

**SAFETY DATA SHEET**
**SDS Identifier:** Triamcinolone Acetonide Ointment USP, 0.1 %

<b>SECTION 1 - CHEMICAL / PRODUCT AND COMPANY IDENTIFICATION</b>	
<b>Product Name</b>	Triamcinolone Acetonide Ointment USP, 0.1 %
<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 May 2016	
<b>SECTION 2 – COMPOSITION AND INGREDIENTS</b>	
<b>Active Ingredient</b>	Triamcinolone Acetonide 0.1 %
	CAS # 76-25-5      LD50: 1451 mg/kg
<b>Other Ingredients</b>	Light Mineral Oil and White Petrolatum
The product does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.	
<b>SECTION 3 – HAZARDS 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>	None
<b>Inhalation</b>	May cause irritation of nose and throat
<b>Ingestion</b>	May be harmful if swallowed
<b>SECTION 4 – FIRST AID MEASURES</b>	
<b>After Eye Contact</b>	Immediately flush with plenty amounts of water for at least 15 minutes. If irritation continues, seek medical attention.
<b>After Skin Contact</b>	Wash exposed areas with plenty amounts of water. If adverse skin occur, discontinue use. Seek medical attention.
<b>After Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention or call Poison Control Center immediately.
<b>After Ingestion</b>	Flush out mouth with water, consult a physician immediately.
<b>SECTION 5 – FIRE FIGHTING MEASURES</b>	
<b>Fire Fighting Instructions</b>	Wear approved breathing apparatus and full protective turn out gear.
<b>Explosion Hazards</b>	When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and hydrogen fluoride).
<b>Extinguishing Media</b>	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
<b>Flash Point</b>	Not available
<b>SECTION 6 – ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal Safeguards</b>	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
<b>Environmental Precautions</b>	Treat dispose in accordance with all regulations.

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<p><b>Spill Clean-up Procedures</b></p>	<p>This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.</p> <p><i>Industrial / large spill:</i> Contain the source of the spill or leak if it is safe to do so. Collect spill with non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Minimum Personal Protective Equipment should be triple gloves (rubber gloves over nitrile over latex gloves) rubber boots, face shield, and self-contained breathing apparatus. Decontaminate the area of the spill thoroughly using detergent and water.</p> <p><i>Household / small spill:</i> Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Wear gloves during clean-up. Decontaminate the area of the spill thoroughly using detergent and water.</p>
<p><b>SECTION 7 – HANDLING AND STORAGE</b></p>	
<p><b>Handling procedures</b></p>	<p>Avoid contact with eyes. Follow all SDS and label precautions.</p>
<p><b>Storage</b></p>	<p>Store at room temperature 15°- 25°C (59°- 77°F) in its original container. Avoid freezing and excessive heat above 40°C.</p>
<p><b>Other Precautions</b></p>	<p>Avoid direct sunlight, read label and package insert carefully.</p>
<p><b>SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION</b></p>	
<p><b>Personal Protection Equipment:</b></p>	
<p><b>Ventilation</b></p>	<p>Good general ventilation is sufficient to control airborne levels.</p>
<p><b>Eye Protection</b></p>	<p>Wear safety glasses or goggles if eye contact is possible.</p>
<p><b>Skin Protection</b></p>	<p>Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.</p>
<p><b>Hand Protection</b></p>	<p>Wear protective gloves to avoid repeated skin contact.</p>
<p><b>Respiratory Protection</b></p>	<p>Wear an appropriate respirator or mask.</p>
<p><b>SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES</b></p>	
<p><b>Description</b></p>	<p>A white, faintly yellowish unctuous, translucent ointment</p>
<p><b>Specific Gravity</b></p>	<p>~ 0.85 (water = 1)</p>
<p><b>pH</b></p>	<p>N/A</p>
<p><b>Boiling Point:</b></p>	<p>Mixture</p>
<p><b>Freezing Point</b></p>	<p>38 – 45 °C</p>
<p><b>Vapor Density</b></p>	<p>Not available</p>
<p><b>Vapor Pressure</b></p>	<p>Not available</p>
<p><b>Evaporation Rate</b></p>	<p>Not available</p>
<p><b>Solubility in Water</b></p>	<p>Dispersible in hot water</p>
<p><b>SECTION 10 – STABILITY AND REACTIVITY</b></p>	
<p><b>Stable</b></p>	<p>Yes</p>
<p><b>Hazardous Polymerization</b></p>	<p>Will not occur</p>
<p><b>Conditions to Avoid</b></p>	<p>Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing.</p>

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<b>Incompatibility</b>	Strong bases, acids and oxidizing agents								
<b>Hazardous Decomposition</b>	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and hydrogen fluoride).								
<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 [0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe]									
	<table border="1"> <tr> <td>Health (blue)</td> <td>1</td> </tr> <tr> <td>Fire Hazard (Red)</td> <td>0</td> </tr> <tr> <td>Reactivity (Yellow)</td> <td>0</td> </tr> <tr> <td>Personal Protection</td> <td>See section 8</td> </tr> </table>	Health (blue)	1	Fire Hazard (Red)	0	Reactivity (Yellow)	0	Personal Protection	See section 8
Health (blue)	1								
Fire Hazard (Red)	0								
Reactivity (Yellow)	0								
Personal Protection	See section 8								
<b>Acute and Chronic Toxicity</b>									
<b>General Toxicity</b>	Individuals who have had allergic reactions to products containing the Triamcinolone Acetonide component of this product or any other components of this product may experience allergic reactions to this product. Persons using the product in therapeutic doses may experience burning, itching, irritation, dryness, inflammation of hair follicles, excessive hair growth, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, striae, and prickly heat.								
<b>Skin Sensitivity</b>	Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis								
<b>Eye Sensitivity</b>	Eye contact will cause irritation.								
<b>Respiratory Sensitization</b>	Although unlikely, inhalation can irritate the respiratory system.								
<b>Carcinogenicity</b>	Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows: MINERAL OIL: IARC-3 (Not Classifiable as to Carcinogenicity to Humans) WHITE PETROLATUM: Not listed by ACGIH, IARC, NTP, or CA Prop 65.								
<b>Mutagenicity/ Embryo Toxicity/ Reproductive Toxicity</b>	The active component of this product, Triamcinolone Acetonide, is rated as Pregnancy Category C (RISK CANNOT BE RULED OUT; Human evidence is lacking, but animal evidence is positive). Listed below is information concerning the effects of this compound on animal or human reproductive system. Animal studies have not been performed to evaluate the mutagenicity, teratogenicity or reproductive toxicity of Triamcinolone Acetonide. No human data are available.								

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<b>Teratogenicity</b>	Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. No human data are available.
<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>	Dispose of in accordance with all applicable federal, state and local regulations.
<b>Packaging</b>	Disposal in compliance with official regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.
<b>SECTION 14 – TRANSPORTATION INFORMATION</b>	
Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.	
<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).	
<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 past 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.	