MATERIAL SAFETY DATA SHEET

Product Name: CIMETIDINE HYDROCHLORIDE ORAL SOLUTION 300mg/5mL

NDC Product(s) Code(s): 60432-007-08
Prep. Date: 04/28/04 Rev.

1. Manufacturer:

Morton Grove Pharmaceuticals, Inc.
6451 W. Main Street
Morton Grove, IL 60053

Emergency Telephone: (847) 967-5600  
(800) 346-6854

2. Product Identification:

Product Name: CIMETIDINE HYDROCHLORIDE ORAL SOLUTION 300mg/5mL
Product NDC Code: 60432-007-08
Chemical Family: Mixture/Liquid
Synonym(s): Tagamet Oral Solution
Product Category: Histamine (H-2) blocking drug

3. Composition/Ingredient Information:

Each 5mL contains:

Actives: Cimetidine HCL 300mg

Other Ingredients: Purified Water; Saccharin Sodium; Sodium Chloride; Sodium Phosphate Dibasic; Propylene Glycol; Sorbitol Solution; Natural and Artificial Peach flavor; Dehydrated Alcohol; Methylparaben; Propylparaben; F.D,& C Yellow #6; May also contain Sodium Phosphate Monobasic for pH adjustment.

4. Physical and Chemical Properties:

Appearance: Light Orange
Odor: Peach
pH Range: 5.3-6.2
Specific Gravity: 1.16
Boiling Point: Not Determined
Evaporation Rate: Slower than Ether
Clarity: Clear
Vapor Density: Lighter than air
5. **Stability and Reactivity:**

Stability: Stable

Physical conditions to avoid: Excessive Heat and/or Freezing

Incompatibility with other materials: None

Hazardous Decomposition Products: None

Hazardous Polymerization: Will not occur

6. **Hazards Identification:**

Primary Route(s) of Exposure: Ingestion

Effects of Over Exposure: Skin Rash; dizziness; drowsiness

Threshold Limit Value: Not Determined

7. **Side Effects:**

May include any of the following:

- Headache; dizziness; constipation; diarrhea; muscle pain; drowsiness; breast enlargement; and/or soreness; nausea; vomiting.

**Possible Adverse Effects:**

- Heartburn; indigestion; sour stomach; difficulty breathing; skin rash; mental confusion; itching; hives; hallucinations; irregular heartbeat.

**Symptoms of Overdose:**

- Confusion; tachycardia; sweating; drowsiness; seizures; respiratory failure; twitching; CNS symptoms.

8. **Emergency and First-Aid Measures:**

**Skin Contact:** Remove any contaminated clothing immediately. Wash affected areas with soap and large amounts of water.

**Eye Contact:** Immediately flush eyes with water and continue flushing for several minutes. Seek medical attention.

**Inhalation:** Remove to fresh air; get medical attention for any breathing difficulty.

**Excess Ingestion:** See section 7 under “Symptoms of Overdose.” Contact a doctor or poison control.
9. Fire Fighting Measures:

- Flammability Classification: Non-Flammable
- Flash Point: Not Determined
- Lower Explosion Limit: Not Determined
- Upper Explosion Limit: Not Determined
- Extinguishing Media: Water
- Fire Fighting Measures: Normal
- Unusual Fire or Explosion Hazards: None

10. Toxicological Information:

CAUTION:

- Pregnancy: Category “B”. Adequate studies of pregnant women are not available.
- Nursing Mothers: Cimetidine is present in breast milk. Avoid drug or refrain from nursing.
- Children: Routine use is not recommended for those under 16 years old.
- Adults/Geriatrics: If over 60 years of age check for thinking/mental status changes. Look for decreased appetite, stomach fullness, nausea and vomiting.

11. Spill and Leak Procedures:

Steps to be taken if material is spilled:

Provide adequate ventilation to keep vapor levels as low as possible. Use proper personal protective equipment to avoid overexposure. Stop leak if you can do so without risk. Small spills can be absorbed with proper material, e.g., rags, paper towels, etc. Large spills should be contained and vacuumed and placed in a suitable container.

Contains Cimetidine HCL. Flush to sanitary system with copious amounts of water following local and federal requirements for disposal.

12. Waste Disposal Method:

Dispose of this material in accordance with applicable international, national, state, and local waste regulations.

13. Storage and Handling Precautions:

As with any drug/medicine, keep out of the reach of children. Store at a controlled room temperature, 15 °C - 30°C (59°F - 86°F). Dispense in tight, light resistant container. Store away from heat and direct light.
Always follow the advice of your physician while using this drug. Make sure your healthcare professional is aware of any allergies or any other medical problems that you may have.

14. **Process Handling Precautions:**

A system of local exhaust is recommended to keep employee exposure below the airborne exposure limits.

Local exhaust is usually preferred because it controls the emission at its source, preventing dispersion of it into the general work area.

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with this material. Wash thoroughly after handling.

15. **Personal Protection/ Exposure Controls:**

<table>
<thead>
<tr>
<th>Protection Type</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Protection</td>
<td>Not required</td>
</tr>
<tr>
<td>Ventilation</td>
<td>Local exhaust</td>
</tr>
<tr>
<td>Protective Gloves</td>
<td>Yes</td>
</tr>
<tr>
<td>Eye Protection</td>
<td>Yes</td>
</tr>
</tbody>
</table>

16. **Shipping Regulations (Ref: 49 CFR § 172.101):**

<table>
<thead>
<tr>
<th>Regulation Type</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProperShippingName</td>
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</tr>
<tr>
<td>Hazard Class</td>
<td>None</td>
</tr>
<tr>
<td>UN/NA Number</td>
<td>None Listed</td>
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<tr>
<td>Subsidiary Risk</td>
<td>None</td>
</tr>
<tr>
<td>US DOT Emergency Response Guide</td>
<td>None</td>
</tr>
<tr>
<td>Transportation Label Required</td>
<td>None</td>
</tr>
</tbody>
</table>

17. **Disclaimer:**

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