

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Diclofenac Sodium Topical Gel, 1% w/w

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Amneal Pharmaceuticals
85 Adams Ave
Hauppauge, NY 11788
T 631-952-0214 - F 631-656-1009

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Flam. Liq. 3 H226
Eye Irrit. 2A H319
Repr. 2 H361
STOT SE 3 H336
STOT RE 2 H373

Full text of H-phrases: see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS02

GHS07

GHS08

Signal word (GHS-US) :

Warning

Hazard statements (GHS-US) :

H226 - Flammable liquid and vapor
H319 - Causes serious eye irritation
H336 - May cause drowsiness or dizziness
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS-US) :

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/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
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
P370+P378 - In case of fire: Use dry chemical, foam, carbon dioxide to extinguish

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P403+P233 - Store in a well-ventilated place. Keep container tightly closed
P403+P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	Trade Secret	Not classified
Isopropyl alcohol	(CAS No) 67-63-0	Trade Secret	Flam. Liq. 2, H225 Eye Irrit. 2A, H319 STOT SE 3, H336
1,2-Propylene glycol	(CAS No) 57-55-6	Trade Secret	Not classified
Fatty acids, C8-10, C12-18-alkyl esters	(CAS No) 95912-86-0	Trade Secret	Not classified
White mineral oil, petroleum	(CAS No) 8042-47-5	Trade Secret	Not classified
Acrylic resin	(CAS No) 9003-01-4	Trade Secret	Not classified
Alcohols, C16-18, ethoxylated	(CAS No) 68439-49-6	Trade Secret	Acute Tox. 4 (Oral), H302
Ammonium hydroxide	(CAS No) 1336-21-6	Trade Secret	Acute Tox. 4 (Oral), H302
Benzenecetic acid, 2-[(2,6-dichlorophenyl)amino]-, monosodium salt	(CAS No) 15307-79-6	Trade Secret	Acute Tox. 3 (Oral), H301 Repr. 2, H361 STOT RE 2, H373
Fragrance	None	Trade Secret	Not classified

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- First-aid measures after skin contact : Flush with water for at least 15 minutes. Seek medical attention if irritation develops or persists.
- First-aid measures after eye contact : Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists.
- First-aid measures after ingestion : Do NOT induce vomiting. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : None under normal use. May cause drowsiness or dizziness.
- Symptoms/injuries after skin contact : Causes skin irritation
- Symptoms/injuries after eye contact : Causes serious eye irritation.
- Symptoms/injuries after ingestion : None under normal use.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Dry chemical, foam, carbon dioxide.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Flammable liquid and vapor.
- Explosion hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.
Methods for cleaning up : Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes, skin and clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in dry, cool, well-ventilated area.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

ACGIH	Not applicable
OSHA	Not applicable

Benzeneacetic acid, 2-[(2,6-dichlorophenyl)amino]-, monosodium salt (15307-79-6)

ACGIH	Not applicable
OSHA	Not applicable

1,2-Propylene glycol (57-55-6)

ACGIH	Not applicable
OSHA	Not applicable

Alcohols, C16-18, ethoxylated (68439-49-6)

ACGIH	Not applicable
OSHA	Not applicable

Acrylic resin (9003-01-4)

ACGIH	Not applicable
OSHA	Not applicable

Isopropyl alcohol (67-63-0)

ACGIH	ACGIH TWA (ppm)	200 ppm
ACGIH	ACGIH STEL (ppm)	400 ppm
OSHA	OSHA PEL (TWA) (mg/m ³)	980 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	400 ppm

Fatty acids, C8-10, C12-18-alkyl esters (95912-86-0)

ACGIH	Not applicable
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Fatty acids, C8-10, C12-18-alkyl esters (95912-86-0)

OSHA	Not applicable
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Ammonium hydroxide (1336-21-6)

ACGIH	Not applicable
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OSHA	Not applicable
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White mineral oil, petroleum (8042-47-5)

ACGIH	Not applicable
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OSHA	Not applicable
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8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use impervious gloves such as neoprene, nitrile, or rubber for hand protection.
Eye protection	: Safety glasses.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless
Odor	: Sweet
Odor 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 (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: 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

