



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Consumer Healthcare Pfizer Inc 201 Tabor Road Morris Plains, New Jersey 07950	Emergency telephone Hours of operation	+1-973-385-2000 24 hours
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Trade names	Benadryl® FASTMELT Tablets
Product name	Children's Benadryl® Allergy and Cold FASTMELT Tablets
Therapeutic use	Decongestant and Antihistamine
Description	Pink/red convex tablet with fruity odor and taste.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Diphenhydramine citrate*	88637-37-0	19 mg/tablet (4.61%)**
Pseudoephedrine hydrochloride*	345-78-8	30 mg/tablet (7.29%)
Aspartame	22839-47-0	Trade Secret***
Flavor*	Not assigned	Trade secret
Citric acid*	77-92-9	Trade secret
D&C Red #7 Calcium Lake	52821-04-9	Trade secret
Ethylcellulose	9004-57-3	Trade secret
Lactitol	585-86-4	Trade secret
Magnesium stearate*	557-04-0	Trade secret
Mannitol	69-65-8	Trade secret
Polyethylene	9002-88-4	Trade secret
Stearic acid*	57-11-4	Trade secret

*Hazardous

Note: ** Equivalent to 12.5 mg Diphenhydramine hydrochloride

*** Contains phenylalanine (4.6 mg/tablet)

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

Signal word CAUTION!

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Statements of hazard	MAY CAUSE LIVER, CARDIOVASCULAR AND CENTRAL NERVOUS SYSTEM EFFECTS.
Eye effects	Dust may cause transient irritation.
Skin effects	Dust may cause transient irritation.
Inhalation effects	Not expected due to physical form. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion effects	Accidental ingestion may cause effects similar to those seen in clinical use. See 'Statements of hazard' and 'Known clinical effects' in this section.
Known clinical effects	Diphenhydramine citrate and pseudoephedrine hydrochloride are widely used over-the-counter medications. Adverse effects associated with the therapeutic use of diphenhydramine and/or pseudoephedrine HCl include drowsiness, excitability, nausea, nervousness, dizziness, sleeplessness, fast or irregular heart rate, and increased blood pressure.
Other potential health effects	Phenylketonurics: Contains phenylalanine (4.6 mg/tablet)
Additional data	For a more detailed discussion of potential health hazards and toxicity see Section 11.
NOTE:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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 for exposure in your workplace.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin	Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If discomfort persists, get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Flash point	Not applicable
Hazardous combustion products	May emit toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and other chlorine containing compounds.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Vacuum or sweep material into appropriate container for disposal. Clean spill area thoroughly.
Large spill	Vacuum or sweep material into appropriate container for disposal. Close container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.
Storage conditions	Store in a cool, dry place.
Temperature range for storage	59-77°F

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

<u>Exposure limits</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
<u>Compound</u> Diphenhydramine citrate	Pfizer	TWA-8 Hr	0.05 mg/m ³ (as Diphenhydramine)
Pseudoephedrine hydrochloride	Pfizer	TWA-8 Hr	0.7 mg/m ³
Mannitol	ACGIH	TWA-8 Hr	10 mg/m ³ (total dust)
	OSHA	TWA-8 Hr	15 mg/m ³ (total dust)
	OSHA	TWA-8 Hr	5 mg/m ³ (respirable fraction)
Exposure information	The exposure limit(s) listed for solid components are only relevant if dust may be generated.		
Measurement method	An analytical method may be available for the compound(s) listed above. Contact Pfizer for further information.		
Ventilation	General room ventilation is adequate unless the process generates dust.		

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Eye protection	Wear safety glasses with sideshields.
Skin protection	Wear protective clothing when working with large quantities.
Hand protection	Wear gloves when working with large quantities.
Respiratory protection	If the applicable Occupational Exposure Limits (OELs) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Convex Tablet
Color	Pink/red
Odor	Fruity
Taste	Fruity
Molecular weight	Mixture
Molecular formula	Mixture
pH	No data available
Water solubility	No data available
Solvent solubility	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Conditions to avoid	None known
Incompatibilities	None known
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient(s).

Acute toxicity	Type	Route	Species	Result
<u>Compound</u> Diphenhydramine citrate	LD ₅₀	Oral	Rat	856 mg/kg
Pseudoephedrine hydrochloride	LD ₅₀	Oral	Rat	660 mg/kg

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Eye	Not determined for this product. Dust may cause transient irritation if tablets are crushed or broken.
Skin	Not determined for this product.
Inhalation	Not determined for this product. Dust may cause transient irritation if tablets are crushed or broken.
Ingestion	See Acute toxicity table.
Mutagenicity	Not determined for this product.
Additional acute toxicity information	Phenylketonurics: This product contains phenylalanine (4.6 mg/tablet)
Subchronic effects	In a 13-week oral study with diphenhydramine, dose-related liver toxicity (vacuolization, characteristic of fat accumulation) was seen in rats at doses of 313 ppm or greater.
Chronic effects/ carcinogenicity	Liver toxicity (granuloma, cytoplasmic vacuolation) was seen in a two-year oral study in rats treated with diphenhydramine. A No-Observed-Adverse-Effect-Level (NOAEL) of 15 mg/kg/day was obtained for female animals.
Carcinogen status	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Reproductive effects	Not determined for this product.
Teratogenicity	Not determined for this product.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
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SECTION 13 - DISPOSAL INFORMATION

Disposal procedure	Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.
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SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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SECTION 15 - REGULATORY INFORMATION

EU Classification
Canadian WHMIS

Not classified
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

SECTION 16 - OTHER

Disclaimer

The information contained in this Material Safety Data Sheet is believed to be accurate, and while it is provided in good faith, it is without a warranty of any kind, express or implied.