

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Diclofenac Sodium Topical Solution 1.5% w/w</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Pithampur (M.P.) – 454 775 INDIA.
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

### Section 2: Hazard(s) Identification

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<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Diclofenac sodium is contraindicated in patients with a known hypersensitivity to diclofenac sodium or any other component of diclofenac sodium topical solution. Diclofenac sodium is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Diclofenac sodium is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Diclofenac Sodium USP	15307-79-6

## Section 4: First-Aid Measures

### Section 4, First-aid measures

<b>Ingestion</b>	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
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### OVERDOSAGE

There have been no known experiences of overdose with diclofenac sodium topical solution.

Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

Manage patients using symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis is not recommended due to a possibility of aspiration and subsequent respiratory irritation by DMSO contained in diclofenac sodium topical solution. Activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

For additional information about overdose treatment, call a poison control center (1-800-222-1222).

## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
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<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

<b>Section 6, Accidental release measures</b>	
<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## Section 7: Handling and Storage

<b>Section 7, Handling and storage</b>	
<b>Handling</b>	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [See USP Controlled Room Temperature].

## Section 8: Exposure Controls/Personal Protection

<b>Section 8, Exposure controls/personal protection</b>	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	

## Section 9: Physical and Chemical Properties

<b>Section 9, Physical and chemical properties</b>	
<b>Physical Form</b>	<b>How Supplied</b> Diclofenac Sodium Topical Solution, 1.5% w/w is supplied as a clear, colorless to faintly pink orange solution containing 16.05 mg of

diclofenac sodium per mL of solution, in a white high density polyethylene bottle with a white low density polyethylene dropper cap.

**NDC Number and Size**

5 FL.OZ. (150 mL) bottle in cartons of one

NDC # 68180-538-01

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies in mice and rats administered diclofenac sodium topical solution as a dietary constituent for 2 years resulted in no significant increases in tumor incidence at doses up to 2 mg/kg/day corresponding to approximately 0.35- and 0.7-fold (mouse and rat, respectively) of the maximum recommended human topical dose (MRHD) of diclofenac sodium (based on apparent bioavailability and body surface area comparison).

In a dermal carcinogenicity study conducted in albino mice, daily topical applications of diclofenac sodium for two years at concentrations up to 0.035% diclofenac sodium (a 43-fold lower diclofenac sodium concentration than present in diclofenac sodium topical solution) did not increase neoplasm incidence.

In a photocarcinogenicity study conducted in hairless mice, topical application of diclofenac sodium at doses up to 0.035% diclofenac sodium (a 43-fold lower diclofenac sodium concentration than present in diclofenac sodium topical solution) resulted in an earlier median time of onset of tumors.

Diclofenac was not mutagenic or clastogenic in a battery of genotoxicity tests that included the bacterial reverse mutation assay, *in vitro* mouse lymphoma point mutation assay, chromosomal aberration studies in Chinese hamster ovarian cells *in vitro*, and *in vivo* rat chromosomal aberration assay of bone marrow cells.

Fertility studies have not been conducted with diclofenac sodium. Diclofenac sodium administered to male and female rats at doses up to 4 mg/kg/day (1.4-fold of the MRHD of diclofenac sodium based on apparent bioavailability and body surface area comparison) did not affect fertility. Studies have not been conducted to determine the safety of DMSO on fertility.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

### Section 14: Transport Information

#### IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

#### IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

#### DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

## Section 15: Regulatory Information

### Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## 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.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.