

SAFETY DATA SHEET

SDS Identifier: Diclofenac Sodium Topical Solution 1.5 % w/w

SECTION 1 - IDENTIFICATION	
Product Name	Diclofenac Sodium Topical Solution 1.5 % w/w
Company Identification	<i>Manufactured for:</i>
	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
	<i>Manufactured By:</i>
	Teligent Pharma Inc.
	105 Lincoln Avenue, Buena, New Jersey 08310
	Phone: (856) 697-1441
	SDS revised April 2019
SECTION 2 – HAZARD(S) IDENTIFICATION	
<p>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.</p> <p>WARNING! Flammable liquid and vapor. May be harmful if swallowed, inhaled or absorbed through skin. May cause irritation to skin, eyes, and respiratory tract. Can cause adverse reproductive effects - such as birth defects, miscarriages, or infertility. Cancer hazard. Prolonged exposure may cause chronic effects.</p>	
Eyes	Contact with eyes may cause irritation
Skin	May cause skin irritation. May be absorbed through the skin.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Avoid breathing vapors or mists of this product. Organic solvents may be absorbed into the body by inhalation and cause permanent damage to the nervous system, including the brain. May be irritating. May cause cancer by inhalation. Prolonged inhalation may be harmful. Allergic reactions are possible
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Components of the product may be absorbed into the body by ingestion. Do not ingest. Product is not intended for ingestion.
SECTION 3 – COMPOSITION AND INGREDIENTS	
Active Ingredient	Diclofenac Sodium, CAS # 15307-79-6, LD50: 53 mg/kg (acute, oral; rat)
Other Ingredients	Alcohol, Dimethyl Sulfoxide, Glycerin, Propylene Glycol, and Purified Water
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	Not expected route of exposure, but if inadvertent eye contact occurs, 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. If signs/symptoms develop, get medical attention or call Poison Control Center immediately.

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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	
Flammable properties	FLAMMABLE. NFPA Rating Fire = 2. Materials that must be moderately heated or exposed to relative high ambient temperatures before ignition can occur.
Fire Fighting Instructions	Wear approved breathing apparatus and full protective turn out gear. Fire may produce irritating, corrosive and/or toxic gases. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Explosion Hazards	When involved in a fire, this material may decompose and produce irritating vapors and toxic gases.
Extinguishing Media	Water. Foam. Dry powder. Carbon dioxide (CO ₂).
Flash Point	129.2 °F (54 °C) Open cup
SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	Ensure adequate ventilation. Avoid excessive contact and contact with eyes. Wear safety goggles or shield. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
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. Collect spill with non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Prevent material from entering sewer or confined spaces, waterways, soil or public waters.</p> <p>Dispose of in accordance with applicable Federal, State, and local procedures.</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.</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. Keep away from sources of ignition - No smoking. Use personal protective equipment as required.

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Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°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			
Occupational exposure limits			
ACGIH			
Components	Type	Value	Form
Ethanol (64-17-5)	STEL	1000.0000 ppm	
Glycerin (56-81-5)	TWA	10.0000 mg/m3	Mist
U.S. - OSHA			
Components	Type	Value	Form
Ethanol (64-17-5)	PEL	1900.0000 mg/m3	
Glycerin (56-81-5)	PEL	5.0000 mg/m3	Respirable fraction
		15.0000 mg/m3	Total dust
Personal Protection Equipment:			
Ventilation	Use with adequate ventilation. Non-sparking ventilation should be used. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.		
Eye Protection	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present.		
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.		
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES			
Description	A clear, colorless to faintly pink-orange solution		
Specific Gravity	1.07 (water = 1)		
pH	8 – 10		
Boiling Point:	338.3 °F (170.2 °C) estimated		
Freezing Point	No data available		
Vapor Density	No data available		
Vapor Pressure	No data available		
Evaporation Rate	Not available		
Solubility in Water	Miscible with water.		
SECTION 10 – STABILITY AND REACTIVITY			
Stable	Material is stable under normal conditions. Risk of ignition.		

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Hazardous Polymerization	Hazardous polymerization does not occur.	
Conditions to Avoid	Heat, flames and sparks. Avoid temperatures exceeding the flash point.	
Incompatibility	Acids. Alkaline metals. Fluoride. Isocyanates. Strong oxidizing agents.	
Hazardous Decomposition	Irritants. 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]		
	Health (blue)	1
	Fire Hazard (Red)	2
	Reactivity (Yellow)	0
	Personal Protection	See section 8
Acute and Chronic Toxicity		
Local effects	May be harmful if swallowed. May be harmful by inhalation. May be harmful in contact with skin. May cause irritation to the respiratory system. May irritate eyes and skin.	
Chronic effects	Prolonged inhalation may be harmful. Repeated absorption may cause disorder of central nervous system, liver, kidneys and blood. Prolonged exposure may cause chronic effects. The product contains organic solvents which may be absorbed into the body by skin contact and cause permanent damage to the nervous system, including the brain. Organic solvents may be absorbed into the body by inhalation and ingestion and cause permanent damage to the nervous system, including the brain	
Genotoxicity study	No data available	
General Toxicity	No data available	
Embryotoxicity/ Teratogenicity	No data available	
Reproductive toxicity	Possible reproductive hazard. Can cause adverse reproductive effects – such as birth defects, miscarriages or infertility	
Carcinogenicity	May cause cancer. Risk of cancer cannot be excluded with prolonged exposure.	
Mutagenicity	No data 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		
Waste codes D001	Waste Flammable material with a flash point <140 F	
Product Disposal	Dispose of in accordance with all applicable federal, state and local regulations. Disposal instructions collect and reclaim or dispose in sealed containers at licensed	

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	waste disposal site. If discarded, this product is considered a RCRA ignitable waste, D001. Dispose in accordance with all applicable regulations.										
Packaging	Disposal in compliance with official regulations. Handle packaging in the same way as the product itself.										
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											
<p>US federal regulations: This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii). TSCA exempt status.</p> <p>The product described in this MSDS 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). The finished product is labeled in compliance with the requirements of the FDA and must be used in prescribed manner.</p> <p>Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2)</p> <p>Not regulated DEA Essential Chemical Code Number</p> <p>Not regulated Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))</p> <p>Not regulated DEA Exempt Chemical Mixtures Code Number</p> <p>Not regulated CERCLA (Superfund) reportable quantity ETHANOL: 100.0000</p> <p>Superfund Amendments and Reauthorization Act of 1986 (SARA)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Hazard categories</td> <td>Immediate Hazard - Yes</td> </tr> <tr> <td></td> <td>Delayed Hazard - Yes</td> </tr> <tr> <td></td> <td>Fire Hazard - Yes</td> </tr> <tr> <td></td> <td>Pressure Hazard - No</td> </tr> <tr> <td></td> <td>Reactivity Hazard - No</td> </tr> </table> <p>Section 302 extremely hazardous substance: No</p> <p>Section 311 hazardous Chemical: No</p>		Hazard categories	Immediate Hazard - Yes		Delayed Hazard - Yes		Fire Hazard - Yes		Pressure Hazard - No		Reactivity Hazard - No
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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.											