



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 (973) 385-2000
Hours of operation 24 hours

Product name	Benadryl Allergy Ultratab Kapseal Capsules
Therapeutic use	Allergy medication
Description	Solid

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Diphenhydramine hydrochloride*	147-24-0	13.9%
Magnesium stearate*	557-04-0	1.1%
Lactose NF, monohydrate	64044-51-5	Proprietary

*Hazardous

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

SECTION 3 - HAZARDS IDENTIFICATION

Signal word	CAUTION!
Statements of hazard	MAY CAUSE NERVOUS SYSTEM EFFECTS. MAY CAUSE EYE IRRITATION.
Eye effects	Possible eye irritant
Skin effects	Negligible skin irritant.
Inhalation effects	No data available. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion effects	No data available.
Additional data	For a more detailed discussion of potential health hazards and toxicity see Section 11.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

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 discomfort persists, get medical attention.
Ingestion	In the event of swallowing this material, dilute with large quantities of water or milk. Medical treatment should be supportive and symptomatic.
Note to physician	Drowsiness may occur if swallowed.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Flash point	Not applicable

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	Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal. Clean spill area thoroughly.

SECTION 7 - HANDLING AND STORAGE

General handling	IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING.
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SECTION 7 - HANDLING AND STORAGE ... continued

Storage conditions	Keep in tightly closed containers away from heat and light.
Temperature range for storage	No data available

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits				
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>	
Diphenhydramine hydrochloride	Pfizer	TWA-8 Hr	0.05 mg/m ³ (as Diphenhydramine)	
Magnesium stearate	ACGIH	TWA-8 Hr	10 mg/m ³ (stearates)	
Exposure information	The exposure limit(s) listed for solid components are only relevant if dust may be generated.			
Ventilation	Good general ventilation should be sufficient to control airborne levels.			
Eye protection	Glasses or goggles are recommended if eye contact is possible.			
Skin protection	Wear protective clothing when working with large quantities.			
Hand protection	Wear gloves when working with large quantities.			
Respiratory protection	Respirators are not required for normal use of this material. 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	Solid
Color	Colorless
Molecular weight	Mixture
Molecular formula	Mixture
pH	No data available
Water solubility	Soluble
Solvent solubility	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Conditions to avoid	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.

SECTION 10 - STABILITY AND REACTIVITY ... continued

Incompatibilities	None known
Hazardous decomposition products	None known
Hazardous polymerization	No data available

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Diphenhydramine hydrochloride	LD ₅₀	Oral	Rat	500 mg/kg
	LD ₅₀	Oral	Mouse	114 mg/kg
	Irritation	Ocular	Rabbit	Mild
	LD ₅₀	Oral	Guinea Pig	284 mg/kg
	LDmin.	Oral	Human	10.1 mg/kg
	LD ₅₀	IV	Dog	24 mg/kg
	LD ₅₀	IV	Hamster	10 mg/kg
Magnesium stearate	LD ₅₀	IV	Mouse	20 mg/kg
	LC ₅₀ /1H	Inhalation	Rat	>2000 mg/m ³
	LD ₅₀	Oral	Rat	>2000 mg/kg
	LD ₅₀	Oral	Rat	>1000 mg/kg
	LC50	Inhalation	Rat	>2000 mg/m ³

Eye	Possible eye irritant
Skin	Negligible skin irritation is possible
Inhalation	Not determined for this product.
Ingestion	Not determined for this product.
Mutagenicity	Not determined for this product.
Subchronic effects	Not determined for this product.
Chronic effects/ carcinogenicity	Not determined for this product.
Carcinogen status	None of the components of this formulation is listed as a carcinogen by IARC, NTP or OSHA.
Reproductive effects	Not determined for this product
Teratogenicity	Not determined for this product.
Additional information	Effects reported during consumer use include drowsiness and excitation.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure Observe all local and national regulations when disposing of this material.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

EU Classification Not classified

Canadian WHMIS 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.**