

# LUPIN PHARMACEUTICALS, INC.

## SAFETY DATA SHEET

### Section 1: Identification

#### Identification

<b>Material</b>	<b>Diclofenac Topical Solution 2%</b>
<b>Manufacturer</b>	Horizon Pharma USA, Inc. 150 S. Saunders Road Lake Forest, Illinois 60045 - United States T +1-224-383-3000
<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
<b>Use of the Substance/mixture</b>	Pharmaceuticals

### Section 2: Hazard(s) Identification

#### Hazard(s) identification

##### GHS-US classification

Flammable liquids, Category 3	H226
Reproductive toxicity, Category 2	H361
Specific target organ toxicity - Repeated exposure, Category 1	H372

##### Label elements

##### GHS-US labelling

Hazard pictograms (GHS-US)



GHS02



GHS08

Signal word (GHS-US)

Danger

Contains

Diclofenac sodium

Hazard statements (GHS-US)

H226 - Flammable liquid and vapour  
H361 - Suspected of damaging fertility or the unborn child  
H372 - Causes damage to organs through prolonged or repeated exposure  
P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat, sparks, open flames. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/bond container and receiving equipment  
P241 - Use explosion-proof electrical, lighting, ventilating equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P260 - Do not breathe mist, vapours  
P264 - Wash hands thoroughly after handling

Precautionary statements (GHS-US)

P270 - Do not eat, drink or smoke when using this product  
 P280 - Wear eye protection, protective gloves  
 P303 + P361 + P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
 P308 + P313 - If exposed or concerned: Get medical advice/attention  
 P314 - Get medical advice/attention if you feel unwell  
 P370 + P378 - In case of fire: Use carbon dioxide (CO<sub>2</sub>), foam, dry extinguishing powder, Water to extinguish  
 P403 + P235 - Store in a well-ventilated place. Keep cool  
 P405 - Store locked up  
 P501 - Dispose of contents/container to Collection point

**Other hazards**

No additional information available

**Unknown acute toxicity (GHS US)**

2% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal)  
 2% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

### Section 3: Composition/Information on Ingredients

**Composition/information on ingredients**

**Mixtures**

Name	Product identifier	%	GHS-US classification
ethanol	(CAS No) 64-17-5	20 - 40	Flam. Liq. 2, H225
Diclofenac sodium (Main constituent)	(CAS No) 15307-79-6	2	Acute Tox. 3 (Oral), H301 Repr. 2, H361 STOT RE 1, H372

\*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

### Section 4: First-Aid Measures

**First-aid measures**

**Description of first aid measures**

First-aid measures general	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	Remove person to fresh air and keep comfortable for breathing. Artificial respiration and/or oxygen if necessary.
First-aid measures after skin contact	Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.
First-aid measures after eye contact	In case of contact, immediately flush eyes with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting unless directed to do so by medical personnel. Rinse mouth.

### Most important symptoms and effect both acute and delayed

Symptoms/injuries	Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
Symptoms/injuries after inhalation	Inhalation of vapours may cause respiratory irritation.
Symptoms/injuries after skin contact	May cause slight irritation. Repeated exposure may cause skin dryness or cracking.
Symptoms/injuries after eye contact	May cause slight irritation.
<b>Indication of any immediate medical attention and special treatment needed</b>	Treat symptomatically.

## Section 5: Fire-Fighting Measures

### Fire-fighting measures

#### Extinguishing Media

Suitable extinguishing media	Carbon dioxide. Dry chemical. Foam. Water.
Unsuitable extinguishing media	None known.

#### Special hazards arising from the substance or mixture

Fire hazard	Flammable liquid and vapour. Burning produces irritating, toxic and noxious fumes.
Explosion hazard	May form flammable/explosive vapour-air mixture.
Reactivity	No dangerous reactions known.

#### Advice for firefighters

Firefighting instructions	Exercise caution when fighting any chemical fire. Evacuate area.
Protection during firefighting	Firefighting personnel should wear full protective gear and a MSHA/NIOSH (approved or equivalent) self-contained breathing apparatus (SCBA) in pressure-demand mode.

## Section 6: Accidental Release Measures

### Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

General measures	Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Avoid all eye and skin contact and do not breathe vapour and mist.
<b>For non-emergency personnel</b>	
Protective equipment	Wear suitable protective clothing and gloves.
Emergency procedures	Evacuate unnecessary personnel.
<b>For emergency personnel</b>	
Protective equipment	Wear suitable protective clothing and gloves.
Emergency procedures	Ventilate area. Stop leak if safe to do so.

**Environmental precautions** Prevent entry to sewers and public waters. Do not discharge into drains or the environment

**Methods and material for containment and cleaning up**

For containment Eliminate all ignition sources.

