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NGHS / English

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## 1. IDENTIFICATION

### Product identifier

**Product Name** Childrens Ibuprofen 100 mg Oral suspension Grape

### Other means of identification

**Product Code(s)** 0121-0914-05; 0121-1828-10

### Recommended use of the chemical and restrictions on use

**Recommended Use** Oral Pain Relief

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

**Supplier Identification** Pharmaceutical Associates, Inc.

**Address**  
201 Delaware Street  
Greenville, SC 29605

**Telephone** (864) 277 -7282

### Emergency telephone number

**Company Emergency Phone Number** 516-CHEMTREC 800.424.9300

## 2. HAZARDS IDENTIFICATION

### Classification

Not classified.

The product contains no substances which at their given concentration, are considered to be hazardous to health

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Appearance Purple

Physical state Liquid

Odor Sweet

**GHS Label elements, including precautionary statements**

**Hazard statements**

Not classified.

**Other information**

**Unknown acute toxicity** 13.5 % of the mixture consists of ingredient(s) of unknown toxicity  
1.5 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
13.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance**

Not applicable.

**Mixture**

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Sucrose	57-50-1	44.44	-	-
Glycerin	56-81-5	10	-	-
Ibuprofen	15687-27-1	2	-	-
Maize starch	9005-25-8	1.5	-	-

**4. FIRST AID MEASURES**

**First aid measures**

**Inhalation** Remove to fresh air.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**Skin contact** Wash skin with soap and water.

**Ingestion** Clean mouth with water and drink afterwards plenty of water.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

**5. FIRE-FIGHTING MEASURES**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical** No information available.

**Hazardous Combustion Products** Carbon oxides.

**Explosion Data**

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

**Personal precautions** Avoid contact with eyes.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

**7. HANDLING AND STORAGE**

Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	
Glycerin 56-81-5	TWA: 10 mg/m <sup>3</sup> mist	TWA: 15 mg/m <sup>3</sup> mist, total particulate TWA: 5 mg/m <sup>3</sup> mist, respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate (vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction		
Maize starch 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Glycerin 56-81-5	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>		TWA: 10 mg/m <sup>3</sup>
Maize starch 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>

**Other Exposure Guidelines**

Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering controls**

Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

No special protective equipment required.

**Skin and body protection**

No special protective equipment required.

**Respiratory protection**

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Physical and Chemical Properties**

Physical state	Liquid
Appearance	Purple
Odor	Sweet
Color	No information available
Odor Threshold	Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks Method</u>
pH	3	
Melting / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	No data available	None known
Evaporation Rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	1	
Water Solubility	Mostly soluble	
Solubility(ies)	No data available	None known
Partition coefficient: n-octanol/water	0	
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

**Other Information**

Explosive properties	No information available
Oxidizing properties	No information available
Softening Point	No information available
Molecular Weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk Density	No information available
Particle Size	No information available
Particle Size Distribution	No information available

**10. STABILITY AND REACTIVITY**

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.  
**Eye contact** Specific test data for the substance or mixture is not available.  
**Skin contact** Specific test data for the substance or mixture is not available.  
**Ingestion** Specific test data for the substance or mixture is not available.

**Information on toxicological effects**

**Symptoms** No information available.

**Numerical measures of toxicity**

**Acute Toxicity**

The following values are calculated based on chapter 3.1 of the GHS document .

**ATEmix (oral)** 25,391.60 mg/kg

**Unknown acute toxicity** 13.5 % of the mixture consists of ingredient(s) of unknown toxicity  
 1.5 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
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 13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 13.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg ( Rat )	-	-
Glycerin	= 12600 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 570 mg/m <sup>3</sup> ( Rat ) 1 h
Ibuprofen	= 636 mg/kg ( Rat )	-	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** No information available.  
**Serious eye damage/eye irritation** No information available.  
**Respiratory or skin sensitization** No information available.  
**Germ cell mutagenicity** No information available.  
**Carcinogenicity** No information available.  
**Reproductive toxicity** No information available.  
**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Aspiration hazard** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

Chemical name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Glycerin	-	96h LC50: 51 - 57 mL/L (Oncorhynchus mykiss)	-	24h EC50: > 500 mg/L
Ibuprofen	120h EC50: = 39.9 mg/L (Skeletonema costatum)	96h LC50: = 173 mg/L (Lepomis macrochirus)	EC50 = 12.3 mg/L 5 min EC50 = 13.12 mg/L 15 min EC50 = 13.82 mg/L 30 min	48h EC50: = 9.06 mg/L

**Persistence and Degradability** No information available.

**Bioaccumulation**

### Component Information

Chemical name	Log Pow
Glycerin	-1.76
Ibuprofen	3.3

**Mobility** No information available.

**Other adverse effects** No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

**California Waste Codes** 311

## 14. TRANSPORT INFORMATION

**DOT**  
**Proper Shipping Name** NOT REGULATED  
**Hazard Class** NON-REGULATED  
 N/A

**TDG** Not regulated

**MEX** Not regulated

**ICAO** Not regulated

**IATA**  
**Proper Shipping Name** Not regulated  
**Hazard Class** NON REGULATED  
 N/A

<u>IMDG/IMO</u> Hazard Class	Not regulated N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Regulations

Ozone-depleting substances (ODS) Not applicable

Persistent Organic Pollutants Not applicable

Export Notification requirements Not applicable

#### International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

#### Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List  
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
ENCS - Japan Existing and New Chemical Substances  
KECL - Korean Existing and Evaluated Chemical Substances  
PICCS - Philippines Inventory of Chemicals and Chemical Substances  
AICS - Australian Inventory of Chemical Substances

#### US Federal Regulations

##### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

##### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

##### CWA (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



This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product may contain substances regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Sucrose 57-50-1		X	X		
Glycerin 56-81-5	X	X	X	X	
Maize starch 9005-25-8		X	X		

**16. OTHER INFORMATION**

<b>NFPA</b>	Health hazards 1	Flammability 0	Instability 0	<b>Physical and Chemical Properties - Personal Protection X</b>
<b>HMIS</b>	Health hazards 1	Flammability 0	Physical hazards 0	

**Prepared By** Pharmaceutical Associates, Inc.  
09JUL2020

**Issuing Date** 09JUL2020

**Revision Date** No information available

**Revision Note**

**Disclaimer**

The information provided in this Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text

**End of Safety Data Sheet**