

Safety Data Sheet

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

GHS product identifier

Product name: Bromfed
Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan
Hydrobromide Syrup 2mg/30 mg/10 mg per 5 mL

Other means of identification

Product code(s): 0121-0933- 04, 0121-0933-16
UN-Number: NA

Recommended use of the chemical and restrictions on use

- Recommended use: Pharmaceutical product used for coughing, sneezing, and nasal congestion caused by allergies or the common cold. **Do not take with a MAO inhibitor.**

Uses advised against: Do not use except as directed or with a MAO inhibitor,

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: May cause drowsiness or dizziness. Do not Take with a MAO inhibitor or if you have recently taken a MAO inhibitor,

Additional Hazard Information:
Known Clinical Effects:

EU Indication of danger: Not classified.

Health Hazard:

Type	Category
Acute Toxicity	NA
Carcinogenicity	NA
Reproductive Toxicity	NA
Specific Target Organ Toxicity	NA

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Label elements

Emergency Overview

Danger

Hazard statements

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: Clear, pink liquid

Physical state: Liquid

Odor:

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.

3. Composition/Information on ingredients

Chemical name	CAS-No	Weight mg	Trade Secret
Brompheniramine Maleate	980-71-2	2mg/5 mL	
Dextromethorphan HBr	125-69-9	10 mg/5 mL	
Pseudoephedrine HCl	345-78-8	30 mg/5 mL	
Methylparaben	5026-62-0		X
Sodium Benzoate	532-32-1		X
Glycerin	56-81-5		X
Citric Acid	77-92-9		X
Sodium Citrate	68-04-2		X
Sucrose	57-50-1		X
FD&C Red 40	25956-17-6		X
Purified water	7732-18-5		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

Phenobarbital can cause fetal harm when administered to a pregnant woman. Barbiturates readily cross the placental barrier and are distributed throughout fetal tissues; the highest concentrations are found in the placenta, fetal liver, and brain.

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
Brompheniramine Maleate	Not Available	Not Available Acute Toxicity Oral Cat 4	Not Available
Dextromethorphan HBr	Not Available	Not Available	Not Available
Pseudoephedrine HCl	Not Available	Not Available	Not Available
Methylparaben	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available
Glycerin	Not Available	5 mg/m ³	Not Available
Sodium Citrate	Not Available	Not Available	Not Available
Citric Acid	Not Available	Not Available	Not Available
Sucrose	10 mg/m ³	15 mg/m ³	10 mg/m ³ TWA
FD&C Red 40	Not Available	Not Available	Not Available
Purified water	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: Solution
 Odor: Citrus
 Appearance: Clear, pink to red liquid
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	4,5 – 5.5	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	1.1438-1.1596	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
 VOC – 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
Brompheniramine Maleate	318 mg/kg Rat	Not Available	Not Available
Dextromethorphan HBr	Not Available	Not Available	20000 ppm 10hr. Rat
Pseudoephedrine HCl	371 mg/kg mouse	Not Available	Not Available
Methylparaben	Not Available	Not Available	Not Available
Sodium Benzoate			
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Citric Acid	2100 mg/kg Rat	No skin Irritation Rabbit	Not Available
Sodium Citrate	5400 mg/kg Mouse	Not Available	Not Available
Sucrose	29700 mg/kg Rat	Not Available	Not Available
FD&C Red 40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
Purified water	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: No data available
- Reproductive toxicity: No data available.
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available

Aspiration hazard: Based on available data, the classification criteria are not met

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)
Brompheniramine maleate	Not Available	Not Available	Not Available	Not Available
Dextromethorphan HBR	Not Available	Not Available	Not Available	Not Available
Pseudoephedrine HCl	Not Available	Not Available	Not Available	Not Available
Methyl Paraben	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	LC50 piimephales promelas 484mg/L 96 hr	Not Available	EC50 5600-10000 mg/ L 48 hr.
Citric Acid		LC100 goldfish 894 mg/L lifetime exposure	Pseudomonas putida Toxicity threshold >10 g/ L	LD20080 mg/L Lifetime exposure
Sodium Citrate	Not Available	LC50 poecilid reticulata 18000 – 32000mg/L 96 hr,		
Glycerin	Not Available	.LC50 Trout >51000to >57000 mg/L 96 hr.	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
FD&C Red 40	Not Available	Not Available	Not Available	Not Available
Purified water	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.

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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
Brompheniramine maleate	No	No		
Dextromethorphan HBR	No	No	No	No
Pseudoephedrine HCl	No	Listed	Listed	No
Methyl Paraben	No	No	No	No
Sodium Benzoate	No	No	No	No
Citric Acid	No	Listed	Listed	No
Sodium Citrate	No	Listed	Listed	No
Glycerin	No	No	Not Available	Listed
Sucrose	Not Available	Not Available	Not Available	Not Available
FD&C Red 40	No	Listed	Listed	Not Available
Purified water	No	No	No	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.

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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
Brompheniramine Maleate	No	No	No	Not Available	Not Available
Dextromethorphan HBr	No	No	No	No	No
Pseudoephedrine HCl	No	No	No	No	No
Methylparaben	Not Available	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available	Not Available	Not Available
Citric Acid	Not Available	Not Available	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available	Not Available	Not Available
Glycerin	X	X	X	X	X
Sucrose	X	X	X		
FD&C Red 40	Not Available	Not Available	Not Available	Not Available	Not Available
Purified water	Not Available	Not Available	Not Available	Not Available	Not Available

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Inc.

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Revision note:

New SDS

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