

SAFETY DATA SHEET

SDS Identifier: Lidocaine Ointment USP, 5 %

SECTION 1 - IDENTIFICATION	
Product Name	Lidocaine Ointment USP, 5 %
Company Identification	Teligent Pharma, Inc.
	105 Lincoln Avenue
	Buena, New Jersey 08310
	Emergency: Call Poison Control Center: 1 – 800 – 222 – 1222
	SDS prepared July 2017
SECTION 2 – HAZARD(S) IDENTIFICATION	
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.	
Eyes	Will cause irritation to the eyes
Skin	May cause skin irritation. May be absorbed through the skin.
Inhalation	May cause respiratory irritation in some sensitive individuals.
Ingestion	If swallowed may cause gastrointestinal discomfort and diarrhea.
SECTION 3 – COMPOSITION AND INGREDIENTS	
Active Ingredient	Lidocaine 5 %, CAS # 137-58-6, LD50 (acute): 317 mg/kg (oral rat)
Other Ingredients	Polyethylene glycols
The product does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.	
SECTION 4 – FIRST AID MEASURES	
After Eye Contact	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.
After Skin Contact	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.
After Inhalation	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.
After Ingestion	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.
SECTION 5 – FIRE FIGHTING MEASURES	
Fire Fighting Instructions	Wear approved breathing apparatus and full protective turn out gear. Wear full protective clothing and use positive pressure self-contained breathing apparatus (SCBA).
Explosion Hazards	This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides). The Lidocaine component of this product is a skin sensitizer, and so it poses a contact hazard to firefighters. Closed containers may explode from the heat of fire.

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Extinguishing Media	Water Spray, Carbon Dioxide, Foam, Dry Chemical, Halon.
Flash Point	Data not available
SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8. Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.
Environmental Precautions	Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil
Spill Clean-up Procedures	Contain spilled product. 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.
SECTION 7 – HANDLING AND STORAGE	
Handling procedures	Avoid contact with eyes. Follow all SDS and label precautions.
Storage	Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.
Other Precautions	Store at 20 - 25°C (68 - 77°F). Avoid excessive heat above 40°C. 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.
SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION	
Personal Protection Equipment:	
Ventilation	Good general ventilation is sufficient to control airborne levels. Follow standard medical product handling procedures.
Eye Protection	Not normally needed during normal use. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin Protection	No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.
Hand Protection	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

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	material is protective against the solvent being used. Use handling practices that 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.								
Respiratory Protection	A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).								
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES									
Description	white to off-white colored ointment								
Specific Gravity	1.05 (water is 1)								
pH	N/A								
Boiling Point:	225°C (437°F)								
Freezing Point	40 °C (104 °F)								
Vapor Density	Not available								
Vapor Pressure	Not available								
Evaporation Rate	Not available								
Solubility in Water	Dispersible in water.								
SECTION 10 – STABILITY AND REACTIVITY									
Stable	Stable under recommended storage conditions.								
Hazardous Polymerization	Will not occur								
Conditions to Avoid	Excess heat or cold, freezing.								
Incompatibility	Oxidizers, acids, bases								
Hazardous Decomposition	No data available								
SECTION 11 – TOXICOLOGICAL INFORMATION									
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>1</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)	1	Reactivity (Yellow)	0	Personal Protection	See section 8
Health (blue)	1								
Fire Hazard (Red)	1								
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Personal Protection	See section 8								
Acute and Chronic Toxicity									
Genotoxicity study	No data available								
General Toxicity	No data available								
Skin Sensitivity	No data available								
Eye Sensitivity	Eye contact will cause irritation.								
Respiratory Sensitization	Although unlikely, inhalation can irritate the respiratory system.								
Carcinogenicity	Not a carcinogen								
Mutagenicity/ Embryo / Reproductive Toxicity	No data available								

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Teratogenicity	No data available
Other information	Systemic effects of topical corticosteroids may include reversible hypothalamicpituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.
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.	
SECTION 13 – DISPOSAL INFORMATION	
Product Disposal	Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
Packaging	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
SECTION 14 – TRANSPORTATION INFORMATION	
Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.	
SECTION 15 – REGULATORY INFORMATION	
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.	
SECTION 16 – OTHER INFORMATION	
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.	