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
- P204 - Ground/bond container and receiving equipment
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P231 - Keep container tightly closed
- P240 - 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+P351+P338 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- P304+P313 - 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
- P309 - 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
Diclofenac Sodium Topical Gel, 1% w/w
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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

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

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.
Diclofenac Sodium Topical Gel, 1% w/w
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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

<table>
<thead>
<tr>
<th>Water (7732-18-5)</th>
<th>ACGIH: Not applicable</th>
<th>OSHA: Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzeneacetic acid, 2-{(2,6-dichlorophenyl)amino}-, monosodium salt (15307-79-6)</td>
<td>ACGIH: Not applicable</td>
<td>OSHA: Not applicable</td>
</tr>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td>ACGIH: Not applicable</td>
<td>OSHA: Not applicable</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated (68439-49-6)</td>
<td>ACGIH: Not applicable</td>
<td>OSHA: Not applicable</td>
</tr>
<tr>
<td>Acrylic resin (9003-01-4)</td>
<td>ACGIH: Not applicable</td>
<td>OSHA: Not applicable</td>
</tr>
<tr>
<td>Isopropyl alcohol (67-63-0)</td>
<td>ACGIH TWA (ppm): 200 ppm</td>
<td>OSHA STEL (ppm): 400 ppm</td>
</tr>
<tr>
<td></td>
<td>ACGIH STEL (ppm): 200 ppm</td>
<td>OSHA PEL (TWA) (mg/m³): 980 mg/m³</td>
</tr>
<tr>
<td>Fatty acids, C8-10, C12-18-alkyl esters (95912-86-0)</td>
<td>ACGIH: Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>OSHA</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatty acids, C8-10, C12-18-alkyl esters (95912-86-0)</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ammonium hydroxide (1336-21-6)</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>White mineral oil, petroleum (8042-47-5)</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>Sweet</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available
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

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50 oral rat</th>
<th>ATE US (oral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (7732-18-5)</td>
<td>&gt; 90 ml/kg</td>
<td></td>
</tr>
<tr>
<td>Benzeneacetic acid, 2-[(2,6-dichlorophenyl)amino]-, monosodium salt (15307-79-6)</td>
<td>53 mg/kg</td>
<td>53.000 mg/kg body weight</td>
</tr>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td>20 g/kg</td>
<td>20000.000 mg/kg body weight</td>
</tr>
<tr>
<td>Alcohol, C16-18, ethoxylated (68439-49-6)</td>
<td>1260 mg/kg</td>
<td>1260.000 mg/kg body weight</td>
</tr>
<tr>
<td>Acrylic resin (9003-01-4)</td>
<td>2500 mg/kg</td>
<td>2500.000 mg/kg</td>
</tr>
<tr>
<td>Isopropyl alcohol (67-63-0)</td>
<td>1870 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Ammonium hydroxide (1336-21-6)</td>
<td>350 mg/kg</td>
<td></td>
</tr>
<tr>
<td>White mineral oil, petroleum (8042-47-5)</td>
<td>&gt; 5000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

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
Diclofenac Sodium Topical Gel, 1% w/w  
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>IARC group</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Isopropyl alcohol (67-63-0)       | 3 - Not classifiable | 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**

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 fish 1</th>
<th>EC50 Daphnia 1</th>
<th>LC50 fish 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td>51600 mg/l</td>
<td>&gt; 1000 mg/l</td>
<td>41 - 47 ml/l</td>
</tr>
<tr>
<td>Acrylic resin (9003-01-4)</td>
<td>580 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isopropyl alcohol (67-63-0)</td>
<td>9640 mg/l</td>
<td>13299 mg/l</td>
<td>11130 mg/l</td>
</tr>
<tr>
<td>Ammonium hydroxide (1336-21-6)</td>
<td>8.2 mg/l</td>
<td>0.66 mg/l</td>
<td>0.66 mg/l</td>
</tr>
<tr>
<td>White mineral oil, petroleum (8042-47-5)</td>
<td>&gt; 10000 mg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

<table>
<thead>
<tr>
<th>Compound</th>
<th>BCF fish 1</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td>&lt; 1</td>
<td>0.05 (at 25 °C)</td>
</tr>
<tr>
<td>Isopropyl alcohol (67-63-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White mineral oil, petroleum (8042-47-5)</td>
<td></td>
<td>&gt; 6</td>
</tr>
</tbody>
</table>

**12.4. Mobility in soil**

No additional information available

**12.5. Other adverse effects**

Effect on ozone layer: No additional information available
Diclofenac Sodium Topical Gel, 1% w/w
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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
Diclofenac Sodium Topical Gel, 1% w/w
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1,2-Propylene glycol (57-55-6)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 3 (Oral)</td>
<td>Acute toxicity (oral) Category 3</td>
</tr>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral) Category 4</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Flam. Liq.</td>
<td>Flammable liquids Category 2</td>
</tr>
<tr>
<td>Flam. Liq. 2</td>
<td>Flammable liquids Category 3</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity Category 2</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific target organ toxicity (repeated exposure) Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H225</td>
<td>Highly flammable liquid and vapor</td>
</tr>
<tr>
<td>H226</td>
<td>Flammable liquid and vapor</td>
</tr>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H336</td>
<td>May cause drowsiness or dizziness</td>
</tr>
<tr>
<td>H360</td>
<td>Suspected of damaging fertility or the unborn child</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

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 Tox. 4 (Oral)
- Eye Irrit. 2A
- Flam. Liq. 2
- Flam. Liq. 3
- Repr. 2
- STOT RE 2
- STOT SE 3
- H225
- H226
- H301
- H302
- H319
- H336
- H360
- H373

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.