

**Section 1: Identification****Material Name: CHILDREN'S ACETAMINOPHEN ORAL SUSPENSION**

NDC - 0121 - 1781

<b>Intended Use:</b>	Pharmaceutical product used to temporarily relieve minor aches and pains.
<b>Restrictions on Use:</b>	Patients who are allergic to acetaminophen or any of the inactive ingredients of this product.
<b>Manufacturer:</b>	<b>Pharmaceutical Associates, Inc.</b> A Subsidiary of Beach Products, Inc. 201 Delaware Street Greenville, SC 29605 USA Phone: (864) 277-7282
<b>Emergency telephone number:</b>	Poison Control Center: 1-800-222-1222

**Section 2: Hazard Identification**

<b>Primary Route of Entry:</b>	Ingestion/ Non-Hazardous
<b>Hazards associated with Material:</b>	Non-hazardous in accordance with standards for workplace safety.
<b>Carcinogen Listed:</b>	Not Listed

**Section 3: Composition**

<b>Active Ingredients:</b>	Acetaminophen, USP (160 mg/5 mL)
<b>Other Components:</b>	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**

<b>Potential Health Effects:</b>	<b>Acute:</b> (Acetaminophen) Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.  <b>Chronic:</b> (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.
<b>Overexposure Health Effects:</b>	Hypersensitivity to any of the components.
<b>Emergency Procedures:</b>	Contact Employee Health Services Immediately.
<b>Inhalation:</b>	Remove to fresh air and contact a physician or poison control center.
<b>Eye Contact:</b>	Flush with running water for 15 minutes holding eyelids open. Then contact physician.
<b>Skin Contact:</b>	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.
<b>Ingestion:</b>	<b>Over usage:</b> 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**

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	May emit toxic fumes on combustion.
<b>Fire Fighting Procedures:</b>	During firefighting activities, wear appropriate protective equipment, which may include self-contained breathing apparatus.
<b>Fire/Explosion Hazards:</b>	May be combustible at high temperature.

**Section 6: Accidental Release Measures**

<b>Safety Precautions:</b>	Personnel involved in clean-up should minimize exposure and wear appropriate personal protective equipment.
<b>Cleaning Procedure:</b>	Contain source of spill if it is safe to do so. Collect spilled material by means that controls dust generation. Clean spill area thoroughly.
<b>Environmental Protection Measures:</b>	Deposit waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid any environmental release.

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**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

<b>General Handling:</b>	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
<b>Storage Conditions:</b>	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames
<b>Additional Measures:</b>	None

## Section 8: Exposure Controls/Personal Protection

<b>Ventilation:</b>	Not required under normal conditions of therapeutic use.
<b>Respiratory Protections:</b>	Not required under normal conditions of therapeutic use.
<b>Protective Gloves and Clothing:</b>	Not required under normal conditions of therapeutic use.
<b>Eye Protection:</b>	Safety glasses recommended.

Chemical Name	OSHA PEL	ACGIH TLV	Other Limits
Acetaminophen	10 mg/m <sup>3</sup>	200 ppm	None Listed
Butylparaben NF	Not Available	Not Available	None Listed
Glycerin	15 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>	None Listed
Propylene Glycol, USP	Not Available	Not Available	AIHA: 10 mg/m <sup>3</sup>
Sodium Benzoate NF	Not Available	Not Available	None Listed
Sorbitol Solution 70%, USP	Not Available	Not Available	None Listed
High Fructose Corn Syrup	Not Available	Not Available	None Listed
Citric Acid Anhydrous, USP	Not Available	Not Available	None Listed
Veegum (Magnesium Aluminum Silicate)	15 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup>	None Listed
Xanthan Gum NF	Not Available	Not Available	None Listed
Polysorbate 80	Not Available	Not Available	None Listed
Acelsulfame K	Not Available	Not Available	None Listed

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F D & C Red No. 40	Not Available	Not Available	None Listed
Artificial Strawberry Flavor	Not Available	Not Available	None Listed

## Section 9: Physical and Chemical Properties

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

## Section 10: Stability and Reactivity

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

## Section 11: Toxicological Information

**Routes of Entry:** Oral

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

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Sodium Benzoate, NF	Oral	4070 mg/kg	Rat
Citric Acid Anhydrous, USP	Oral	5040 mg/kg	Rat
Veegum (Magnesium Aluminum Silicate)	Not Available	Not Available	Not Available
Xanthan Gum NF	Not Available	Not Available	Not Available
Polysorbate 80	Oral	25000 mg/kg	Mouse
Acesulfame K	Oral	7431 mg/kg	Rat
FD & C Red No. 40	Oral	1000 mg/kg	Rat
Artificial Strawberry Flavor	Not Available	Not Available	Not Available

**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.

# Safety Data Sheet

**Prepared By:** Pharmaceutical Associates, Inc. Regulatory Group.

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.