Methods for cleaning up Small spills: Wipe up with absorbent material (e.g. cloth, fleece). Large spills: Cover spill with non combustible material, e.g.: sand, earth, vermiculite. Sweep or shovel spills into appropriate container for disposal. Following recovery, flush area with water. Clean surface thoroughly to remove residual contamination.

**Section 7: Handling and Storage**

**Handling and storage**

**Precautions for safe handling**

Additional hazards when processed Handle empty containers with care because residual vapours are flammable.

Precautions for safe handling No open flames. No smoking. Take precautionary measures against static discharge. Use only non-sparking tools. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist, vapours. Do not get in eyes, on skin, or on clothing.

Hygiene measures Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

**Conditions for safe storage, including any incompatibilities**

Technical measures Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof electrical, lighting, ventilating equipment.

Storage conditions Keep container tightly closed.

Incompatible products Acids. Alkali. Fluorides. Isocyanates. Strong oxidizers.

Incompatible materials Heat sources.

Storage 25 °C

Heat and ignition sources Keep away from heat, sparks and flame.

Prohibitions on mixed storage Incompatible materials.

Storage area Store in dry, cool, well-ventilated area.

**Section 8: Exposure Controls/Personal Protection**

**Control parameters**

<b>Diclofenac sodium (15307-79-6)</b>	Not applicable	
<b>ethanol (64-17-5)</b>		
ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	1884 mg/m <sup>3</sup>
ACGIH	ACGIH TWA (ppm)	1000 ppm

ACGIH	ACGIH STEL (ppm)	1000 ppm
ACGIH	Remark (ACGIH)	URT irr
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
<b>ethanol (64-17-5)</b>		
OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm

#### Exposure controls

Appropriate engineering controls	Ensure good ventilation of the work station.
Personal protective equipment	Avoid all unnecessary exposure.
Hand protection	Wear suitable gloves.
Eye protection	Chemical goggles or safety glasses.
Respiratory protection	In case of inadequate ventilation wear respiratory protection. respirator with combination filter for vapour/particles.
Environmental exposure controls	Prevent leakage or spillage.
Consumer exposure controls	Avoid contact during pregnancy/while nursing.
Other information	Do not eat, drink or smoke when using this product.

## Section 9: Physical and Chemical Properties

### Information on basic physical and chemical properties

Physical state	Liquid
HOW SUPPLIED	Diclofenac sodium topical solution 2% w/w, is supplied as a clear, colorless to faintly pink or orange solution containing 20 mg of diclofenac sodium per gram of solution, in a white polypropylene-dose pump bottle with a clear cap. Each pump actuation delivers 20 mg of diclofenac sodium in 1 gram of solution. 112 g bottle - NDC # 70748-335-01
Appearance	Clear.
Colour	Colourless
Odour	Odourless
Odour threshold	No data available
pH	8 - 10
Melting point	No data available
Freezing point	No data available
Boiling point	146.6 °C estimated
Flash point	26 °C
Relative evaporation rate (butylacetate=1)	No data available
Flammability (solid, gas)	No data available
Explosive limits	No data available
Explosive properties	No data available
Oxidising properties	No data available
Vapour pressure	23.58 hPa
Relative density	0.99
Relative vapour density at 20 °C	No data available
Density	0.99 g/cm <sup>3</sup>
Solubility	No data available
Log Pow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
<b>Other information</b>	
VOC content	30 %

## Section 10: Stability and Reactivity

<b>Reactivity</b>	No dangerous
<b>Chemical stability</b>	Flammable liquid and vapour. May form flammable/explosive vapour-air mixture.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization will not occur.
<b>Conditions to avoid</b>	Open flame. Overheating. Direct sunlight. Heat. Sparks.
<b>Incompatible materials</b>	Acids. Alkali metals. Fluorides. Isocyanates. Strong oxidizers.
<b>Hazardous decomposition products</b>	May release flammable gases. Burning produces irritating, toxic and noxious fumes. Sulphur oxides.

## Section 11: Toxicological Information

### Toxicological information

#### Information on toxicological effects

Likely routes of exposure	Inhalation; Skin and eye contact
Acute toxicity	Not classified

#### Diclofenac sodium (15307-79-6)

LD50 oral rat	53 mg/kg
ATE US (oral)	53.000 mg/kg bodyweight

#### ethanol (64-17-5)

LD50 oral rat	10470 mg/kg
LD50 dermal rabbit	> 20000 mg/kg
LC50 inhalation rat (mg/l)	133.8 mg/l/4h
ATE US (oral)	10470.000 mg/kg bodyweight
ATE US (vapours)	133.800 mg/l/4h
ATE US (dust,mist)	133.800 mg/l/4h

Skin corrosion/irritation	Not classified (Slightly irritant but not relevant for classification)
Serious eye damage/irritation	Not classified (Slightly irritant but not relevant for classification)
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Causes damage to organs through prolonged or repeated exposure.

