1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Hydrocortisone Cypionate Oral Suspension, USP

Trade Name: Cortef (R) Oral Suspension
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anti-inflammatory.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Cypionate</td>
<td>508-99-6</td>
<td>208-091-0</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>234-394-2</td>
<td>*</td>
</tr>
<tr>
<td>Flavors</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Yellow Liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, weakness muscle cramps, nervousness, restlessness, trouble sleeping. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Clinical use may cause an increase in blood pressure (hypertension). Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

EU Indication of danger: Not classified
Material Name: Hydrocortisone Cypionate Oral Suspension, USP
Revision date: 15-Dec-2006

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glycerin, USP
MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension, USP
Revision date: 15-Dec-2006

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Version: 1.1

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
- Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
- Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
- Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
- Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Yellow</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

- Glycerin, USP
  - Mouse Oral LD50 4090 mg/kg
  - Rat Oral LD50 12.6 g/kg
  - Rabbit Dermal LD50 > 10 g/kg
  - Rat Inhalation LC50 1hr > 570 mg/m³
  - Rat Dermal LD 50 > 21.9 g/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Irritation / Sensitization: (Study Type, Species, Severity)**

**Glycerin, USP**
- Eye Irritation  Rabbit  Mild

**Hydrocortisone**
- Eye Irritation  Rabbit  Minimal

**Benzoic acid**
- Skin Sensitization - GPMT  Guinea Pig  Negative
- Skin Sensitization - Beuhler  Guinea Pig  Negative
- Eye Irritation  Rabbit  Severe

**Citric acid**
- Eye Irritation  Rabbit  Severe
- Skin Irritation  Rabbit  Mild

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Hydrocortisone**
Material Name: Hydrocortisone Cypionate Oral Suspension, USP

Revision date: 15-Dec-2006

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC-50 96 Hours 50 mg/L
Daphnia Magna (Water Flea) EC-50 24 Hours >500 mg/L
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class: None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Hydrocortisone Cypionate
EU EINECS List 208-091-0

Glycerin, USP
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-289-5

Sucrose
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-334-9

FD&C Yellow No. 6; (Sunset yellow)
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet