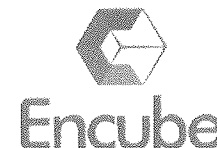


MATERIAL SAFETY DATA SHEET**Product Name:** Diclofenac Sodium Topical Gel, 1%**Revision Date:** January 22, 2020**Version No.:** 00**1. IDENTIFICATION**

Product Name	Diclofenac Sodium Topical Gel, 1%
Manufacturer Name	Encube Ethicals Pvt. Ltd.
Address	Plot No.C-1, Madkaim Industrial Estate Madkaim, Post- Mardol, Ponda. Goa – 403 404, India.
Chemical Name	Sodium;2-[2-(2,6-dichloroanilino) phenyl]acetate
Recommended Use	Indicated for the relief from joint pain caused by osteoarthritis.
Restrictions on use	Use only as directed by the physician

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.

3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	Diclofenac
CAS No.	15307-79-6
Concentration	1%
Other Ingredients	Isopropyl Alcohol, Propylene Glycol, Ammonia Water, Mineral Oil, Cetareths.

The product does not contain ingredient considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.

4. FIRST-AID MEASURES

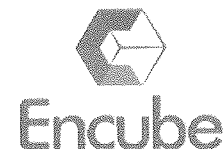
Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal
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conditions of intended use, this material is not expected to be an inhalation hazard.

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 advice from poison control center.

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

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 labelled container for recovery or disposal.

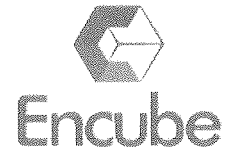
Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers.

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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 (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

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 flame. Store in original tightly closed container.
Other Precautions	Avoid direct sunlight, read label and package insert carefully.

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/fume at levels exceeding the exposure limits.

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 point/freezing point	Not available
Boiling Point	Not available
Vapor Density	Not available

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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 ₂ NNaO ₂

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.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

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, redness, 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.
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Components		Species	Test Results
AMMONIA WATER (CAS 1336-21-6)			
<u>Acute</u>			
Inhalation	LCLo	Human	5000 ppm
Oral	LD	Human	43 mg/kg
DICLOFENAC SODIUM (CAS 15307-79-6)			
<u>Acute</u>			
Oral	LD50	Dog	500 mg/kg
		Monkey	3200 mg/kg
		Rat	55 - 240 mg/kg
			62.5 mg/kg
			55 mg/kg
<u>Sub-acute</u>			
Oral	LOAEL	Dog	>= 0.3 mg/kg/day, 4 weeks
<u>Sub chronic</u>			
Oral		Dog	0.03 - 0.3 mg/kg/day, 13 weeks
	NOAEL	Rat	2.5 mg/kg/day, 13 weeks
	TD	Rat	>= 5 mg/kg/day, 13 weeks
ISOPROPYL ALCOHOL (CAS 67-63-0)			
<u>Acute</u>			
Dermal	LD50	Rabbit	12.8 g/kg
Inhalation	LC50	Rat	39 mg/l 8-hr
Oral	LD50	Rat	5045 mg/kg
<u>Sub chronic</u>			
Inhalation	LOEL	Mouse	1500 ppm
		Rat	1500 ppm
	NOEL	Mouse	500 ppm, 13 weeks
		Rat	500 ppm, 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 Acute dermal irritation; OECD 404

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	ALCOHOL	Result: Non-irritant
		Notes: UN SIDS evaluation: 2-Propanol
Serious eye damage/eye irritation:	Health injuries are not known or expected under normal use.	
Eye	ISOPROPYL	OECD 405
	ALCOHOL	Result: Mild irritant
		Species: Rabbit
		Notes: UN SIDS evaluation: 2-Propanol

Respiratory or skin sensitization

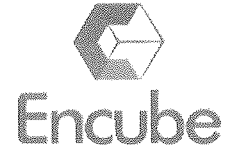
Respiratory sensitization No studies have been conducted.

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 - male 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

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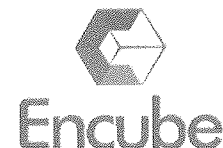
	Result: Negative
	Species: Mouse
DICLOFENAC SODIUM	L5178Y mouse lymphoma thymidine kinase locus assay
	Result: Negative
ISOPROPYL ALCOHOL	mammalian cell mutation assay (CHO/HGPRT forward mutation assay)
	Result: Negative
	SA7 - Sister Chromatid Exchange
	Result: Negative
	Sister Chromatid Exchange, V79 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-	3 Not classifiable as to carcinogenicity to humans.
5)	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)	Not regulated.

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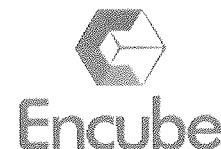
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.
Reproductive toxicity	Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.
Re-productivity	
ISOPROPYL ALCOHOL	<p>< 1200 mg/kg/day Embryo-foetal development, Developmental neurotoxicity Result: Foetal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol</p> <p>< 240 mg/kg/day Epidemiology Result: Maternal NOAEL Species: Human</p> <p>< 400 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol</p> <p>< 480 mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human</p> <p>< 500 mg/kg/day Two generation study Result: Maternal toxicity; adverse effects on offspring. Species: Rat Notes: UN SIDS evaluation: 2-Propanol</p>
DICLOFENAC SODIUM	<p>>= 2 mg/kg/day Embryofetal Development Result: maternal toxicity; reduced foetal weight; foetal resorptions Species: Rat</p> <p>>= 2 mg/kg/day Embryofetal Development Result: Reduced survival, reduced birth rate, reduced growth rate</p>

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	Species: Rat
	>= 2.5 mg/kg/day Embryofetal Development
	Result: maternal toxicity; reduced foetal weight; foetal resorptions
	Species: Rabbit
	>= 4 mg/kg/day Fertility
	Result: NOAEL
	Species: Rat
	>= 5 mg/kg/day Embryofetal Development
	Species: Rabbit
	10 mg/kg/day Teratogenicity
	Result: NOAEL
	Species: Rabbit
	10 mg/kg/day Teratogenicity
	Result: NOAEL
	Species: Rat
	Embryofetal Development
	Species: Rabbit
Specific target organ toxicity - 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, 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

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Species: Human

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.

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.

14. TRANSPORT INFORMATION

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

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).


16. OTHER INFORMATION

Contact Information

Encube Ethicals, Inc.
200 Meredith Avenue, Suite 101A, Durham,
NC27713, USA
<https://www.encubeethicals.com/>

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Disclaimer: This material safety data sheet has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

End of Safety Data Sheet**Compiled by:**
22.01.2020**Approved by:**
22.01.2020