

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : Diclofenac Sodium Topical Gel, 1%

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals
 Restrictions on use : No additional information available

1.3. Supplier

Dr. Reddy's Laboratories Ltd.
 8-2-337 Road No. 3, Banjara Hills
 Hyderabad 500-034, - India
 T +91-40-49002900 - F +91-40-49002999

1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture


GHS classification

Serious eye damage/eye irritation, Category 2A	H319 Causes serious eye irritation.
Reproductive toxicity, Category 2	H361 Suspected of damaging fertility or the unborn child.
Specific target organ toxicity — Single exposure, Category 3, Narcosis	H336 May cause drowsiness or dizziness.
Specific target organ toxicity — Repeated exposure, Category 1	H372 Causes damage to organs through prolonged or repeated exposure.

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS-US labelling

Hazard pictograms (GHS) : 

Signal word (GHS) : Danger

Hazard statements (GHS US) : H319 - Causes serious eye irritation.
 H336 - May cause drowsiness or dizziness.
 H361 - Suspected of damaging fertility or the unborn child.
 H372 - Causes damage to organs through prolonged or repeated exposure.

Precautionary statements (GHS) : P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
 P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264 - Wash hands, forearms and face thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.
 P271 - Use only outdoors or in a well-ventilated area.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P312 - Call a poison center/doctor if you feel unwell
 P314 - Get medical advice/attention if you feel unwell.
 P337+P313 - If eye irritation persists: Get medical advice/attention.
 P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
 P405 - Store locked up.
 P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

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2.4. Unknown acute toxicity (GHS_US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS classification
Isopropanol	(CAS-No.) 67-63-0	15 - 25	Flam. Liq. 2, H225 Eye Irrit. 2A, H319 STOT SE 3, H336
Mineral oil	(CAS-No.) mixture	1 - <3	Asp. Tox. 1, H304
Alcohols, C16-18, ethoxylated	(CAS-No.) 68439-49-6	1 - <3	Eye Dam. 1, H318
Diclofenac sodium	(CAS-No.) 15307-79-6	1	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

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.
- First-aid measures after inhalation : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
- First-aid measures after skin contact : None necessary.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
- Symptoms/effects after inhalation : May cause drowsiness or dizziness.
- Symptoms/effects after skin contact : Prolonged or repeated contact may cause skin to become dry or cracked.
- Symptoms/effects after eye contact : Causes serious eye irritation.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

- Fire hazard : Burning produces irritating, toxic and noxious fumes.
- Reactivity : No dangerous reactions known.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Do not breathe aerosol. Do not breathe vapour. Do not get in eyes.

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.2.

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Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Refer to section 8.2.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so.

Methods for cleaning up : On land, sweep or shovel into suitable containers.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe vapours. Use only outdoors or in a well-ventilated area. Do not breathe aerosol.

Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool well ventilated place. Keep container tightly closed.

Incompatible materials : Sources of ignition. Direct sunlight.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Diclofenac sodium (15307-79-6)		
Not applicable		
Mineral oil (mixture)		
ACGIH	ACGIH TWA (mg/m ³)	5 mg/m ³ oil mist
ACGIH	ACGIH STEL (mg/m ³)	10 mg/m ³ oil mist
Alcohols, C16-18, ethoxylated (68439-49-6)		
Not applicable		
Isopropanol (67-63-0)		
ACGIH	Local name	2-Propanol
ACGIH	ACGIH TWA (mg/m ³)	490 mg/m ³
ACGIH	ACGIH TWA (ppm)	200 ppm
ACGIH	ACGIH STEL (mg/m ³)	960 mg/m ³
ACGIH	ACGIH STEL (ppm)	400 ppm
ACGIH	Remark (ACGIH)	TLV® Basis: Eye & URT irr; CNS impair. Notations: A4 (Not classifiable as a Human Carcinogen); BEI
ACGIH	Regulatory reference	ACGIH 2020
OSHA	OSHA PEL (TWA) (mg/m ³)	980 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	400 ppm
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
NIOSH	NIOSH REL (TWA) (mg/m ³)	980 mg/m ³
NIOSH	NIOSH REL TWA [ppm]	400 ppm
NIOSH	NIOSH REL (STEL) (mg/m ³)	1225 mg/m ³
NIOSH	NIOSH REL STEL [ppm]	500 ppm

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8.2. Appropriate engineering controls

Appropriate engineering controls : Avoid creating mist or spray. Either local exhaust or general room ventilation is usually required. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

In case of repeated or prolonged contact wear gloves. nitrile rubber gloves

Eye protection:

Chemical goggles or safety glasses

Respiratory protection:

