

Safety Data Sheet

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1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Children's Ibuprofen Oral Suspension

Other means of identification

Product code(s): 0121-1836-05

UN-Number: NA

Synonyms: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used for pain relief and to reduce fever.

Uses advised against: Do not use except as recommended.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family:

Mixture

Statement of Hazard:

Product is generally safe used as recommended.

Additional Hazard Information:

Short term:

Ibuprofen is a NSAID (nonsteroidal anti-inflammatory drug) and may cause an increased risk of gastrointestinal adverse events, including bleeding, ulceration, and perforation of the stomach or intestines.

Long term:

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke.

Known Clinical Effects:

Acute over-dosage or chronic abuse may cause kidney effects. Adverse effects associated with the therapeutic use include gastrointestinal effects such as nausea, pain heartburn, bleeding, ulceration, and perforation. It may also cause prolonged bleeding time. Drowsiness, fatigue, or headaches are also possible. Other NSAID's are known to impact delivery, late fetal development, and lactation.

EU Indication of danger:

Not classified.

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Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

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 of exposure in your workplace.

Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

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

3. Composition/Information on ingredients

Chemical name	CAS-No	mg/5 mL	Trade Secret
Ibuprofen	15687-27-1	100 mg/5 mL	
Citric Acid Anhydrous	77-92-9		X
Glycerin	56-81-5		X
Hypromellose	9004-65-3		X
Polysorbate 80	9005-65-6		X
Sodium Benzoate	532-32-1		X
Sucrose	57-50-1		X
Xanthan Gum	11138-66-2		X
D&C Yellow No. 10	8004-92-0		X
FD&C Red No. 40	25956-17-6		X
Berry Flavor	Mixture		X

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4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Over-dosage or accidental ingestion – Contact medical personnel or a Poison Control Center immediately.

Most important symptoms/effects, acute and delayed

Over-dosage may cause kidney effects.

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

May burn emitting oxides of chlorine and nitrogen.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

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

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures.
Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

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7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ibuprofen	Not Available	Not Available	Not Available
Citric Acid Anhydrous	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Glycerin	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Hypromellose	Not Available	10 mg/m ³ TWA	Not Available
Polysorbate 80	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available
Sucrose	10 mg/m ³	15 mg/m ³	10 mg/m ³ TWA
Xanthan Gum	Not Available	Not Available	Not Available
D&C Yellow No. 10	Not Available	Not Available	Not Available
FD&C Red No. 40	Not Available	Not Available	Not Available
Berry Flavor	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures:

Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection:

Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures:

Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Suspension
Odor: Berry
Appearance: Orange suspension
Odor threshold: Not available

Property	Values	Remarks/Method
pH	3.6 – 4.6	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.1 - 1.2	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%)

NA

10. Stability and reactivity

Reactivity Stable at normal conditions

Chemical stability Stable at normal conditions

Possibility of hazardous reactions Stable at normal conditions

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Conditions to avoid None known

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Ibuprofen	636 mg/kg Rat	Not Available	Not Available
Citric Acid Anhydrous	5400 mg/kg Rat	>2000 mg/kg Rat	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Hypromellose	>10000 mg/kg Rat	Not Available	Not Available
Polysorbate 80	25000 mg/kg Mouse	Not Available	Not Available
Sodium Benzoate	2100 mg/kg Rat	Not Available	Not Available
Sucrose	29700 mg/kg Rat	Not Available	Not Available
Xanthan Gum	45000 mg/kg Rat	Not Available	Not Available
FD&C Red No. 40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
D&C Yellow No. 10	2000 mg/kg Rat	Not Available	Not Available
Berry Flavor	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristic:

No data available

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available
- Numerical measures of toxicity – product No data available

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12. Ecological information

Ecotoxicity: Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability: No data available

Bioaccumulation: No data available

Other adverse effects: No data available

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Ibuprofen	Not Available	Not Available	Not Available	Not Available
Citric Acid	Not Available	440 mg/L 48 hr Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Hypromellose	Not Available	Not Available	Not Available	Not Available
Polysorbate 80	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	484 mg/L 96 hr. Pimephales Promelas	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
Xanthan Gum	Not Available	320 – 560 mg/L 96 hr. Rainbow trout	Not Available	Not Available
FD&C Red No. 40	Not Available	Not Available	Not Available	Not Available
D&C Yellow No. 10	Not Available	Not Available	Not Available	Not Available
Berry Flavor	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods

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

Contaminated packaging

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

14. Transport information

Notes:

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

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15. Regulatory information

International inventories

Legend

TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The following components are included on the inventory: Ibuprofen, Citric Acid, Glycerin, Hypromellose, Polysorbate 80, Sodium Benzoate, Sucrose, Xanthan Gum, D&C Yellow No. 10 and FD&C Red No. 40.

EINECS:

Ibuprofen, Citric Acid, Glycerin, Hypromellose, Sodium Benzoate, Sucrose, Xanthan Gum, D&C Yellow No. 10, and FD&C Red No. 40 are listed on the EINECS inventory.

U.S. Federal regulations

OSHA Label:

Not applicable

SARA 311/312 Hazard categories:

Not applicable

Clean Water Act:

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA:

No components are listed under CERCLA.

California Proposition 65:

This product does not contain any chemical which is listed as under Proposition 65.

U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Ibuprofen	X		X		
Citric Acid Anhydrous	X		X		
Glycerin	X	X	X	X	X
Hypromellose	X		X		
Polysorbate 80					
Sodium Benzoate	X		X		
Sucrose	X	X	X		
Xanthan Gum	X		X		
FD&C Red No. 40					
D&C Yellow No. 10					
Berry Flavor					

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U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Regulatory Affairs Department

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General 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.

End of Safety Data Sheet