

### 1. IDENTIFICATION

**Product identifier:** Diclofenac Sodium Topical Gel 1%

**Synonyms:** 2G3, 87A

**Manufacturer Name:** Perrigo Company.  
**Address:** 515 Eastern Avenue  
 Allegan, MI 49010 USA

**Telephone number:** 269-673-8451

**Emergency phone number::** 888-464-2986

**Recommended use:** Human drug – for treatment of pain of osteoarthritis of the joints.

**Restrictions on use:** For external use only. Use only as directed.

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Flammable Liquid Category 3	Eye Irritation Category 2A Specific Target Organ Toxicity Single Exposure Category 3 (narcotic effects) Reproductive Toxicity Category 2

**Label Elements:**  
**WARNING!**



**Hazard statement(s)**

Flammable liquid and vapor  
 Causes serious eye irritation.  
 May cause drowsiness or dizziness.  
 Suspected of damaging fertility or the unborn child.

**Precautionary statement(s)**

Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Keep away from heat, sparks, open flames and hot surfaces. No smoking.  
 Keep container tightly closed.  
 Ground and bond container and receiving equipment.  
 Use explosion-proof electrical, ventilating and lighting equipment.  
 Use only non-sparking tools.

**Precautionary statement(s)**

Avoid breathing vapors.  
 Use only outdoors or in a well-ventilated area.  
 Wash hands thoroughly after handling.  
 Wear eye protection.  
 Wear protective gloves and eye protection.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.  
 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell.  
 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
 IF exposed or concerned: Get medical attention.  
 In case of fire: Use water spray, carbon dioxide or alcohol-resistant foam to extinguish.  
 Store in a well-ventilated place. Keep cool.

Take precautionary measures against static discharge.

Store locked up.  
Dispose in accordance with local and national regulations.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Diclofenac Sodium	15307-79-6	1%
Isopropanol	67-63-0	20%
Propylene Glycol	57-55-6	Proprietary
Cocoyl Caprylocaprate	95912-86-0	Proprietary
Mineral Oil	8042-47-5	<10%
Polyoxyl 20 Cetostearyl Ether	68439-49-6	Proprietary
Carbomer Homopolymer Type C	9003-01-4	Proprietary
Ammonia Solution	7664-41-7	<2%
Fragrance	Mixture	<1%
Water	7732-18-5	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** For unintended skin contact immediately remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. If irritation or other symptoms develop, get immediate medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids for 15 minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, then continue flushing. Get medical attention if irritation persists.

**Ingestion:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

**Most important symptoms/effects, acute and delayed:** Causes serious eye irritation. Ingestion may cause gastrointestinal irritation and nervous system effects. Inhalation of vapors may cause respiratory irritation and dizziness and drowsiness. Swallowing may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding, ulceration and heart attack and stroke. This product is formulated to allow the drug to be well absorbed through the skin. Skin contact will have the same effects as ingestion.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is recommended for other than incidental ingestion.

### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

**Specific hazards arising from the chemical:** Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area with explosion-proof equipment. Prevent entry into basements or confined areas.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid eye contact. Avoid unintentional contact with skin. Avoid breathing vapors. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from heat, sparks and all other sources of ignition. Electrically bond and ground transfer equipment, Use appropriately rated electrical equipment in areas where this material is handled and stored. Keep containers closed when not in use.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Keep containers closed when not in use. Store away from oxidizers.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Diclofenac Sodium	250 ug/m <sup>3</sup> TWA PERRIGO OEB2
Isopropanol	400 ppm TWA OSHA PEL 200 ppm TWA, 400 ppm STEL ACGIH TLV
Propylene Glycol	10 mg/m <sup>3</sup> TWA AIHA WEEL
Cocoyl Caprylocaprate	None Established
Mineral Oil	5 mg/m <sup>3</sup> TWA OSHA PEL 5 mg/m <sup>3</sup> (inhalable) TWA ACGIH TLV
Polyoxyl 20 Cetostearyl Ether	None Established
Carbomer Homopolymer Type C	None Established
Ammonia Solution	50 ppm TWA OSHA PEL 25 ppm TWA, 35 ppm STEL ACGIH TLV
Fragrance	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor or supplied air respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** Chemical safety goggles recommended if contact with the drug product is possible.  
**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** White, opaque gel

