SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Product	Diclofenac Sodium Topical Gel 1%
Recommended Use	Indicated for the relief from joint pain caused by osteoarthritis
Restrictions on Use	Use only as directed by the physician
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-106-10 (100g)

Section 2: Hazard(s) Identification

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. 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	Health injuries are not known or expected under normal use.
Skin	Health injuries are not known or expected under normal use.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Ingestion	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.

Section 3: Composition/Information on Ingredients

Section 3, Composition/Information on Ingredients

Common Name/Chemical Name	Diclofenac
CAS No.	15307-79-6
Concentration	1%
Other Ingredients	Isopropyl Alcohol (20%), Propylene Glycol, Ammonia Water, Mineral Oil, Ceteareths

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

Section 4, First-Aid Measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin Contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a POISON CONTROL center immediately. Do not induce vomiting without advise from a poison control center.

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Extinguishing Media	Foam. Dry chemical powder. Carbon dioxide (CO_2).
Explosion Hazards	During fire, gases hazardous to health may be formed.
Special Protective Equipment And Precautions for Fire-Fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Flash Point	86°F (30°C) Closed Cup

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Avoid contact with eyes, skin, and clothing.
Environmental Precautions	Do not discharge into drains, water courses or onto the ground.
Spill Clean-Up Procedures	Spread an inert absorbent on the spill and place in a suitable, properly labeled container for recovery or disposal.
Large Spills	Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand, or eath and place into containers. Following product recovery, flush area with water.

Small Spills	Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (i.e., cloth, fleece). Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Section 7, Handling and Storage

Precautions for Safe Handling	**Keep away from heat/sparks/open flames/hot surfaces. No smoking.**
Conditions for Safe Storage, Including Any Incompatibilities	Keep away from heat, sparks and open flames. Store in original tightly closed container.
Other Precautions	Avoid direct sunlight, read label and package insert carefully.

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure Controls / Personal Protection

Ventilation	General ventilation normally adequate.
Eye Protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin Protection	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Hand Protection	Not normally needed. For prolonged or repeated skin contact, use suitable protective gloves.
Respiratory Protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fune at levels exceeding the exposure limits.

Section 9: Physical and Chemical Properties

Section 9, Physical and Chemical Properties

Description	Solid – determined to be a pasty solid via the ADR test for determining fluidity; the penetrometer test.
Specific Gravity	0.900 – 1.100 (water = 1)
pH	Not applicable
Melting/Freezing Point	Not available
Boiling Point	Not available
Vapor Density	Not available
Vapor Pressure	Not available
Evaporation Rate	Not available
Solubility in Water	Not available

Substance Class	Non-steroidal anti-inflammatory
Molecular Weight	318.1
Molecular Formula	$C_{14}H_{10}Cl_2NN_aO_2$

Section 10: Stability and Reactivity

Section 10, Stability and Reactivity

Stable	The product is stable and non-reactive under normal conditions of use, storage and transport.
Possibility of Hazardous Polymerization	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11: Toxicological Information

Section 11, Toxicological Information

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact Health injuries are not known or expected under normal use.

Eye Contact Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms Related to the Physical, Chemical, and toxicological Characteristics

Severe eye irritation. Symptoms may include stinging, tearing, readness, swelling and blurred vision. The following adverse effects have been noted with therapeutic use of this material: may cause drowsiness and dizziness. Headache. Nausea. Vomiting.

Information on Toxicological Effects

Acute Toxicity Health injuries are not known or expected under normal use. Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components		Species	Test Results
Ammonia Water (CAS 1336-21-6)			
Acute			
Inhalation	LCLo	Human	5000ppm
Oral	LD	Human	43mg/kg
Diclofenac Sodium (CAS 15307-79-6)			

Acute			
Oral	LD50	Dog	500mg/kg
		Monkey	3200mg/kg
		Rat	55 – 240mg/kg 62.5mg/kg 55mg/kg
Sub-Acute			
Oral	LOAEL	Dog	>0.3mg/kg/day, 4 weeks
Sub-Chronic			
Oral		Dog	0.03 – 0.3mg/kg/day/13 weeks
	NOAEL	Rat	2.5mg/kg/day, 13 weeks
	TD	Rat	>=5mg/kg/day, 13 weeks
Isopropyl Alcohol (CAS 67-63-0)			
Acute			
Dermal	LD50	Rabbit	12.8g/kg
Inhalation	LC50	Rat	39mg/l, 8 hours
Oral	LD50	Rat	5045mg/kg
Sub-Chronic			
Inhalation	LOEL	Mouse	1500ppm
		Rat	1500ppm
	LOEL	Mouse	500ppm, 13 weeks
		Rat	500ppm, 13 weeks

*Estimates for product may be based on additional component data not shown.

