1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: RANITIDINE HCL ORAL SOLUTION
Synonyms: --
Company Identification: Amneal Pharmaceuticals, Inc.
For product information: 973-357-0222
For emergencies – CHEMTREC: 1-202-483-7616

2. COMPOSITION / INFORMATION ON INGREDIENTS

CONTAINING: HAZARDOUS AND/OR REGULATED COMPONENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Amount</th>
<th>CAS Number</th>
<th>Hazardous</th>
<th>OSHA PEL (ppm)</th>
<th>ACGIH TLV (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>&lt;2%</td>
<td>66357-59-3</td>
<td>YES</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>8-12%</td>
<td>57-55-6</td>
<td>YES</td>
<td>10</td>
<td>N.E.</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>5-8%</td>
<td>50-70-4</td>
<td>YES</td>
<td>N.E.</td>
<td>N.E.</td>
</tr>
<tr>
<td>Balance Non-regulated components / water</td>
<td>Balance</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

COMPOSITION COMMENT: Pharmaceutical Grade Product.

California Prop 65: This product does not contain any ingredients, above the safe harbor limits, which are known to the state of California to cause cancer, birth defects, or other reproductive harm.

HAZARDS DISCLOSURE: This product contains hazardous materials in reportable levels as defined by the OSHA Hazard Communication Standard 29 CFR 1910.1200 except as listed above. As defined under Sara 311 and 312, this product contains NO known hazardous materials.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
MAY CAUSE IRRITATION TO AREAS OF CONTACT. AVOID SKIN CONTACT.

HMIS/NFPA Rating:
Health - 1, Flammability - 0, Reactivity – 0, Personal Protection Index - C
NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme, Protective Equipment: N/A.

POTENTIAL HEALTH EFFECTS

INHALATION: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

INGESTION: contains Ranitidine which is hazardous if ingested at high dosages.

SKIN CONTACT: May cause irritation. May be absorbed with skin contact.

EYE CONTACT: A possible eye irritant. Redness, tearing, or pain may occur.

CHRONIC EXPOSURE: No information found.

AGGRAVATION OF PRE-EXISTING CONDITIONS: No information found.
4. FIRST AID MEASURES

INHALATION FIRST AID: If a respiratory problem develops. Remove victim to fresh air and provide oxygen if breathing is difficult. Get medical attention immediately.

SKIN CONTACT FIRST AID: Immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if symptoms develop.

EYE CONTACT FIRST AID: Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention if symptoms develop.

INGESTION FIRST AID: In the event of an overdose, induce vomiting. Give large amounts of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

STATEMENT OF PRACTICAL TREATMENT: Always have plenty of water available for first aid. Get medical attention if any symptoms develop or persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES: Not Flammable - Not considered to be a fire hazard.

AUTO IGNITION TEMPERATURE: N/A  
FLASH POINT: N/A

FLAMMABLE LIMITS IN AIR, % by Volume: N/A

EXTINGUISHING MEDIA: Water, dry chemical, alcohol foam, or carbon dioxide. Water spray may be used to keep exposed material cool.

FIRE & EXPLOSION HAZARDS: Combustion/fires produce smoke consisting of carbon dioxide, carbon monoxide, and other potentially toxic gases.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear appropriate personal protective equipment as specified in Section 8.

SPILLS PROCEDURE: Ventilate area of leak or spill. Spills: Place in a suitable container for disposal.

ENVIRONMENTAL PRECAUTIONS: Not applicable.

7. HANDLING AND STORAGE

RECOMMENDED STORAGE CONDITIONS: Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues; observe all warnings and precautions listed for the product.

SHELF LIFE: See Label on packaging.

HANDLING (PERSONNEL): Handle in accordance with good hygiene and safety procedures. Wash thoroughly after handling.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**AIRBORNE EXPOSURE LIMITS:** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**VENTILATION SYSTEM:** A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Please refer to the ACGIH document, Industrial Ventilation, A Manual of Recommended Practices, most recent edition, for details.