**Odor:** Alcohol odor

<b>Odor threshold:</b> 200 ppm (isopropanol)	<b>pH:</b> 6.8-8.3
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> 30.4°C (86.7°F) (Closed Cup)	<b>Evaporation rate:</b> Not determined
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> 2% (isopropanol)	<b>UEL:</b> 12.7% (isopropanol)
<b>Vapor pressure:</b> 45.4 mmHg @ 25°C (isopropanol)	<b>Vapor density:</b> 2.1 (isopropanol)
<b>Relative density:</b> Not determined	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> 80,000-200,000 cP

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** Reaction with strong oxidizers will generate heat and cause fire.

**Conditions to avoid:** Avoid heat, sparks, flames, and all other sources of ignition.

**Incompatible materials:** Avoid oxidizing agents, acids and bases.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

**Acute effects of exposure:**

**Inhalation:** Inhalation of vapors may cause irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache.

**Ingestion:** Swallowing may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding, ulceration and heart attack and stroke.

**Skin contact:** This product is formulated to allow the drug to be well absorbed through the skin. Skin contact will have the same effects as ingestion.

**Eye contact:** Contact may cause irritation with redness, pain and tearing.

**Chronic Effects:** NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

**Sensitization:** Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity. 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. .

**Reproductive Toxicity:** Diclofenac sodium administered to male and female rats at doses up to 4 mg/kg/day did not affect fertility. Studies have not been conducted to determine the safety of dimethyl sulfoxide on fertility. Starting at 30 weeks gestation, diclofenac and other NSAIDs should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur. Developmental studies in animals demonstrated that diclofenac sodium administration did not produce teratogenicity despite the induction of

maternal toxicity and fetal toxicity in mice at doses up to 20 mg/kg/day, and in rats and rabbits at doses up to 10 mg/kg/day. Published reproductive and developmental studies of dimethyl sulfoxide are equivocal as to potential teratogenicity. In rats, maternally toxic doses of diclofenac were associated with dystocia, prolonged gestation, reduced fetal weights and growth, and reduced fetal survival. Ethanol is known to cause developmental toxicity when intentionally ingested during pregnancy.

**Carcinogenicity:** None of the components are listed as carcinogens by IARC, NTP or OSHA. Carcinogenicity studies in mice and rats administered diclofenac sodium as a dietary constituent for 2 years resulted in no significant increases in tumor incidence at doses up to 2 mg/kg/day. 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 did not increase neoplasm incidence.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg  
Diclofenac Sodium: LD50 oral rat 53 mg/kg  
Isopropanol: LD50 oral rat 5045 mg/kg; LD50 dermal rabbit 12,800 mg/kg.  
Propylene Glycol: LD50 oral rat 22,000 mg/kg, LD50 dermal rabbit >2000 mg/kg

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity values:

Isopropanol: LC50 fathead minnows (*Pimephales promelas*), 230 mg/L/96 hr  
EC50 water flea (*Daphnia magna*), immobilization: 7,550-13,299 mg/L/48 hr  
EC50 alga *Scenedesmus* sp., Growth rate inhibition: >1,000 mg / 72 hr

**Persistence and degradability:** Isopropanol is readily biodegradable.

**Bioaccumulative potential:** Isopropanol does not bioaccumulate

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

## 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
<b>DOT</b>	UN1987	Alcohols, n.o.s.	3	III	No
<b>TDG</b>	UN1987	Alcohols, n.o.s. (isopropanol)	3	III	No
<b>IMDG</b>	UN1987	Alcohols, n.o.s. (isopropanol)	3	III	No
<b>IATA</b>	UN1987	Alcohols, n.o.s. (isopropanol)	3	III	No

**Note:** In the U.S. and Canada this product can be shipped as unregulated per the aqueous alcohol exception found at 49CFR 173.150 (e) and Canada TDG 1.36.

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**Canadian WHMIS Classification:** Drugs are exempt from WHMIS

## 16. OTHER INFORMATION

**NFPA Rating:** Health = 2      Flammability = 3      Instability = 0  
**HMIS Rating:** Health = 2\*      Flammability = 3      Physical Hazard = 0

**SDS Revision History:** Revise Section 14

**Date of preparation:** April 8, 2020

**Disclaimer:** This SDS 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).