

**SAFETY DATA SHEET**

SDS Identifier: Triamcinolone Acetonide Cream USP

<b>SECTION 1 - CHEMICAL / PRODUCT AND COMPANY IDENTIFICATION</b>	
<b>Product Name</b>	Triamcinolone Acetonide Cream USP, 0.1 % OR Triamcinolone Acetonide Cream USP, 0.5 %
<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 August 2017
<b>SECTION 2 – 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 3 – COMPOSITION AND INGREDIENTS</b>	
<b>Active Ingredient</b>	Triamcinolone Acetonide
	CAS # 76-25-5   LD50: 1451 mg/kg
<b>Other Ingredients</b>	Benzyl alcohol, Cetyl alcohol, Emulsifying wax, Glycerin, Isopropyl Palmitate, Lactic acid, Sorbitol solution, and Purified water.
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>	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.

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<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.
<b>Spill Clean-up Procedures</b>	<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>
<b>SECTION 7 – HANDLING AND STORAGE</b>	
<b>Handling procedures</b>	Avoid contact with eyes. Follow all SDS and label precautions.
<b>Storage</b>	Store at room temperature 20°- 25°C (68° - 77°F) in its original container. See USP controlled room temperature. Avoid freezing.
<b>Other Precautions</b>	Avoid direct sunlight, read label and package insert carefully.
<b>SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION</b>	
<b>Personal Protection Equipment:</b>	
<b>Ventilation</b>	Good general ventilation is sufficient to control airborne levels.
<b>Eye Protection</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin Protection</b>	Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.
<b>Hand Protection</b>	Wear protective gloves to avoid repeated skin contact.
<b>Respiratory Protection</b>	Wear an appropriate respirator or mask.
<b>SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>Description</b>	White to off-white cream
<b>Specific Gravity</b>	~ 0.95 (water = 1)
<b>pH</b>	2.5 – 5.5
<b>Boiling Point:</b>	Mixture
<b>Freezing Point</b>	Mixture
<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Evaporation Rate</b>	Not available

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<b>Solubility in Water</b>	Dispersible in water	
<b>SECTION 10 – STABILITY AND REACTIVITY</b>		
<b>Stable</b>	Yes	
<b>Hazardous Polymerization</b>	Will not occur	
<b>Conditions to Avoid</b>	Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing.	
<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]		
	Health (blue)	2
	Fire Hazard (Red)	1
	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. Exposure to this product may cause the following health effects: <b>Acute:</b> This product may cause irritation via inhalation or eye contact. Ingestion may be harmful. <b>Chronic:</b> Repeated skin contact may cause dermatitis (dry, red skin).	
<b>Skin Sensitivity</b>	Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis Rare instances of anaphylactoid reactions have occurred in persons receiving corticosteroid therapy. Due the presence of Benzyl Alcohol (a weak skin sensitizer) skin contact may cause an allergic reaction in sensitive individuals; subsequent exposure to very small amounts may cause an allergic reaction in sensitive individuals with redness, itching, welts, and irritation.	
<b>Eye Sensitivity</b>	Eye contact will cause irritation, itching.	
<b>Respiratory Sensitization</b>	Although unlikely, inhalation can irritate the respiratory system.	

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<p><b>Carcinogenicity</b></p>	<p>Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or</p>
<p><b>Mutagenicity/ Embryo Toxicity/ Reproductive Toxicity</b></p>	<p>This product is rated as Pregnancy Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). Listed below is information concerning the effects of this compound on animal or human reproductive systems. <b>Mutagenicity:</b> No studies available. <b>Embryotoxicity/Teratogenicity:</b> <i>Human Data:</i> As a group, corticosteroids have not been associated with congenital malformations in humans. <i>Animal Data:</i> Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. <b>Reproductive Toxicity:</b> No human reproductive effects have been described for this material. Corticosteroids are secreted in human milk. Because of the potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure. <b>Non-Teratogenic Effects:</b> Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy.</p>
<p><b>Teratogenicity</b></p>	<p>No data available.</p>

**SECTION 12 – ECOLOGICAL INFORMATION**

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

**MOBILITY:** This product has not been tested for soil absorption or mobility. The following information is for some components.

**BENZYL ALCOHOL:** Experimental Koc values for Benzyl Alcohol are < 5 for three different soils; Apison (0.11% organic carbon), Fullerton (0.06% organic carbon), and Dormont (1.2% organic carbon). An experimental Koc of 15 was determined for Benzyl Alcohol on a red-brown Australian soil (1.09% organic carbon). According to a classification scheme, these Koc values suggest that Benzyl Alcohol is expected to have very high mobility in soil.

**GLYCERIN:** Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, soil adsorption coefficients for Glycerin can be estimated at 3 and 2, respectively, using regression-derived equations. The magnitude of these values indicate that glycerin will display very high mobility in soil.

**PERSISTENCE AND BIODEGRADABILITY:** This product has not been tested for persistence or biodegradability. The following information is for some components.

**BENZYL ALCOHOL:** If released to air, a vapor pressure of 0.094 mm Hg at 25°C indicates Benzyl Alcohol will exist solely as a vapor in the ambient atmosphere. Vapor-phase Benzyl Alcohol will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 17 hours. If released to soil, Benzyl Alcohol is expected to have very high mobility based upon Koc values of less than 5 to 15 measured in various soils. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 3.1X10<sup>-7</sup> atm-cu m/mole. Benzyl Alcohol is not expected to volatilize rapidly from dry soil surfaces based on its vapor pressure. Benzyl Alcohol is expected to undergo biodegradation under both aerobic and anaerobic conditions based upon results in a number of aqueous biodegradation tests. If released into water, Benzyl Alcohol is not expected to adsorb to suspended solids and sediment based upon the Koc data. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 75 days and 2.2 years, respectively. Hydrolysis is not expected to be an important environmental fate process since Benzyl Alcohol lacks hydrolyzable functional groups.

**GLYCERIN:** If released to soil, glycerin is expected to undergo rapid biodegradation under aerobic conditions. It is expected to display very high mobility in soil and it is not expected to significantly volatilize to the atmosphere. If released to water, glycerin is expected to rapidly degrade under aerobic conditions. Biodegradation in seawater and under anaerobic conditions is also expected. Glycerin is not

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<p>expected to bioconcentrate is fish and aquatic organisms nor is it expected to adsorb to sediment and suspended organic matter. Volatilization to the atmosphere is expected to be slower than for water itself. If released to the atmosphere, Glycerin may undergo a gas-phase oxidation with photochemically produced hydroxyl radicals with a half-life of 33 hrs. It may also undergo atmospheric removal by wet deposition processes.</p> <p><b>BIOACCUMULATION:</b> This product has not been tested for bioconcentration. The following information is for some components.</p> <p><b>BENZYL ALCOHOL:</b> An estimated BCF of 1 was calculated for Benzyl Alcohol, using a log Kow of 1.1 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.</p> <p><b>GLYCERIN:</b> Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, bioconcentration factors for Glycerin can be estimated at 3 and 0.2, respectively, using regression-derived equations. The magnitude of these values indicate that bioconcentration of Glycerin in fish and aquatic organisms will not be significant. Log KOW = -1.76.</p> <p><b>ECOTOXICITY:</b> No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following are aquatic toxicity data currently available for components of this product. Only select data are presented on this SDS. Contact Fougere for information on additional available data.</p> <p><b>BENZYL ALCOHOL:</b>            LC50 (<i>Pimephales promelas</i> fathead minnows) 96 hours = 460 mg/L (static bioassay in Lake Superior water at 18-22°C)            LC50 (<i>Lepomis macrochirus</i> bluegill sunfish) 96 hours = 10 ppm/L (static bioassay in fresh water at 23°C, mild aeration after 24 hours)            LC50 (<i>Medina beryllina</i> tidewater silverside fish) 96 hours = 15 ppm (static bioassay in synthetic seawater at 23°C, mild aeration after 24 hours)            LC50 (<i>Daphnia</i>) 24 hours = 55; 400 mg/L ; LC50 (<i>Petromyzon marinus</i> larvae) 24 hours = &gt;5 mg/L            EC50 (<i>Photobacterium phosphoreum</i>) 30 minutes = 71 mg/L ; EC50 (<i>Scenedesmus quadricauda</i>) 3 hours = 79 mg/L</p> <p><b>BENZYL ALCOHOL (continued):</b>            EC50 (<i>Haematococcus pluvialis</i>) 4 hours = 2,600 mg/L            EC50 (<i>Anabaena cylindrica</i>) 3 hours = 90 mg/L            EC50 (<i>Anabaena variabilis</i>) 3 hours = 35 mg/L            EC50 (<i>Chlorella pyrenoidosa</i>) 3 hours = 95 mg/L</p> <p><b>GLYCERIN:</b>            Toxicity threshold (cell multiplication inhibition test) Algae (<i>Microcystis aeruginosa</i>) = 2900 mg/L            Toxicity threshold (cell multiplication inhibition test) Protozoa (<i>Entosiphon sulcatum</i>) = 3200 mg/L            LC50 (Goldfish) 24 hours = &gt; 5000 mg/L/modified ASTM D 1345</p>	
<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.	