

SAFETY DATA SHEET

SDS Identifier: Lidocaine Cream 4 %

SECTION 1 - IDENTIFICATION	
Product Name	Lidocaine Cream 4 %
Company Identification	Teligent Pharma, Inc.
	105 Lincoln Avenue
	Buena, New Jersey 08310
	Emergency: Call Poison Control Center: 1 – 800 – 222 – 1222
	SDS prepared September 2018
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 Ingredients	Lidocaine 4 %, CAS# 137-58-6, LD50 (acute): 317 mg/kg (oral rat)
Other Ingredients	Butylated Hydroxytoluene, Cetostearyl Alcohol, Citric Acid, Edetate Disodium, Light Mineral Oil, Methylparaben, Polyoxyl-20-Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate 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.	
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	May produce numbness of the tongue and anesthetic effects on the stomach. Wash out mouth with water and give 200-300 mL water to drink. 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).

SAFETY DATA SHEET

SDS Identifier: Lidocaine Cream 4 %

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.
Extinguishing Media	Water Spray, Carbon Dioxide, Foam, Dry Chemical.
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	As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this material. Avoid contact with eyes. Follow all SDS and label precautions.
Storage	Store at 20 - 25°C (68 - 77°F). [See USP Controlled Room Temperature].
Other Precautions	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	Wear splash goggles or safety glasses with side shields as appropriate for the task. If necessary, refer to appropriate regulations. 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.

SAFETY DATA SHEET

SDS Identifier: Lidocaine Cream 4 %

Hand Protection	Not normally needed during normal use. Wear protective gloves when handling bulk product. Chemically compatible gloves especially for alkaline pH are recommended. For handling solutions, ensure that the glove 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 cream.	
Specific Gravity	~ 1 (water is 1)	
pH	7.0 – 9.0	
Boiling Point:	Data not available	
Freezing Point	Data not available	
Vapor Density	Data not available	
Vapor Pressure	Data not available	
Evaporation Rate	Data not available	
Solubility in Water	Miscible 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	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g. carbon and nitrogen oxides).	
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]		
	Health (blue)	2
	Fire Hazard (Red)	1
	Reactivity (Yellow)	0
	Personal Protection	See section 8
Acute and Chronic Toxicity		
Genotoxicity study	Data not available	
General Toxicity	Data not available	
Skin Sensitivity	Data not available	
Eye Sensitivity	Eye contact will cause irritation.	

SAFETY DATA SHEET

SDS Identifier: Lidocaine Cream 4 %

Sensitization	Data not available
Carcinogenicity	Data not available
Mutagenesis / Genotoxicity	Data not available
Reproductive Toxicity / Embryo Toxicity / Teratogenicity	Data not available
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	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.
Packaging	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations. Observe all hazard precautions.
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 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). This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by Toxic Substances Control Act (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.	