

# SAFETY DATA SHEET

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Revision Number: 03

## 1. IDENTIFICATION

**Product identifier:** Children's Ibuprofen Dye Free Berry 100 mg/5 mL & 200 mg/10 mL

**Product Codes:** 00121-1022-00, 00121-2044-00

**Supplier Name and Address:** Pharmaceutical Associates, Inc.  
201 Delaware Street

Greenville, SC 29605

**Telephone number:** (864) 277-7282

**Emergency phone number:** CHEMTREC 800-424-9300

**Recommended use:** Human drug – fever and pain reliever

**Restrictions on use:** Use only as directed.

## 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

**Label Elements:**

**Warning!**



**Hazard statement(s)**

Suspected of damaging the unborn child.

**Precautionary statement(s)**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Wear protective clothing and gloves.

IF exposed or concerned: Get medical attention.

Store locked up.

Dispose in accordance with local and national regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Ibuprofen	15687-27-1	2%
Acesulfame Potassium	55589-62-3	<0.1%
Glycerin	56-81-5	Proprietary
Sucrose	57-50-1	Proprietary
Citric Acid	77-92-9	<1%
Sodium Benzoate	532-32-1	<1%
Propylene Glycol	57-55-6	Proprietary
Carboxymethylcellulose sodium	9004-32-4	Proprietary
Microcrystalline cellulose	9004-34-6	Proprietary

Flavor	Mixture	Proprietary
Polysorbate 80	9005-65-6	Proprietary
Xanthan gum	11138-66-2	Proprietary
Water	7732-18-5	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs, get medical attention.

**Skin contact:** First aid is generally not required. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdosage.

**Most important symptoms/effects, acute and delayed:** May cause mild eye irritation. Swallowing amounts above the recommended dosage may cause gastrointestinal effects dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding, ulceration and heart attack and stroke. Suspected to cause adverse reproductive effects.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for large unintended ingestion.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

**Specific hazards arising from the chemical:** This product is not a fire hazard but may burn under fire conditions after the water has evaporated.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Caution – spilled liquid may present a slip hazard.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

**7. HANDLING AND STORAGE**

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****Exposure guidelines:**

Ibuprofen	None Established
Acesulfame Potassium	None Established
Glycerin	None Established
Sucrose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Citric Acid	None Established
Sodium Benzoate	2.5 mg/m3 (inhalable) skin ACGIH TLV
Propylene Glycol	10 mg/m3 TWA AIHA WEEL
Carboxymethylcellulose sodium	None Established
Microcrystalline cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Flavor	None Established
Polysorbate 80	None Established
Xanthan gum	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance (physical state, color, etc.):** Off-white to light brown colored suspension

**Odor:** Berry

<b>Odor threshold:</b> Not applicable	<b>pH:</b> 3.6-4.6
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> Not applicable	<b>Evaporation rate:</b> Not determined

<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Vapor density:</b> Not determined
<b>Relative density:</b> Not determined	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> Not determined

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Acute effects of exposure:

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

**Ingestion:** Swallowing amounts above the recommended dosage may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding and ulceration.

**Skin contact:** May cause mild irritation.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

**Sensitization:** Components are not known to be sensitizers.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity.

Ibuprofen was not mutagenic in in-vitro bacterial reverse mutation assay.

**Reproductive Toxicity:** Reproductive studies conducted with ibuprofen in rats and rabbits have not demonstrated evidence of developmental abnormalities. Ibuprofen is a member of the nonsteroidal anti-inflammatory drug (NSAID) drug class. Usage in late pregnancy is associated with a significant increase in the risk of premature closure of the ductus arteriosus.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Ibuprofen: LD50 oral rat 636 mg/kg

Glycerin: LD50 oral rat 12.6 g/kg

Propylene Glycol: LD50 oral rat 21-33.7 g/kg; LD50 dermal rabbit 20.8 g/kg

## 12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

**Ecotoxicity values:** Ibuprofen: EC50 daphnia magna 36.6 mg/L/48 hr.; LC50 Lepomis macrochirus 173 mg/L/96 hr.

Glycerin: LC50 goldfish >5000 mg/L/24 hr; LC50 daphnia magna >10,000 mg/L/24 hr.

Propylene glycol: LC50 Cyprinodon variegatus 48,000 mg/L/96 hr; EC50 daphnia magna 43,500 mg/L/48 hr.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

### 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

### 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**California Proposition 65:** This product is not known to contain regulated chemicals.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**16. OTHER INFORMATION**

**Issue Date:** 10/19/2023

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**SDS Revision History:** Change in Section 3

**Disclaimer:** The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.