

SAFETY DATA SHEET

SDS Identifier: Hydrocortisone Butyrate Lotion, 0.1%

SECTION 1 - IDENTIFICATION	
Product Name	Hydrocortisone Butyrate Lotion, 0.1%
Company Identification	SOLA Pharmaceuticals
	655 Highlandia Drive, Suite B Baton Rouge, LA 70810
	Phone (866) 747-7365
	Emergency: Call Poison Control Center: 1 – 800 – 222 – 1222
	SDS prepared February 2019
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	Allergic or sensitivity reactions are possible, causing irritation or redness.
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	Hydrocortisone Butyrate 0.1%, CAS # 13609-67-1, LD50: >3000 mg/kg (mouse)
Other Ingredients	Butylparaben, Butylated hydroxy toluene, Ceteth-20, Cetostearyl Alcohol, Citric acid, Light mineral oil, 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	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.

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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	When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides).
Extinguishing Media	SMALL FIRES: Dry chemical, CO ₂ , water spray or regular foam. LARGE FIRE: Water spray, fog or regular foam.
Flash Point	> 230 °F (> 110 °C)
SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	No special controls or personal protection required under conditions of intended use. 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. Spill area may be slippery.
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	Avoid direct sunlight, and temperature above 40 °C. Protect from freezing, read label and package insert carefully.
SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION	
Personal Protection Equipment:	
Ventilation	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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Eye Protection	Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.	
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	Wear protective gloves when handling bulk product before closed in final packaging.	
Respiratory Protection	In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) - certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.	
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES		
Description	White to off-white lotion.	
Specific Gravity	~ 1 (water is 1)	
pH	3.5 – 4.5	
Boiling Point:	Mixture	
Freezing Point	Not available	
Vapor Density	Not available	
Vapor Pressure	Not available	
Evaporation Rate	Not available	
Solubility in Water	Dispersible in water.	
SECTION 10 – STABILITY AND REACTIVITY		
Stable	Yes under specified storage conditions.	
Hazardous Polymerization	No data available	
Conditions to Avoid	Excess heat or cold, freezing.	
Incompatibility	No data available	
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]		
	Health (blue)	1
	Fire Hazard (Red)	1
	Reactivity (Yellow)	0
	Personal Protection	See section 8

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Acute and Chronic Toxicity	
Genotoxicity study	The product showed no biological reactivity in a genotoxicity study. A primary dermal irritation study in the rabbit showed the product to be a minimal irritant consistent with corticosteroid effect.
General Toxicity	Acute Toxicity: Ingestion/Oral-Rat LD50 • >3 g/kg; Nutritional and Gross Metabolic: Gross Metabolite Changes: Weight loss or decreased weight gain.
Skin Sensitivity	Possible skin irritation.
Eye Sensitivity	Eye contact will cause irritation.
Respiratory Sensitization	Although unlikely, inhalation can irritate the respiratory system.
Carcinogenicity	Data not available.
Mutagenicity/ Embryo / Reproductive Toxicity	<p>In a series of genetic toxicology studies, hydrocortisone butyrate was found to be devoid of mutagenic potential in the Ames test, the mouse lymphoma assay and the in vivo micronucleus assay in the mouse. This indicates that this material lacks the ability to produce gene mutations and is not clastogenic.</p> <p>Hydrocortisone butyrate did not produce effects on fertility in male and female rats at doses up to and including 1.8 mg/kg/day. Mild effects on maternal animals, such as reduced food consumption and a subsequent reduction in body weight gain, were seen at 0.6 mg/kg/day and above. In a similar study, hydrocortisone butyrate was evaluated for effects on lactation and development of newborn rat offspring, no effect of these offspring were seen following evaluation of survival, behavioral and developmental parameters and subsequent reproductive performance at doses up to 1.8 mg/kg/day.</p> <p>The effects seen in these reproduction studies are frequently common findings in studies with various corticosteroids, and these agents have been shown to produce teratogenic effects in rats and/or rabbits. There is nothing unique in these observed findings that would suggest that hydrocortisone butyrate produces effects that are not already attributed to drugs in this class.</p>
Teratogenicity	<p>Hydrocortisone butyrate was not teratogenic in rats at doses up to and including 5.4 mg/kg/day. At this highest dose of 5.4 mg/kg/day, delayed ossification, considered a developmental variation, was seen and is considered a consequence of a reduction in maternal weight gain at this dose. Reduction in maternal weight gain was also seen at the lower doses of 0.6 and 1.8 mg/kg/day.</p> <p>Hydrocortisone butyrate was similarly evaluated for teratogenicity in rabbits at doses up to and including 0.3 mg/kg/day. At the two high doses of 0.2 and 0.3 mg/kg/day, post-implantation loss that resulted in a reduction in litter size was observed, and the incidence of fetal malformations was increased. Thus, hydrocortisone butyrate produced developmental toxicity, including some teratogenic effects, in these offspring.</p>

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Other information	Systemic effects of topical corticosteroids may include reversible hypothalamic-pituitary-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).	
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, SOLA Pharmaceuticals and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.	