITION AND INGREDIENTS</b>	
<b>Active Ingredient</b>	Erythromycin 2 %, CAS # 114-07-8, LD50: 9272 mg/kg (oral rat)
<b>Other Ingredients</b>	Alcohol, Hydroxypropyl Cellulose
The product does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.	
<b>SECTION 4 – FIRST AID MEASURES</b>	
<b>After Eye Contact</b>	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
<b>After Skin Contact</b>	Remove contaminated clothing immediately. For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. If irritation (redness, rash, blistering) develops, get medical attention. If skin irritation occurs get medical advice/ attention.
<b>After Inhalation</b>	Remove from source of exposure. Move individual(s) to fresh air. No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention or call Poison Control Center immediately.
<b>After Ingestion</b>	Wash out mouth with water if conscious. Do not induce vomiting unless directed to do so by medical personnel. If large quantities of material are swallowed, obtain medical attention.
<b>SECTION 5 – FIRE FIGHTING MEASURES</b>	
<b>Fire Fighting Instructions</b>	Wear approved breathing apparatus and full protective turn out gear. Wear full protective clothing and use positive pressure self-contained breathing apparatus (SCBA).
<b>Explosion Hazards</b>	Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.
<b>Extinguishing Media</b>	Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.
<b>Flash Point</b>	12-14°C (53.6-57.2°F) (Closed Cup)

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<b>SECTION 6 – ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal Safeguards</b>	Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area with explosion-proof equipment. Prevent entry into basements or confined areas.
<b>Environmental Precautions</b>	Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil
<b>Spill Clean-up Procedures</b>	Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.
<b>SECTION 7 – HANDLING AND STORAGE</b>	
<b>Handling procedures</b>	Avoid eye and skin contact. Avoid breathing vapors. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from heat, sparks and all other sources of ignition. Electrically bond and ground transfer equipment, Use appropriately rated electrical equipment in areas where this material is handled and stored. Keep containers closed when not in use.
<b>Storage</b>	Store as indicated on product packaging. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Keep containers closed when not in use. Store away from oxidizers. Keep tightly closed. Store at 20-25°C (68-77°F)
<b>Other Precautions</b>	Store at 20 - 25°C (68 - 77°F). Avoid excessive heat above 40°C. Keep away from excessive heat and open flames. May appear soft or liquefy when exposed to high heat conditions. Avoid direct sunlight, and temperature above 40 °C. Read label and package insert carefully.
<b>SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION</b>	
<b>Personal Protection Equipment:</b>	
<b>Ventilation</b>	Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.
<b>Eye Protection</b>	Chemical safety goggles recommended if contact with the drug product is possible.
<b>Skin Protection</b>	Impervious gloves recommended if contact with the drug product is possible
<b>Hand Protection</b>	Not normally needed during normal use. Wear protective gloves when handling bulk product. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that

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	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>Respiratory Protection</b>	None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor or supplied air respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.									
<b>SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES</b>										
<b>Description</b>	Clear colorless gel with alcohol odor									
<b>Specific Gravity</b>	~ 0.8 (water is 1)									
<b>pH</b>	8 – 10.5									
<b>Boiling Point:</b>	~ 78 °C (~172 °F)									
<b>Freezing Point</b>	Not available									
<b>Vapor Density</b>	1.59 (ethanol)									
<b>Vapor Pressure</b>	59.3 mmHg @ 25°C (ethanol)									
<b>Evaporation Rate</b>	Not available									
<b>Solubility in Water</b>	Dispersible in water.									
<b>SECTION 10 – STABILITY AND REACTIVITY</b>										
<b>Stable</b>	Not reactive under normal conditions of use.									
<b>Hazardous Polymerization</b>	Reaction with strong oxidizers will generate heat and cause fire.									
<b>Conditions to Avoid</b>	Avoid heat, sparks, flames, and all other sources of ignition									
<b>Incompatibility</b>	Oxidizers, acids, bases									
<b>Hazardous Decomposition</b>	Thermal decomposition may yield carbon oxides									
<b>SECTION 11 – TOXICOLOGICAL INFORMATION</b>										
Individuals who have had allergic reactions to products containing any component of this product may experience allergic reactions to this product. This product may be mildly to moderately irritating. Hazardous Scale [ <b>0</b> = Minimal <b>1</b> = Slight <b>2</b> = Moderate <b>3</b> = Serious <b>4</b> = Severe]										
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">Health (blue)</td> <td style="text-align: center;">2</td> </tr> <tr> <td style="text-align: center;">Fire Hazard (Red)</td> <td style="text-align: center;">3</td> </tr> <tr> <td style="text-align: center;">Reactivity (Yellow)</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">Personal Protection</td> <td style="text-align: center;">See section 8</td> </tr> </table>	Health (blue)	2	Fire Hazard (Red)	3	Reactivity (Yellow)	0	Personal Protection	See section 8	
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<b>Acute and Chronic Toxicity</b>										
<b>Genotoxicity study</b>	No data available									
<b>General Toxicity</b>	No data available									
<b>Skin Sensitivity</b>	No data available									
<b>Eye Sensitivity</b>	Eye contact will cause irritation.									
<b>Sensitization</b>	Erythromycin is a skin and respiratory sensitizer. Allergic reactions may occur in sensitized individuals.									
<b>Carcinogenicity</b>	Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). A 2 year oral studies in rats with erythromycin									

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	ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity.																																		
<b>Mutagenicity/ Embryo / Reproductive Toxicity / Teratogenicity</b>	<p>None of the components have been shown to cause germ cell mutagenicity.</p> <p>There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet. There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation and through weaning of two successive litters. Ethanol is known to cause developmental toxicity when intentionally ingested during pregnancy.</p>																																		
<b>SECTION 12 – ECOLOGICAL INFORMATION</b>																																			
The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.																																			
<b>SECTION 13 – DISPOSAL INFORMATION</b>																																			
<b>Product Disposal</b>	Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.																																		
<b>Packaging</b>	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.																																		
<b>SECTION 14 – TRANSPORTATION INFORMATION</b>																																			
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<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):</b> Not applicable – product is transported only in packaged form.																																			
<b>SECTION 15 – REGULATORY INFORMATION</b>																																			
The product described in this SDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable). This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.																																			
<b>SECTION 16 – OTHER INFORMATION</b>																																			
The information contained in this Safety Data Sheet has been compiled from information believed to be accurate and from experience. While we believe that the data presented is factual, Teligent Pharma Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.																																			