

SAFETY DATA SHEET

SDS Identifier: Diflorasone Diacetate Ointment USP, 0.05 %

SECTION 1 - IDENTIFICATION	
Product Name	Diflorasone Diacetate Ointment USP, 0.05 %
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: 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.	
Eyes	Contact with eyes may cause irritation
Skin	None
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause irritation of nose and throat.
Ingestion	Product is not intended for ingestion. May be harmful if swallowed.
SECTION 3 – COMPOSITION AND INGREDIENTS	
Active Ingredient	Diflorasone Diacetate CAS # 33564-31-7, LD50: >3000 mg/Kg (oral; rat)
Other Ingredients	Glyceryl monostearate, Propylene glycol 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	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. If adverse skin reactions occur, discontinue use. Seek medical attention.
After Inhalation	Remove from source of exposure. Move individual(s) to fresh air. 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.
Explosion Hazards	When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (including carbon oxides, hydrogen fluoride).
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water spray, fog or foam.
Flash Point	Not available

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SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	Avoid excessive contact and contact with eyes. Wear safety goggles or shield, and gloves.
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	<p>This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.</p> <p><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 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). Wash thoroughly after handling. Keep containers closed when not in use. Avoid contact with eyes. Do not eat, drink or smoke while handling this product. Follow all SDS and label precautions.
Storage	Store at 20 - 25°C (68 ° - 77°F); [see USP Controlled Room Temperature]. Avoid heat above 40 °C.
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 sufficient to control airborne levels.
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.

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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES									
Description	A white to off-white unctuous translucent ointment								
Specific Gravity	~0.85 (water = 1)								
pH	Not applicable								
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 hot water.								
SECTION 10 – STABILITY AND REACTIVITY									
Stable	Yes, under specified storage conditions.								
Hazardous Polymerization	Will not occur.								
Conditions to Avoid	Excess heat, freezing, strong bases, acids and oxidizing agents								
Incompatibility	Strong bases, acids and oxidizing agents								
Hazardous Decomposition	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, hydrogen fluoride)								
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="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tbody> <tr> <td style="padding: 2px;">Health (blue)</td> <td style="text-align: center; padding: 2px;">1</td> </tr> <tr> <td style="padding: 2px;">Fire Hazard (Red)</td> <td style="text-align: center; padding: 2px;">1</td> </tr> <tr> <td style="padding: 2px;">Reactivity (Yellow)</td> <td style="text-align: center; padding: 2px;">0</td> </tr> <tr> <td style="padding: 2px;">Personal Protection</td> <td style="text-align: center; padding: 2px;">See section 8</td> </tr> </tbody> </table>	Health (blue)	1	Fire Hazard (Red)	1	Reactivity (Yellow)	0	Personal Protection	See section 8
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Fire Hazard (Red)	1								
Reactivity (Yellow)	0								
Personal Protection	See section 8								
General Toxicity	Data not available.								
Genotoxicity study	No data available								
Embryotoxicity/Teratogenicity	No data available								
Reproductive toxicity	No data available								
Carcinogenicity	No data available								
Mutagenicity	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	Dispose of in accordance with all applicable federal, state and local regulations.
Packaging	Disposal in compliance with official regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.
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.	