Material Safety Data Sheet
Material Name: Felbamate Oral Suspension

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information
Amneal Pharmaceuticals
85 Adams Ave.
Hauppauge, NY 11788
Phone: 631.952.0214
Fax: 631.656.1009

*** Section 2 - Hazards Identification ***

Emergency Overview
May cause eye, skin and respiratory tract irritation.

Potential Health Effects: Eyes
May cause eye irritation.

Potential Health Effects: Skin
May cause skin irritation.

Potential Health Effects: Ingestion
Not considered a likely route of exposure under normal industrial use. May cause adverse effects as described in product insert when ingested.

Potential Health Effects: Inhalation
May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0
Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>7732-18-5</td>
<td>Water</td>
</tr>
<tr>
<td>05-61-5</td>
<td>Glycerin</td>
</tr>
<tr>
<td>2869-83-2</td>
<td>Phenazinium, 3-(diethylamino)-7-[4-(dimethylamino)phenylazo]-5-phenyl- chloride</td>
</tr>
<tr>
<td>9004-34-6</td>
<td>Cellulose</td>
</tr>
<tr>
<td>9004-32-4</td>
<td>Sodium carboxymethyl cellulose</td>
</tr>
<tr>
<td>Not Available</td>
<td>Simethicone Emulsion</td>
</tr>
<tr>
<td>99-76-3</td>
<td>Methyl p-hydroxybenzoate</td>
</tr>
<tr>
<td>57-55-6</td>
<td>1,2-Propylene glycol</td>
</tr>
<tr>
<td>532-32-1</td>
<td>Sodium benzoate</td>
</tr>
<tr>
<td>2783-94-0</td>
<td>FD&amp;C yellow No. 6</td>
</tr>
<tr>
<td>25956-17-6</td>
<td>FD&amp;C red No. 40</td>
</tr>
<tr>
<td>9005-65-6</td>
<td>Polyoxyethylene 20 sorbitan monooleate</td>
</tr>
<tr>
<td>6155-57-3</td>
<td>1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt, dihydrate</td>
</tr>
<tr>
<td>77-92-9</td>
<td>Citric acid</td>
</tr>
<tr>
<td>94-13-3</td>
<td>Propyl-p-hydroxybenzoate</td>
</tr>
</tbody>
</table>

*** Section 4 - First Aid Measures ***

First Aid: Eyes
Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
**Material Safety Data Sheet**

Material Name: Felbamate Oral Suspension

**First Aid: Skin**
Rinse immediately with plenty of water for at least 15 minutes.

**First Aid: Ingestion**
Acute overdosage should be followed by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. Contact a physician.

**First Aid: Inhalation**
Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.

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***** Section 5 - Fire Fighting Measures ***

**General Fire Hazards**
See Section 9 for Flammability Properties.
None anticipated.

**Hazardous Combustion Products**
Not Determined

**Extinguishing Media**
Use appropriate extinguishing media for surrounding fire.

**Fire Fighting Equipment/Instructions**
Firefighters should wear full protective gear.

**NFPA Ratings:**
- **Health:** 1
- **Fire:** 0
- **Reactivity:** 0

**Hazard Scale:**
0 = Minimal  1 = Slight  2 = Moderate  3 = Serious  4 = Severe

---

***** Section 6 - Accidental Release Measures ***

**Containment Procedures**
Stop the flow of material, if this is without risk.

**Clean-Up Procedures**
Wipe up spills and rinse area with water. Dispose of these materials in accordance with federal, state, and local regulations.

**Evacuation Procedures**
Isolate area. Keep unnecessary personnel away.

**Special Procedures**
Wear appropriate personal protective equipment.

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***** Section 7 - Handling and Storage ***

**Handling Procedures**
No special handling procedures needed.

**Storage Procedures**
Store at controlled temperatures. Keep tightly closed and out of reach of children.

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***** Section 8 - Exposure Controls / Personal Protection ***

**A: Component Exposure Limits**
**Glycerin (56-81-5)**
- **ACGIH:** 10 mg/m³ TWA (mist)
- **OSHA:** 10 mg/m³ TWA (mist, total particulate); 5 mg/m³ TWA (mist, respirable fraction)
**Material Safety Data Sheet**

**Material Name: Felbamate Oral Suspension**

**Cellulose (9004-34-6)**

- ACGIH: 10 mg/m³ TWA
- OSHA: 15 mg/m³ TWA (total dust); 5 mg/m³ TWA (respirable fraction)
- NIOSH: 10 mg/m³ TWA (total dust); 5 mg/m³ TWA (respirable dust)

**Engineering Controls**

Ensure adequate ventilation, especially in confined areas.

