

Safety Data Sheet

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

GHS product identifier

Product name: Diphenhydramine HCl Oral Solution USP

Other mean of identification

Product code(s): 0121-0489-05, 0121-0489-10, 0121-0489-20, 0121-0489-00, 0121-0978-10, 0121-0978-00

UN-Number: NA

Synonyms: Compare to Benadryl®

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as antihistamine sedative

Uses advised against: Do not use except as prescribed.

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: May be harmful if swallowed.

Additional Hazard Information:

Short term: May cause central nervous system effects. Not an eye irritant, Not a skin irritant or skin sensitizer, based on components.

Long term: Not available.

Known Clinical Effects: Therapeutic use of this substance has resulted in drowsiness, sleepiness, dizziness, sedation, ataxia, confusion, and gastrointestinal disturbances. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

EU Indication of danger: Not classified.

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.

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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/mL	Trade Secret
Diphenhydramine HCl	147-24-0	12.5 mg/5 mL	
Alcohol 190 Proof	Mixture 64-17-5 (200 proof)	14% v/v	
Sucrose	57-50-1		X
Sodium Citrate Dihydrate	6132-04-3		X
Citric Acid Anhydrous	77-92-9		X
Anise Flavor	Mixture		X
Cinnamon Oil	8007-80-5		X
D&C Red No. 33	3567-66-6		X
FD&C Red No.40	25956-17-6		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.

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Ingestion:

Overdosage or accidental ingestion –If vomiting has not occurred spontaneously, the patient should be induced to vomit. This is best done by having the patient drink a glass of water or milk, after which he should be made to gag. Precaution against aspiration must be taken. Contact medical personnel or poison control center.

Most important symptoms/effects, acute and delayed

Overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. Atropine-like signs and symptoms, dry mouth; fixed, dilated pupils; flushing and gastrointestinal symptoms may also occur.

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

NA

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

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

- 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
Diphenhydramine	Not available	0.15 µg/m ³ (OEL)	Not available
Ethanol	Not available	1900 mg/m ³ TWA	1000 ppm TWA
Sucrose	10 mg/m ³	15 mg/m ³	10 mg/m ³ TWA
Sodium Citrate Dihydrate	Not available	Not available	Not available
Citric Acid Anhydrous	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Anise Flavor	Not available	Not available	Not available
Cinnamon Oil	Not available	Not available	Not available
D&C Red No. 33	Not available	Not available	Not available
FD&C Red No.	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: Solution
Odor: Cinnamon, Anise
Appearance: Clear red
Odor threshold: Not available

Property	Values	Remarks/Method
pH	4.8 – 5.8	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	1.2	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 (%) Alcohol 14%

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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 included in this section, below, describes the potential hazards of the individual ingredients.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Diphenhydramine	500 mg/kg Rat	Not Available	Not Available
Ethanol	3632 mg/kg Rat	Not Available	20000 ppm 10h Rat
Sucrose	29700 mg/kg Rat	Not Available	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available
Citric Acid Anhydrous	5400 mg/kg Rat	>2000 mg/kg Rat	Not Available
Anise Flavor	Not Available	Not Available	Not Available
Cinnamon Oil	2000 mg/kg Rat	320 mg/kg Rabbit	Not Available
D&C Red No. 33	Not Available	Not Available	Not Available
FD&C Red No.40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

Therapeutic use of this substance has resulted in drowsiness, sleepiness, dizziness, sedation, ataxia, confusion, and gastrointestinal disturbances. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

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

- Sensitization: Eye and Skin (Diphenhydramine)
- Mutagenic effects: Bacterial mutagenicity (Ames) Negative (Diphenhydramine)
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: Maternal Toxicity, Fetotoxicity (Diphenhydramine)
- STOT – single exposure: Narcotic effects (Diphenhydramine)
- 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 for this product 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)
Diphenhydramine	Not Available	Not Available	Not Available	Not Available
Ethanol	Not Available	Not Available	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available	Not Available
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr. Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Anise Flavor	Not Available	Not Available	Not Available	Not Available
Cinnamon Oil	Not Available	Not Available	Not Available	Not Available
D&C Red No. 33	Not Available	Not Available	Not Available	Not Available
FD&C Red No.40	Not Available	Not Available	Not Available	Not Available

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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

EINECS:

This product contains Diphenhydramine HCl, Ethanol 200 proof, Sucrose, Sodium Citrate Dihydrate, Citric Acid, FD&C Red No. 40 and D&C Red No. 33 which are listed in the EINECS.

IECSC:

Not Listed

Legend

TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The product contains Ethanol, Citric Acid, Sucrose and FD&C Red No. 40 which are listed on the TSCA inventory.

U.S. Federal regulations

Not Available

OSHA Label:

Not Available

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 contain Ethanol which are listed as a Proposition 65 chemical as developmental toxicity.

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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
Diphenhydramine					
Ethanol 200 Proof	X	X	X	X	X
Sucrose	X	X	X		X
Sodium Citrate Dihydrate	X		X		
Citric Acid	X		X		
Anise Flavor					
Cinnamon Oil	X	X	X		
FD&C Red No. 40					
D&C Red No. 33					

U.S. EPA label information Not applicable

16. Other information

Prepared by:

Regulatory Affairs

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Added NDC Numbers 0121-0489-00, 0121-0978-10, 0121-0978-00

Corrected Section 5, Specific Hazards to say "Not Applicable"

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