#### PENNSAID 2%

Additional information	Affected organs: nervous system kidneys liver blood
Aspiration hazard	Not classified
Symptoms/injuries after inhalation	Inhalation of vapours may cause respiratory irritation.
Symptoms/injuries after skin contact	May cause slight irritation. Repeated exposure may cause skin dryness or cracking.
Symptoms/injuries after eye contact	May cause slight irritation.

## Section 12: Ecological Information

### Ecological Information

#### Toxicity

Ecology - general No ecotoxicological data about this product are known.

#### Diclofenac sodium (15307-79-6)

EC50 Daphnia 1 68 mg/l 48 h

#### ethanol (64-17-5)

LC50 fish 1 14200 mg/l

EC50 Daphnia 1 5012 mg/l

### Persistence and degradability

#### PENNSAID 2%

Persistence and degradability Not established.

#### ethanol (64-17-5)

Biodegradation > 96 % 28 d

### Bioaccumulative potential

#### PENNSAID 2%

Bioaccumulative potential Not established.

#### ethanol (64-17-5)

Bioaccumulative potential Not expected to bioaccumulate

### Mobility in soil

#### PENNSAID 2%

Ecology - soil Not established.

### Other adverse effects

Other information No additional information available.

## Section 13: Disposal Considerations

### Disposal Considerations

#### Waste treatment methods

Sewage disposal recommendations Do not dispose of waste into sewer.

Waste disposal recommendations Dispose in a safe manner in accordance with local/national regulations.

Additional information Handle empty containers with care because residual vapours are flammable

## Section 14: Transport Information

### Transport Information

#### Department of Transportation (DOT)

In accordance with DOT

#### Non-bulk

As provided in 49 CFR 173.150(g), it is not necessary to comply with DOT's full hazardous materials regulations if certain conditions are met for retail products that contain ethyl alcohol that are classified as a flammable liquid. These retail products include beverages, food, cosmetics and medicines, medical screening solutions, when the content of ethyl alcohol does not exceed 70% and the individual containers do not exceed 16 fluid ounces.

Although exempt from most DOT requirements, the external package will need to have the marking "Contains Ethyl Alcohol" printed on the sides of the shipping container if volumes of the individual containers would ever exceed 16 fluid ounces. 40 CFR 173.150(g)(3).

**Bulk**

Transport document description	UN1170 Ethanol solutions, 3, III
UN-No.(DOT)	UN1170
Proper Shipping Name (DOT)	Ethanol solutions
Transport hazard class(es) (DOT)	3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120
Packing group (DOT)	III - Minor Danger
Hazard labels (DOT)	3 - Flammable liquid
	
DOT Packaging Non Bulk (49 CFR 173.xxx)	203
DOT Packaging Bulk (49 CFR 173.xxx)	242
DOT Special Provisions (49 CFR 172.102)	24 - Alcoholic beverages containing more than 70 percent alcohol by volume must be transported as materials in Packing Group II. Alcoholic beverages containing more than 24 percent but not more than 70 percent alcohol by volume must be transported as materials in Packing Group III B1 - If the material has a flash point at or above 38 C (100 F) and below 93 C (200 F), then the bulk packaging requirements of 173.241 of this subchapter are applicable. If the material has a flash point of less than 38 C (100 F), then the bulk packaging requirements of 173.242 of this subchapter are applicable IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table 2 for UN2672) T2 - 1.5 178.274(d)(2) Normal..... 178.275(d)(3) TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / (1 + a (tr - tf))$ Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling
DOT Packaging Exceptions (49 CFR 173.xxx)	4b;150
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	60 L
DOT Quantity Limitations Cargo aircraft only (49CFR 175.75)	220 L
DOT Vessel Stowage Location	A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel Emergency Response Guide (ERG) Number
Other information	No supplementary information available.
<b>Transport by sea</b>	
UN-No. (IMDG)	1170
Proper Shipping Name (IMDG)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Class (IMDG)	3 - Flammable liquids
Packing group (IMDG)	III - substances presenting low danger
Limited quantities (IMDG)	5 L
<b>Air transport</b>	
UN-No. (IATA)	1170
Proper Shipping Name (IATA)	Ethanol solution
Class (IATA)	3 - Flammable Liquids
Packing group (IATA)	III-Minor Danger

## Section 15: Regulatory Information

### Regulatory Information

This product or mixture does not contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

#### **Diclofenac sodium (15307-79-6)**

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

#### **ethanol (64-17-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

### International regulations

#### **CANADA**

No additional information available

### EU-Regulations

#### **Diclofenac sodium (15307-79-6)**

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

### National regulations

#### **ethanol (64-17-5)**

Listed on IARC (International Agency for Research on Cancer)

### US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

#### **ethanol (64-17-5)**

U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances

U.S. - Washington - Permissible Exposure Limits - TWAs

## 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.