**PERSONAL RESPIRATORS (NIOSH APPROVED):** For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

**SKIN PROTECTION:** Wear protective gloves and clean body-covering clothing.

**EYE PROTECTION:** Use chemical safety glasses or goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

| FORM: Liquid | COLOR: colorless |
| ODOR: mild | VOC = 0 |
| SOLUBILITY IN WATER: complete | SPECIFIC GRAVITY: 1.035 g/L |
| MELTING/FREEZING POINT: ~32F (~0C) | Evaporation Rate: N/D |
| MOLECULAR WEIGHT: mixture | FLASH POINT: N/A |
| pH: N/D | VAPOR PRESSURE: N/D @ 72°F Not applicable |

10. STABILITY AND REACTIVITY

**STABILITY:** Stable under ordinary conditions of use and storage.

**CONDITIONS TO AVOID:** No Data Available.

**POLYMERIZATION:** No Data Available.

**INCOMPATIBILITY WITH OTHER MATERIALS:** No Data Available.

**DECOMPOSITION:** May produce carbon monoxide, carbon dioxide, nitrogen oxides and irritating fumes.
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>CANCER LISTS:</th>
<th>NTP Carcinogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient</td>
<td>Known</td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>NO</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>NO</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Toxicity:**

RANITIDINE HYDROCHLORIDE: Acute oral toxicity (LD50): 1100 mg/kg [Mouse]. LDL [Dog] - Route: Oral; Dose: 3,000 mg/kg. May cause adverse reproductive effects (female fertility) based on animal studies. It is excreted in human milk.

Propylene Glycol: Acute oral toxicity (LD50): 18500 mg/kg [Rabbit]. Acute dermal toxicity (LD50): 20800 mg/kg [Rabbit]. May cause damage to the following organs: central nervous system (CNS). May affect genetic material (mutagenic). May cause adverse reproductive effects and birth defects (teratogenic) based on animal test data.

Sorbitol: No Data Available

**Local effects:** No Data Available.

**Sensitization:** Not known to occur with this material.

**Long term toxicity:** No Data Available.

12. ECOLOGICAL INFORMATION

**ENVIRONMENTAL FATE:** No Data Available.

**ENVIRONMENTAL TOXICITY:** The product itself and its products of degradation are not toxic.

**CHEMICAL FATE:** No Data Available.

13. DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL:** Whatever cannot be saved for recovery or recycling should be handled as a non-hazardous waste and sent to an approved waste facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of material in accordance with federal, state and local requirements.

**CONTAMINATED MATERIALS:** Wash contaminated clothing before reuse.

14. TRANSPORTATION INFORMATION

15. REGULATORY INFORMATION


FEDERAL REGULATORY STATUS

**Chemical Inventory Status - Part 1**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>TSCA</th>
<th>EC</th>
<th>Japan</th>
<th>Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

**Chemical Inventory Status - Part 2**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Korea</th>
<th>DSL</th>
<th>NDSL</th>
<th>Phil.</th>
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</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

**Federal, State & International Regulations - Part 1**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>RQ</th>
<th>TPQ</th>
<th>List</th>
<th>Chemical Catalog</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Federal, State & International Regulations - Part 2**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CERCLA</th>
<th>-RCRA-</th>
<th>-TSCA-</th>
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<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>261.33</td>
<td>8(d)</td>
<td>YES</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Chemical Weapons Convention:** NO

**SARA 311/312:**
- Acute: No
- Chronic: No
- Fire: No
- Pressure: No
- Reactivity: No (Pure / solid)

**Australian Hazchem Code:** None allocated.

**Poison Schedule:** None allocated.

**WHMIS:** This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

This material or all of its components are listed on the Inventory of Existing Chemical Substances under the Toxic Substance Control Act (TSCA). This material or all of its components are listed on the Canadian Domestic Substances List (DSL). This material or all of its components are listed (or considered as having been notified) on the European Inventory of Existing Chemical Substances (EINECS). Other inventory lists: ENCS (Japan), Korea, Australia, China (Draft), PICCS (Philippines), Japan (ENCS).
16. OTHER INFORMATION

Label Hazard Warning:
CAUTION! MAY BE HARMFUL IF SWALLOWED. MAY CAUSE IRRITATION TO SKIN, AND EYES.

Label First Aid:
If swallowed, induce vomiting. Never give anything by mouth to an unconscious person. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. If irritation develops call a physician. If inhaled, remove to fresh air. Get medical attention for any breathing difficulty.

Product Use:
Laboratory & Professional use only.

Prepared By: Donato Polignone (MSDS Authoring Services)
Approved By: Amneal Pharmaceuticals
Approval Date: February 9, 2009 Supersedes Date: New

ADDITIONAL INFORMATION:
The data in this Material Safety Data Sheet relates only to the specific material designated herein. It does not relate to use in combination with any other material or in any process. This Material Safety Data Sheet (MSDS) has been reviewed to fully comply with the guidance contained in the ANSI MSDS standard (ANSI Z400.1-2004)

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Amneal Pharmaceuticals, Inc. The data on this sheet are related only to the specific material designated herein. Amneal Pharmaceuticals, Inc. assumes no legal responsibility for use or reliance upon these data.

END OF MSDS