None under normal use

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Paste. Gel. Determined to be a pasty solid via the ADR test for determining fluidity (penetrometer test).
Colour	: Colourless
Odour	: characteristic
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: Non flammable. Does not sustain combustion. (Burn rate test).
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 0.9 – 1.1
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Diclofenac sodium (15307-79-6)	
LD50 oral rat	53 mg/kg
ATE (oral)	53 mg/kg bodyweight

Alcohols, C16-18, ethoxylated (68439-49-6)	
LD50 oral rat	5300 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l/4h
ATE (oral)	5300 mg/kg bodyweight

Isopropanol (67-63-0)	
LD50 oral rat	5840 mg/kg
LD50 dermal rabbit	16.4 ml/kg
LC50 Inhalation - Rat [ppm]	> 10000 ppm/4h
ATE (oral)	5840 mg/kg bodyweight
ATE (dermal)	16400 mg/kg bodyweight

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Isopropanol (67-63-0)	
IARC group	3 - Not classifiable

Reproductive toxicity : Suspected of damaging fertility or the unborn child.
STOT-single exposure : May cause drowsiness or dizziness.

Isopropanol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : Causes damage to organs through prolonged or repeated exposure.

Diclofenac sodium (15307-79-6)	
STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified
Viscosity, kinematic : No data available
Likely routes of exposure : Skin and eye contact. Inhalation.
Symptoms/effects : Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
Symptoms/effects after inhalation : May cause drowsiness or dizziness.

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Symptoms/effects after skin contact : Prolonged or repeated contact may cause skin to become dry or cracked.
Symptoms/effects after eye contact : Causes serious eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Diclofenac sodium (15307-79-6)	
EC50 crustacea	68 mg/l 48 h
Alcohols, C16-18, ethoxylated (68439-49-6)	
EC50 crustacea	> 100 mg/l 48 h
Isopropanol (67-63-0)	
LC50 fish 1	10000 mg/l

12.2. Persistence and degradability

Diclofenac Sodium Topical Gel, 1%	
Persistence and degradability	Not established.
Isopropanol (67-63-0)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Diclofenac Sodium Topical Gel, 1%	
Bioaccumulative potential	Not established.
Isopropanol (67-63-0)	
Bioaccumulative potential	Not expected to bioaccumulate.

12.4. Mobility in soil

Diclofenac Sodium Topical Gel, 1%	
Ecology - soil	Not established.

12.5. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Disposal 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.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

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Diclofenac sodium (15307-79-6)	
EPA TSCA Regulatory Flag	Exempt from TSCA : Pharmaceutical/drug substance
Alcohols, C16-18, ethoxylated (68439-49-6)	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Isopropanol (67-63-0)	
Subject to reporting requirements of United States SARA Section 313	
SARA Section 311/312 Hazard Classes	Fire hazard

15.2. International regulations

CANADA

Diclofenac sodium (15307-79-6)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
Mineral oil (mixture)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
Alcohols, C16-18, ethoxylated (68439-49-6)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
Isopropanol (67-63-0)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

⚠ WARNING: This product can expose you to Ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Component	Carcinogenicity	Developmental toxicity	Reproductive toxicity male	Reproductive toxicity female	No significant risk level (NSRL)	Maximum allowable dose level (MADL)
1,4-dioxane(123-91-1)	X				30 µg/day	
Ethylene oxide(75-21-8)	X	X	X	X	2 µg/day	20 µg/day

Component	State or local regulations
Isopropanol(67-63-0)	U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations; U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Revision date : 10/26/2020
Data sources : Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition. OSHA 29CFR 1910.1200 Hazard Communication Standard. TSCA Chemical Substance Inventory. Accessed at <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>. ACGIH (American Conference of Government Industrial Hygienists). European Chemicals Agency (ECHA) Registered Substances list. Accessed at <http://echa.europa.eu/>. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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Other information : None.

Full text of H-statements:

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H304	May be fatal if swallowed and enters airways.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.

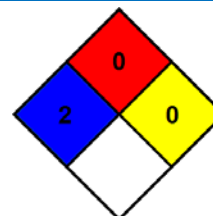
Abbreviations and acronyms:

	ACGIH (American Conference of Government Industrial Hygienists)
	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	CLP: Classification, Labelling, Packaging.
	EC50: Environmental Concentration associated with a response by 50% of the test population.
	LD50: Lethal Dose for 50% of the test population
	OSHA: Occupational Safety & Health Administration
	TSCA: Toxic Substances Control Act
	STEL: Short Term Exposure Limits
	TWA: Time Weighted Average

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



Indication of changes:

Physical and chemical properties. Classification.

Dr. Reddy's Laboratories provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a brief summary and general guide to the appropriate precautionary handling of this material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for any particular purpose. DR. REDDY'S LABORATORIES MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, DR. REDDY'S LABORATORIES WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.