Material Name: CHILDREN’S ACETAMINOPHEN ORAL SUSPENSION

Intended Use: Pharmaceutical product used to temporarily relieve minor aches and pains.

Restrictions on Use: Patients who are allergic to acetaminophen or any of the inactive ingredients of this product.

Manufacturer: Pharmaceutical Associates, Inc.
A Subsidiary of Beach Products, Inc.
201 Delaware Street
Greenville, SC 29605 USA
Phone: (864) 277-7282

Emergency telephone number: Poison Control Center: 1-800-222-1222

Primary Route of Entry: Ingestion/ Non-Hazardous

Hazards associated with Material: Non-hazardous in accordance with standards for workplace safety.

Carcinogen Listed: Not Listed

Active Ingredients: Acetaminophen, USP (160 mg/5 mL)

Other Components: Butylparaben NF
Propylene Glycol, USP
Sorbitol Solution USP
Glycerin USP
High Fructose Corn Syrup
Sodium Benzoate, NF
Citric Acid Anhydrous, USP
Veegum
Xanthan Gum NF
Polysorbate 80
Acesulfame K
FD&C Red No. 40
Artificial Strawberry Flavor
Water, USP Purified
Section 4: First-Aid Measures

Potential Health Effects:

Acute: (Acetaminophen) Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Chronic: (Acetaminophen) CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Overexposure Health Effects: Hypersensitivity to any of the components.

Emergency Procedures: Contact Employee Health Services Immediately.

Inhalation: Remove to fresh air and contact a physician or poison control center.

Eye Contact: Flush with running water for 15 minutes holding eyelids open. Then contact physician.

Skin Contact: Wash contaminated area with water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. If skin irritation occurs, contact a physician.

Ingestion: Over usage: Do not induce vomiting unless directed to do so by medical personnel. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Contact a physician or poison control center.

Section 5: Fire-Fighting Measures

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

Hazardous Combustion Products: May emit toxic fumes on combustion.

Fire Fighting Procedures: During firefighting activities, wear appropriate protective equipment, which may include self-contained breathing apparatus.

Fire/Explosion Hazards: May be combustible at high temperature.

Section 6: Accidental Release Measures

Safety Precautions: Personnel involved in clean-up should minimize exposure and wear appropriate personal protective equipment.

Cleaning Procedure: Contain source of spill if it is safe to do so. Collect spilled material by means that controls dust generation. Clean spill area thoroughly.

Environmental Protection Measures: Deposit waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid any environmental release.
Additional Considerations

For Large Spills:

Report emergency situations immediately. Non-essential personnel should be evacuated from affected area. Clean up operations should be performed by trained personnel only.

Section 7: Handling and Storage

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

Storage Conditions:
Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Additional Measures:
None

Section 8: Exposure Controls/Personal Protection

Ventilation:
Not required under normal conditions of therapeutic use.

Respiratory Protections:
Not required under normal conditions of therapeutic use.

Protective Gloves and Clothing:
Not required under normal conditions of therapeutic use.

Eye Protection:
Safety glasses recommended.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>Other Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>10 mg/m³</td>
<td>200 ppm</td>
<td>None Listed</td>
</tr>
<tr>
<td>Butylparaben NF</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Glycerin</td>
<td>15 mg/m³</td>
<td>10 mg/m³</td>
<td>None Listed</td>
</tr>
<tr>
<td>Propylene Glycol, USP</td>
<td>Not Available</td>
<td>Not Available</td>
<td>AIHA: 10 mg/m³</td>
</tr>
<tr>
<td>Sodium Benzoate NF</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Sorbitol Solution 70%, USP</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>High Fructose Corn Syrup</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Citric Acid Anhydrous, USP</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Veegum (Magnesium Aluminum Silicate)</td>
<td>15 mg/m³ TWA</td>
<td>10 mg/m³</td>
<td>None Listed</td>
</tr>
<tr>
<td>Xanthan Gum NF</td>
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<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
<tr>
<td>Acelsulfame K</td>
<td>Not Available</td>
<td>Not Available</td>
<td>None Listed</td>
</tr>
</tbody>
</table>
Section 9: Physical and Chemical Properties

Physical State: Liquid Solution
Appearance: Clear, red liquid
Melting Point: N/A
Boiling Point: N/A
Specific Gravity: 1.2
pH: 4.0 – 6.9
Water Reactive: No

Section 10: Stability and Reactivity

Stability: Stable under normal conditions of use.
Hazardous Polymerization: Will not occur.
Incompatible Materials: None Listed
Conditions to Avoid: Protect from Light.
Hazardous Decomposition Products: Unknown.

Section 11: Toxicological Information

Routes of Entry: Oral

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Route of Entry</th>
<th>LD50</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Oral</td>
<td>1944 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Butylparaben NF</td>
<td>Oral</td>
<td>13,200 mg/kg</td>
<td>Mouse</td>
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<td>Propylene Glycol, USP</td>
<td>Oral</td>
<td>20000 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Sorbitol Solution 70%, USP</td>
<td>Oral</td>
<td>15900 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Glycerin</td>
<td>Oral</td>
<td>12600 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>High Fructose Corn Syrup</td>
<td>Oral</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

Children’s Acetaminophen Oral Suspension
### Potential Effects on Humans:

(Acetaminophen) Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

### Potential Chronic Effects:

(Acetaminophen) CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

### Section 12: Ecological Information

**Ecological Overview:** Environmental properties have not been evaluated. Releases to the environment should be avoided.

### Section 13: Disposal Considerations

**Waste Disposal Method:** Dispose of material in accordance with all local, state and federal laws and regulations.

### Section 14: Transport Information

**DOT Classification:** Non DOT-Controlled Material.

**Special Considerations:** None Listed.

### Section 15: Regulatory Information

**OSHA Label:** Non-hazardous in accordance with workplace safety.

### Section 16: Other Information

**Data Sources:** Publicly available toxicity information, other information provided from raw material suppliers and Pharmaceutical Associates, Inc.

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representative, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is pharmacologically active.