



## MATERIAL SAFETY DATA SHEET

### SECTION 1: Product and Company Identification

**PRODUCT:** Desoximetasone Ointment USP, 0.25 %

**Manufactured by:**

Teligent Pharma Inc.  
105 Lincoln Avenue  
Buena, New Jersey 08310  
Phone: 856-697-1441

Poison Control Center: 1 – 800 – 222 – 1222

Prepared: March 2016

This MSDS is written to provide health and safety information for individuals who will be handling the product during manufacture and packaging. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

### SECTION 2: Hazards Identification

**Emergency overview:** The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information.

**Routes of exposure:** Ingestion. Skin contact. Eye contact.

**Eyes:** Contact with eyes may cause irritation.

**Skin:** May cause skin irritation. May be absorbed through the skin.

**Inhalation:** Unlikely due to form of product. May cause irritation.

**Ingestion:** Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Components of the product may be absorbed into the body by ingestion. Do not ingest.

**Chronic effects:** Chronic overexposure may have skin, GI, and vascular effects.

**Potential environmental**

**Effects:** May cause long-term adverse effects in the environment.

### SECTION 3: Composition and Ingredients

<u>Ingredients</u>	<u>CAS No.</u>	<u>Quantity</u>	<u>LD50 (Oral, Rat)</u>
Desoximetasone	382-67-2	2.5 mg/g	>5000 mg/Kg

Other ingredients: Fractionated Coconut Oil and White Petrolatum.

### SECTION 4: First Aid Measures

**After Eye Contact:** Immediately flush with plenty amounts of water for at least 15 minutes. If irritation continues, seek medical attention.

**After Skin Contact:** Wash exposed areas with plenty amounts of water for at least 20 minutes. If adverse skin effects occur, discontinue use. Seek medical attention

**After Inhalation:** Remove from source of exposure. Move individual to fresh air. If signs of toxicity occur, seek medical attention or call Poison Control Center immediately.

**After Ingestion:** This product is not intended for ingestion. In case of accidental ingestion, flush out mouth with water, consult POISON CENTER or a physician immediately.

**General advice:** In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### SECTION 5: Fire Fighting Measures

**Extinguishing media** Water. Foam. Dry powder. Carbon dioxide (CO<sub>2</sub>).

**Fire Fighting Instructions:** Wear approved breathing apparatus and full protective turn out gear.

**Specific hazards arising from the chemical:**

Fire may produce irritating, corrosive and/or toxic gases (carbon dioxide, carbon monoxide hydrogen fluoride and maybe oxygen fluoride).

**Fire fighting**

**equipment/ instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand, SCBA, MSHA/NIOSH (approved or equivalent) and full protective gear.

**SECTION 6: Accidental Release Measures**

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**Personal Safeguards:** Avoid excessive contact and contact with eyes. Wear safety goggles or shield. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental Precautions:** Treat dispose in accordance with all regulations.

**Spill Clean-up Procedures:** This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.  
*Industrial / large spill:* 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 with detergent and water. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Dispose of in accordance with applicable Federal, State, and local procedures.  
*Household / small spill:* 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.

**SECTION 7: Handling and Storage**

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**Handling procedures:** Avoid contact with eyes. Do not ingest. Handle in accordance with good industrial hygiene and safety practices. Follow all MSDS and label precautions.

**Storage:** Store at controlled room temperature between 20°-25° C (68°-77° F), excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature] Avoid excessive heat above 40°C. May appear soft or liquefy when exposed to high heat conditions.

**Other Precautions:** Avoid direct sunlight, read label and package insert carefully.

**SECTION 8: Exposure Controls and Personal Protection**

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**Engineering Controls:**

**Ventilation:** Good general ventilation is sufficient to control airborne levels. Follow standard medical product handling procedures.

**Personal Protection:**

**Eye Protection:** Wear safety glasses or goggles if eye contact is possible.

**Skin Protection:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

**Hand Protection:** Wear protective gloves to avoid repeated skin contact.

**Respiratory Protection:** Wear an appropriate respirator or mask.

**SECTION 9: Physical and Chemical Properties**

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**Description:** A white, faintly yellowish unctuous, translucent ointment

**Specific Gravity:** 0.85 (water = 1)

**pH:** N/A

**Boiling Point:** Not available

**Freezing Point:** Not available

**Flash Point:** Not available

**Vapor Density:** Not available

**Vapor Pressure:** Not available

**Evaporation Rate:** Not available

**Solubility in Water:** Dispersible in hot water



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### **SECTION 10: Stability and Reactivity**

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**Stable:** Material is stable under normal conditions.  
**Conditions to Avoid:** Avoid heat, light, and contact with materials it is incompatible.  
**Incompatibility:** Acids, caustics, and other chemicals that could affect its performance should be avoided  
**Hazardous Decomposition:** None if used for intended purpose. If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides)

### **SECTION 11: Toxicological Information**

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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	1
Fire Hazard	1
Reactivity	0

#### **Acute & Chronic Toxicity**

**Skin Sensitivity:** NA  
**Eye Sensitivity:** NA  
**Respiratory Sensitization:** None

**Carcinogenicity:** NTP None IARC None

**Reproductive Toxicity:** No human data is available for this product.  
**Teratogenicity:** No human data is available for this product.  
**Embryotoxicity:** No human data is available for this product.  
**Mutagenicity:** No human data is available for this product.

### **SECTION 12: Ecological Information**

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

### **SECTION 13: Disposal Considerations**

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**Product Disposal:** Dispose in accordance with all applicable federal, state and local regulations. Collect and reclaim or dispose in sealed containers at licensed waste disposal site.  
**Packaging:** Disposal in compliance with official regulations. Handle packaging in the same way as the product itself. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Reusable equipment should be cleaned with soap and water.

### **SECTION 14: Transportation Information**

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Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.



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### **SECTION 15: Regulatory Information**

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The product described in this MSDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable). The finished product is labeled in compliance with the requirements of the FDA and must be used in prescribed manner.

### **SECTION 16: Other Information**

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The information contained in this Material 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.