

Safety Data Sheet

Issuing date: 16AUG2021

Revision date: 17FEB2022

Revision number: 01

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

GHS product identifier

Product name: Acetaminophen Oral Suspension 160 mg per 5 mL (Dye Free-Grape Flavor)
Acetaminophen Oral Suspension 325 mg per 10.15 mL (Dye Free-Grape Flavor)
Acetaminophen Oral Suspension 650 mg per 20.3 mL (Dye Free-Grape Flavor)

Other means of identification

Product code(s): 0121-0941-05; 0121-0941-94; 0121-0941-00; 0121-1882-11; 0121-1882-94; 0121-1882-00; 0121-2823 -21; 0121-2823-94
UN-Number: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as a pain reliever and fever reducer
Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
1700 Perimeter Road
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: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Additional Hazard Information:

Short term: Acetaminophen has been associated with cases of acute liver failure resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen containing product

Long term: No data available

Known Clinical Effects: Overdosage may lead to liver failure.

EU Indication of danger: Not classified.

Health Hazard:

Type	Category
Not Applicable	Not Applicable

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Label elements

Emergency Overview

Danger

Hazard statements

None / Not Applicable

This mixture is a drug product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.

Appearance: White to off-white grape flavored suspension **Physical state:** Liquid **Odor:**
Grape

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.

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.

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3. Composition/Information on ingredients

Chemical name	CAS-No	Weight mg	Trade Secret
Acetaminophen	103-90-02	160 mg/ 5 mL 325 mg/10.15 mL 650 mg/20.3 mL	
Acesulfame potassium	55589-62-3		X
Butylparaben	94-26-8		
Citric acid anhydrous	77-92-9		X
Glycerin	56-81-5		X
High fructose corn syrup	Mixture		X
Polysorbate 80	9005-65-6		X
Propylene glycol	57-55-6		X
Purified water	7732-18-5		X
Sodium benzoate	532-32-1		X
Sorbitol Solution	Mixture		X
Xanthan gum	11138-66-2		X
Grape flavoring	Mixture		X

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:

The product is intended for ingestion. In the case of accidental ingestion or overdose, contact medical personnel.

Most important symptoms/effects, acute and delayed

Toxicity may result from acetaminophen overdose. Contact medical personnel or poison control immediately if overdose is suspected.

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

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

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5. Fire-fighting measures

Suitable extinguishing media:	Use carbon dioxide, dry chemical or water spray.
Specific hazards arising from the chemical	Not applicable.
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	
<ul style="list-style-type: none">• 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.

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.

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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
Acetaminophen	Not available	Not available	Not Available
Acesulfame potassium	Not Available	Not Available	Not Available
Butylparaben	Not Available	Not Available	Not Available
Citric acid	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
High fructose corn syrup	Not Available	Not available	Not Available
Polysorbate 80	Not Available	Not Available	Not Available
Propylene glycol	Not Available	10 mg/m ³ TWA (WEEL)	Not Available
Purified water	Not Applicable	Not Applicable	Not Available
Sodium benzoate	Not Available	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Xanthan gum	Not Available	Not Available	Not Available
Grape flavoring	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.

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: Slight grape
Appearance: White to off-white
Odor threshold: Not available

Property	Values	Remarks/Method
pH	4.0-6.9	cUSP Method
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	1.2192-1.2506	cUSP Method
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 NA

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
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
Acetaminophen	1944 mg/kg Rat	Not Available	Not Available
Acesulfame potassium	7431 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Butylparaben	13200 mg/kg Rat	Mild skin irritation 48 hr. Guinea pig	Not Available
Citric acid anhydrous	5400 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
High Fructose Corn Syrup	Not Available	Not Available	Not Available
Polysorbate 80	25000 mg/kg Mouse	Not Available	Not Available
Propylene Glycol	20000 mg/kg Rat	20800 mg/kg Rabbit	Not Available
Purified Water	Not Available	Not Available	Not Available
Sodium benzoate	2100 mg/kg Rat	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Xanthan gum	45000 mg/kg Rat	Not Available	Not Available

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Grape Flavoring

Not Available

Not Available

Not Available

Symptoms related to the physical, chemical and toxicological characteristics

None

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

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)
Acetaminophen	Not Available	814 mg/L 96 hr.	Acetaminophen	Not Available
Acesulfame potassium	Not Available	Not Available	Not Available	Not Available
Butylparaben	Not Available	Not Available	Not Available	Not Available
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr.	Citric Acid Anhydrous	Not Available
Glycerin	Not Available	58.5 ppm 96 hr	Glycerin	Not Available
High Fructose Corn Syrup	Not Available	Not Available	Not Available	Not Available
Polysorbate 80	Not Available	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	52930 mg/L 96 hr Pimephales	Not Available	13020 mg/L 48 hr.

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Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
		Promelas		
Purified Water	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	484 mg/L 96 hr. Pimephales Promelas	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
Xanthan Gum	Not Available	320 – 560 mg/L 96 hr. Oncorhynchus mykiss	Not Available	Not Available
Grape 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.

15. Regulatory information

International inventories

Legend

U.S. Federal regulations;

Not applicable

Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Acetaminophen	No	Listed	Listed	Not Applicable
Acesulfame potassium	No	No	Listed	Not Applicable
Butylparaben	No	Listed	Listed	Not Applicable
Citric Acid Anhydrous	No	Listed	Listed	Not Applicable
Glycerin	No	Listed	Listed	Not Applicable
High Fructose Corn Syrup	No	No	No	Not Applicable
Polysorbate 80	No	Listed	No	Not Applicable

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Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Propylene Glycol	No	Listed	Listed	Not Applicable
Purified Water	No	No	No	Not Applicable
Sodium Benzoate	No	Listed	Listed	Not Applicable
Sorbitol Solution	No	No	No	Not Applicable
Xanthan Gum	No	Listed	Listed	Not Applicable
Grape Flavor	No	Not Listed	Not Listed	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 ingredients listed as Proposition 65 chemicals.

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
Acetaminophen	X		X		
Acesulfame Potassium					
Butylparaben	X		X		
Citric Acid Anhydrous	X		X		
Glycerin	X	X	X	X	X
High Fructose Corn Syrup					
Polysorbate 80					
Propylene Glycol	X		X		
Purified Water					
Sodium Benzoate	X		X		
Sorbitol Solution	X		X		
Xanthan gum	X		X		
Grape Flavoring					

U.S. EPA label information:

Not applicable

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16. Other information

Prepared by: Pharmaceutical Associates Inc.

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Revision note: 00 – New SDS

Revision date: 17FEB2022

Revision note: 01 – Corrected NDC 0121-1882-94 and added additional strengths to the Product Name and Table 3. Composition/Information on ingredients

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