**PERSONAL PROTECTIVE EQUIPMENT**

**Personal Protective Equipment: Eyes/Face**

Safety glasses with side-shields

**Personal Protective Equipment: Skin**

Use impervious gloves.

**Personal Protective Equipment: Respiratory**

Breathing apparatus only if aerosol or dust is formed.

**Personal Protective Equipment: General**

Eye wash fountain is recommended.

*** Section 9 - Physical & Chemical Properties ***

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colorless</td>
</tr>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>ND</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>ND</td>
</tr>
<tr>
<td>Solubility (H₂O)</td>
<td>Miscible with water</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>ND</td>
</tr>
<tr>
<td>Octanol/H₂O Coeff.</td>
<td>ND</td>
</tr>
<tr>
<td>Flash Point Method</td>
<td>ND</td>
</tr>
<tr>
<td>Lower Flammability Limit (LFL)</td>
<td>ND</td>
</tr>
<tr>
<td>Auto Ignition</td>
<td>ND</td>
</tr>
<tr>
<td>Odor</td>
<td>Bubble Gum</td>
</tr>
<tr>
<td>pH</td>
<td>ND</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>ND</td>
</tr>
<tr>
<td>Melting Point</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>ND</td>
</tr>
<tr>
<td>VOC</td>
<td>ND</td>
</tr>
<tr>
<td>Flash Point</td>
<td>ND</td>
</tr>
<tr>
<td>Upper Flammability Limit (UFL)</td>
<td>ND</td>
</tr>
<tr>
<td>Burning Rate</td>
<td>ND</td>
</tr>
<tr>
<td>Flash Point Method</td>
<td>ND</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>This is a stable material.</td>
</tr>
<tr>
<td>Chemical Stability: Conditions to Avoid</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Incompatibility</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Hazardous Decomposition</td>
<td>None</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>Will not occur.</td>
</tr>
</tbody>
</table>

*** Section 10 - Chemical Stability & Reactivity Information ***

**Chemical Stability**

This is a stable material.

**Chemical Stability: Conditions to Avoid**

Not Determined

**Incompatibility**

Not Determined

**Hazardous Decomposition**

None

**Possibility of Hazardous Reactions**

Will not occur.

*** Section 11 - Toxicological Information ***

**Acute Dose Effects**

**A: General Product Information**

No information available for the product.
### Material Safety Data Sheet

Material Name: Felbamate Oral Suspension

#### B: Component Analysis - LD50/LC50

- **Water (7732-18-5)**
  - Oral LD50 Rat >90 mL/kg

- **Glycerin (56-81-5)**
  - Oral LD50 Rat 12600 mg/kg; Dermal LD50 Rat >21900 mg/kg

- **Cellulose (9004-34-6)**
  - Inhalation LC50 Rat >5800 mg/m3 4 h; Oral LD50 Rat >5 g/kg; Dermal LD50 Rabbit >2 g/kg

- **Sodium carboxymethyl cellulose (9004-32-4)**
  - Inhalation LC50 Rat >5800 mg/m3 4 h; Oral LD50 Rat 27000 mg/kg; Dermal LD50 Rabbit >2 g/kg

- **Methyl p-hydroxybenzoate (99-76-3)**
  - Oral LD50 Rat 2100 mg/kg

- **Citric acid (77-92-9)**
  - Oral LD50 Rat 3000 mg/kg

- **Sodium benzoate (532-32-1)**
  - Oral LD50 Rat 2100 mg/kg

- **FD&C yellow No. 6 (2783-94-0)**
  - Oral LD50 Rat >10 g/kg

- **Polyoxyethylene 20 sorbitan monooleate (9005-65-6)**
  - Oral LD50 Rat 34500 µL/kg

- **1,2-Propylene glycol (57-55-6)**
  - Oral LD50 Rat 20000 mg/kg; Dermal LD50 Rabbit 20800 mg/kg

- **FD&C red No. 40 (25956-17-6)**
  - Oral LD50 Rat >10 g/kg; Dermal LD50 Rabbit >10 g/kg

- **Propyl-p-hydroxybenzoate (94-13-3)**
  - Oral LD50 Mouse 6332 mg/kg

#### Carcinogenicity

**A: General Product Information**

No information available for the product.