Skin Corrosion/Irritation Health injuries are not known or expected under normal use.

Irritation Corrosion – Skin Isopropyl Alcohol
Acute dermal irritation; OECD 404
Result: Non-irritant
Notes UN SIDS evaluation: 2-Propanol

Serious Eye Damage/ Eye Irritation Health injuries are not known or expected uner normal use.

Eye Isopropyl Alcohol
OECD 405
Result: Mild irritant
Species: Rabbit
Notes: UN SIDS evaluation: 2-Propanol

Respiratory or Skin Sensitization

Respiratory Sensitization No studies have been conducted.

Skin Sensitization Health injuries are not known or expected under normal use.

Germ Cell Mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Not expected to be genotoxic under occupational exposure conditions.

Mutagenicity	
Diclofenac Sodium	Ames Result: Negative
Isopropyl Alcohol	Ames Result: Negative
Diclofenac Sodium	Chromosomal Aberration Assay In Vitro Result: Negative Chromosome Aberration – Mal Germinal Epithelium Result: Negative Species: Mouse Dominant Lethal Assay Result: Negative Species: Mouse GreenScreen Mammalian Cell Mutation Assay Result: Negative HPRT Gene Mutation in Human Lymphocytes Result: Negative
Isopropyl Alcohol	In vivo Micronucleus Result: Netagive Species: Mouse
Diclofenac Sodium	L5178Y Mouse Lymphoma Thymidine Kinase Locus Assay Result: Negative
Isopropyl Alcohol	Mammalian Cell Mutation Assay (CHO/HGPRT Forward Mutation Assay) Result: Negative SA7 – Sister Chromatid Exchange Result: Negative Sister Chromatid Exchange, V79 Cells Result: Negative
Carcinogenicity	Health injuries are not known or expected under normal use. Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.
Isopropyl Alcohol	0, Inhalation Study Result: Negative Species: Mouse Notes: UN SIDS evaluation: 2-Propanol 2-year Bioassay, Inhalation Study Result: Negative Species: Rat

Diclofenac Sodium	Result: Negative Species: Mouse Result: Negative Species: Rat

IARC Monographs, Overall Evaluation of Carcinogenicity

Mineral Oil (CAS 8042-47-5)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated

U.S. National Toxicology Program (NTP) Report on Carcinogens
Not listed

Reproductive Toxicity	Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low does did not produce this adverse effects.

Re-Productivity

Isopropyl Alcohol	<1200mg/kg/day Embryo-Foetal Development, Developmental Neurotoxicity Result: Foetal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol <240mg/kg/day Epidemiology Result: Maternal NOAEL Species: Human <400mg/kg/day Embryo-Foetal Development Result: Maternal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol <480mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human <500mg/kg/day Two Generation Study Result: Maternal toxicity; adverse effects on offspring Species: Rat Notes: UN SIDS evaluation: 2-Propanol
Diclofenac Sodium	>=2mg/kg/day Embryofetal Development Result: Maternal toxicity; reduced foetal weight; foetal resorptions Species: Rat >=2mg/kg/day Embryofetal Development Result: Reduced survival, reduced birth rate, reduced growth rate Species: Rat >=2.5mg/kg/day Embryofetal Development Result: Maternal toxicity; reduced foetal weight,; foetal resorptions

	Species: Rabbit >=4mg/kg/day Fertility Result: NOAEL Species: Rat >=5mg/kg/day Embryofetal Development Species: Rabbit 10mg/kg/day Teratogenicity Result: NOAEL Species: Rabbit 10mg/kg/day Teratogenicity Result: NOAEL Species: Rat Embryofetal Development Species: Rabbit

Specific Target Organ Otxicity – Single Exposure
Not assigned.

Isopropyl Alcohol	Result: Narcosis Organ: Central Nervous System

Specific Target Organ Toxicity- Repeated Exposure
Not assigned

Diclofenac Sodium	Epidemiology Species: Human Organ: Gastro-intestinal tract; Cardiovascular system
Aspiration Hazard	Not likely,m due to the form of the product.
Chronic Effects	Not available.
Further Information	Caution – Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
Diclofenac Sodium	Clinical experience, Anaphylactoid response Species: Human

Section 12: Ecological Information

Section 12, Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Product Disposal Considerations
Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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: Transport Information

Section 14, Transport Information

Not regulated for transport under United States Department of Transportation (USDOT) (transportation by l and), International Air Transport Association (IATA) (transportation by sea), or International Maritime Dangerous Goods Code (IMDG) (transportation by air) regulations.

Section 15: Regulatory Information

Section 15, Regulatory Information

The product described in this Safety Data Sheet is 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

Section 16, Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.