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
Benzeneacetic acid, 2-[(2,6-dichlorophenyl)amino]-, monosodium salt (15307-79-6)	
LD50 oral rat	53 mg/kg
ATE US (oral)	53.000 mg/kg body weight
1,2-Propylene glycol (57-55-6)	
LD50 oral rat	20 g/kg
LD50 dermal rabbit	20800 mg/kg
ATE US (oral)	20000.000 mg/kg body weight
ATE US (dermal)	20800.000 mg/kg body weight
Alcohols, C16-18, ethoxylated (68439-49-6)	
LD50 oral rat	1260 mg/kg
ATE US (oral)	1260.000 mg/kg body weight
Acrylic resin (9003-01-4)	
LD50 oral rat	2500 mg/kg
ATE US (oral)	2500.000 mg/kg
Isopropyl alcohol (67-63-0)	
LD50 oral rat	1870 mg/kg
LD50 dermal rabbit	4059 mg/kg
LC50 inhalation rat (mg/l)	72600 mg/m ³ (Exposure time: 4 h)
ATE US (oral)	1870.000 mg/kg body weight
ATE US (dermal)	4059.000 mg/kg body weight
Ammonium hydroxide (1336-21-6)	
LD50 oral rat	350 mg/kg
ATE US (oral)	350.000 mg/kg
White mineral oil, petroleum (8042-47-5)	
LD50 oral rat	> 5000 mg/kg

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

Acrylic resin (9003-01-4)	
IARC group	3 - Not classifiable

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Isopropyl alcohol (67-63-0)

IARC group	3 - Not classifiable
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Reproductive toxicity : Suspected of damaging fertility or the unborn child.

Specific target organ toxicity (single exposure) : May cause drowsiness or dizziness.

Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

1,2-Propylene glycol (57-55-6)

LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Acrylic resin (9003-01-4)

LC50 fish 1	580 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
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Isopropyl alcohol (67-63-0)

LC50 fish 1	9640 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	13299 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	11130 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

Ammonium hydroxide (1336-21-6)

LC50 fish 1	8.2 mg/l (Exposure time: 96 h - Species: Pimephales promelas)
EC50 Daphnia 1	0.66 mg/l (Exposure time: 48 h - Species: water flea)
EC50 Daphnia 2	0.66 mg/l (Exposure time: 48 h - Species: Daphnia pulex)

White mineral oil, petroleum (8042-47-5)

LC50 fish 1	> 10000 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

1,2-Propylene glycol (57-55-6)

BCF fish 1	< 1
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Isopropyl alcohol (67-63-0)

Log Pow	0.05 (at 25 °C)
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White mineral oil, petroleum (8042-47-5)

Log Pow	> 6
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on ozone layer : No additional information available

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Effect on the global warming : No known ecological damage caused by this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description : UN1993 Flammable liquids, n.o.s. (Isopropyl Alcohol), 3, III

UN-No.(DOT) : UN1993

Proper Shipping Name (DOT) : Flammable liquids, n.o.s.
Isopropyl Alcohol

Transport hazard class(es) (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

Hazard labels (DOT) : 3 - Flammable liquid



Packing group (DOT) : III - Minor Danger

DOT Packaging Non Bulk (49 CFR 173.xxx) : 203

DOT Packaging Bulk (49 CFR 173.xxx) : 242

DOT Symbols : G - Identifies PSN requiring a technical name

DOT Special Provisions (49 CFR 172.102) : 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.

B52 - Notwithstanding the provisions of 173.24b of this subchapter, non-reclosing pressure relief devices are authorized on DOT 57 portable tanks.

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).

T4 - 2.65 178.274(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.

TP29 - A portable tank having a minimum test pressure of 1.5 bar (150.0 kPa) may be used provided the calculated test pressure is 1.5 bar or less based on the MAWP of the hazardous materials, as defined in 178.275 of this subchapter, where the test pressure is 1.5 times the MAWP.

DOT Packaging Exceptions (49 CFR 173.xxx) : 150

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 60 L

DOT Quantity Limitations Cargo aircraft only (49 CFR 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.

Other information : No supplementary information available.

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

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

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1,2-Propylene glycol (57-55-6)

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

EPA TSCA Regulatory Flag

Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

Alcohols, C16-18, ethoxylated (68439-49-6)

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

Acrylic resin (9003-01-4)

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

Isopropyl alcohol (67-63-0)

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

Listed on SARA Section 313 (Specific toxic chemical listings)

EPA TSCA Regulatory Flag

T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.

SARA Section 313 - Emission Reporting

1.0 % (only if manufactured by the strong acid process, no supplier notification)

Ammonium hydroxide (1336-21-6)

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

White mineral oil, petroleum (8042-47-5)

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

15.2. US State regulations

1,2-Propylene glycol (57-55-6)

U.S. - Minnesota - Hazardous Substance List

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

U.S. - Pennsylvania - RTK (Right to Know) List

Isopropyl alcohol (67-63-0)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

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

U.S. - Pennsylvania - RTK (Right to Know) List

Ammonium hydroxide (1336-21-6)

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

Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Repr. 2	Reproductive toxicity Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H301	Toxic if swallowed
H302	Harmful if swallowed
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product