**B: Component Carcinogenicity**

- **FD&C yellow No. 6 (2783-94-0)**
  
  IARC: Supplement 7 [1987]; Monograph 8 [1975] (Group 3 (not classifiable))
### Section 12 - Ecological Information

#### Ecotoxicity

**A: General Product Information**

No information available for the product.

**B: Component Analysis - Ecotoxicity - Aquatic Toxicity**

- **Glycerin (56-81-5)**
  - Test & Species: 96 Hr LC50 Oncorhynchus mykiss
  - Conditions: 51 - 57 mL/L [static]
  - Test & Species: 24 Hr EC50 Daphnia magna
  - Conditions: >500 mg/L

- **Citric acid (77-92-9)**
  - Test & Species: 96 Hr LC50 Lepomis macrochirus
  - Conditions: 1516 mg/L [static]
  - Test & Species: 72 Hr EC50 Daphnia magna
  - Conditions: 120 mg/L

- **Sodium benzoate (532-32-1)**
  - Test & Species: 96 Hr LC50 Pimephales promelas
  - Conditions: 420-558 mg/L [flow-through]
  - Test & Species: 96 Hr LC50 Pimephales promelas
  - Conditions: >100 mg/L [static]
  - Test & Species: 48 Hr EC50 Daphnia magna
  - Conditions: <650 mg/L

- **1,2-Propylene glycol (57-55-6)**
  - Test & Species: 96 Hr LC50 Oncorhynchus mykiss
  - Conditions: 51600 mg/L [static]
  - Test & Species: 96 Hr LC50 Oncorhynchus mykiss
  - Conditions: 41 - 47 mL/L [static]
  - Test & Species: 96 Hr LC50 Pimephales promelas
  - Conditions: 51400 mg/L [static]
  - Test & Species: 96 Hr LC50 Pimephales promelas
  - Conditions: 710 mg/L
  - Test & Species: 96 Hr EC50 Pseudokirchneriella subcapitata
  - Conditions: 19000 mg/L
  - Test & Species: 24 Hr EC50 Daphnia magna
  - Conditions: >10000 mg/L
  - Test & Species: 48 Hr EC50 Daphnia magna
  - Conditions: >1000 mg/L [Static]

### Section 13 - Disposal Considerations

**US EPA Waste Number & Descriptions**

No EPA Waste Numbers are applicable for this product's components.

**Disposal Instructions**

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

### Section 14 - Transportation Information

**US DOT Information**

- **Shipping Name:** Not Regulated
Material Safety Data Sheet

Material Name: Felbamate Oral Suspension

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis
None of this product's components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

Component Analysis - State
The following components appear on one or more of the following state hazardous substances lists:

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>1,2-Propylene glycol</td>
<td>57-55-6</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Component Analysis - WHMIS IDL
No components are listed in the WHMIS IDL.

Additional Regulatory Information

Component Analysis - Inventory

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS #</th>
<th>TSCA</th>
<th>CAN</th>
<th>EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Yes</td>
<td>DSL</td>
<td>EINECS</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>Yes</td>
<td>DSL</td>
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<tr>
<td>Phenazinium, 3-(diethylamino)-7-[4-(dimethylamino)phenyl]azo]-5-phenyl-, chloride</td>
<td>2869-83-2</td>
<td>Yes</td>
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<td>Sodium carboxymethyl cellulose</td>
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<td>Yes</td>
<td>DSL</td>
<td>No</td>
</tr>
<tr>
<td>Methyl p-hydroxybenzoate</td>
<td>99-76-3</td>
<td>Yes</td>
<td>DSL</td>
<td>EINECS</td>
</tr>
<tr>
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<td>Yes</td>
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</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>Yes</td>
<td>DSL</td>
<td>EINECS</td>
</tr>
<tr>
<td>FD&amp;C yellow No. 6</td>
<td>2783-94-0</td>
<td>Yes</td>
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<td>Polyoxyethylene 20 sorbitan monooleate</td>
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<td>Yes</td>
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<td>No</td>
<td>No</td>
<td>No</td>
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<td>FD&amp;C red No. 40</td>
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<td>Yes</td>
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<td>94-13-3</td>
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<td>EINECS</td>
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</tbody>
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*** Section 16 - Other Information ***

Other Information
The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.
Material Safety Data Sheet

Material Name: Felbamate Oral Suspension

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration, NJTSR = New Jersey Trade Secret Registry.

End of Sheet