

SAFETY DATA SHEET

SDS Identifier: Gentamicin Sulfate Cream USP, 0.1 %

SECTION 1 - IDENTIFICATION	
Product Name	Gentamicin Sulfate Cream USP, 0.1%
Company Identification	SOLA Pharmaceuticals
	18169 East Petroleum Drive, Suite B Baton Rouge, LA 70809 Phone (866) 747-7365
	Emergency: Call Poison Control Center: 1 – 800 – 222 – 1222
	SDS prepared July 2020
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 or redness
Inhalation	Unlikely due to viscosity of the product.
Ingestion	May be harmful
SECTION 3 – COMPOSITION AND INGREDIENTS	
Active Ingredient	Gentamicin Sulfate 0.167 %, CAS # 1405-41-0, LD50: > 5g/kg (oral rat)
Other Ingredients	Butylparaben, Isopropyl Myristate, Methylparaben, Polysorbate 40, Propylene Glycol, Propylene Glycol Monostearate, Purified Water, Sorbitol Solution and Stearic Acid.
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	This product is intended for use on the skin. If unintended contact occurs, 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.
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	This product is not intended for ingestion. In case of accidental ingestion, flush out mouth with water, consult POISON CENTER or a physician immediately.
SECTION 5 – FIRE FIGHTING MEASURES	
Fire Fighting Instructions	Wear approved breathing apparatus and full protective turn out gear. Assume that this product is capable of sustaining combustion.
Explosion Hazards	Product is not flammable or combustible.
Extinguishing Media	Use water fog or spray, carbon dioxide, dry chemical or foam.
Flash Point	No data available.
SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	Avoid excessive contact and contact with eyes. Wear appropriate protective clothing and equipment as described in Section 8.
Environmental Precautions	Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
Spill Clean-up Procedures	<i>Industrial / large spill:</i> Contain the source of the spill or leak if it is safe to do so. Use a shovel or non-combustible absorbent material to put the material into a convenient waste

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	<p>disposal container. 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>
SECTION 7 – HANDLING AND STORAGE	
Handling procedures	All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Use only with adequate ventilation. Wash thoroughly after handling. Keep containers closed when not in use. Follow all SDS and label precautions.
Storage	Store at 20 – 25 °C (68 – 77 °F); [see USP Controlled Room Temperature] to maintain product integrity. Protect containers from physical damage. Keep containers tightly closed when not in use.
Other Precautions	Avoid direct sunlight. Read label and package insert carefully.
SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION	
Personal Protection Equipment:	
Ventilation	Good general ventilation is adequate to control airborne levels.
Eye Protection	Chemical safety goggles recommended if contact with the drug product is possible.
Skin Protection	For situations in which prolonged skin contact is anticipated, use double impervious gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.
Hand Protection	Not normally needed during normal use. Wear protective gloves when handling bulk product. Chemically compatible gloves are recommended. Use handling practices that minimize direct hand contact.
Respiratory Protection	A respirator is not required for routine conditions of use of this product. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES	
Description	White cream
Specific Gravity	~ 0.96 (water is 1)
pH	3 – 5
Boiling Point:	No data available
Freezing Point	No data available
Vapor Density	No data available
Vapor Pressure	No data available
Evaporation Rate	Not available
Solubility in Water	Dispersible in water.

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SECTION 10 – STABILITY AND REACTIVITY									
Stable	Not reactive under normal conditions of use.								
Hazardous Polymerization	Stable under normal temperature and pressure.								
Conditions to Avoid	Excess heat, strong bases, acids and oxidizing agents.								
Incompatibility	Acids, strong oxidizers, and other chemicals that could affect its performance should be avoided.								
Hazardous Decomposition	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sulfur 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]									
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Health (blue)</td> <td style="width: 50%; text-align: center;">1</td> </tr> <tr> <td style="text-align: center;">Fire Hazard (Red)</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">Reactivity (Yellow)</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">Personal Protection</td> <td style="text-align: center;">See section 8</td> </tr> </table>	Health (blue)	1	Fire Hazard (Red)	0	Reactivity (Yellow)	0	Personal Protection	See section 8
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Fire Hazard (Red)	0								
Reactivity (Yellow)	0								
Personal Protection	See section 8								
Acute and Chronic Toxicity									
Genotoxicity study	No data available								
General Toxicity	Chronic effect: Clinical use of gentamicin sulfate has had adverse effects on the kidneys. Ingredients are not acutely toxic.								
Skin Sensitivity	No adverse effects are expected. Minor irritation is possible.								
Eye Sensitivity	Skin contact may cause redness, itching, and acne-form eruptions. Eye contact may cause irritation, stinging, redness, tearing, and blurred vision.								
Ingestion	Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea. Gentamicin Sulfate is poorly absorbed from the gastrointestinal tract.								
Sensitization	Gentamicin sulfate is a skin sensitizer in some individuals.								
Carcinogenic Information	No carcinogenicity studies have been performed with gentamicin sulfate. None of the components present at 0.1% or greater are listed as carcinogens by IARC, NTP or OSHA.								
Reproductive Toxicity Information	Gentamicin has been shown to depress body weights, kidney weights, and median glomerular counts in newborn rats when administered systemically to pregnant rats. Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Serious side effects to mother, fetus or newborn have not been reported in the treatment of pregnant women with other aminoglycosides. Animal reproduction studies conducted on rats and rabbits did not reveal evidence of impaired fertility or harm to the fetus due to gentamicin sulfate.								
Mutagenicity	None of the components have been shown to cause germ cell mutagenicity. Aminoglycoside antibiotics have been found to be non-mutagenic.								
Embryotoxicity/ Teratogenicity	No data available								

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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. Permeable cardboard containers are not appropriate and should not be used.
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), IMDG (transportation by air) or TDG (transport Canada- road, rail, air or water) 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.	