



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc
Pfizer Pharmaceuticals Group
235 E 42nd Street
New York, NY 10017

Emergency telephone +1-212-573-2222
Hours of operation 24 hours

Product name Benadryl® (Diphenhydramine hydrochloride) 50 mg/ml Solution for Injection
Therapeutic use Antihistamine agent
Description Colorless, odorless solution

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Diphenhydramine hydrochloride*	147-24-0	5.0%
Sodium hydroxide NF*	1310-73-2	to adjust pH
or	-	-
Hydrochloric acid, NF*	7647-01-0	to adjust pH

*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 BE HARMFUL IF SWALLOWED
MAY CAUSE NERVOUS SYSTEM EFFECTS

Eye effects Active ingredient is not an irritant (based on animal data).

Skin effects May cause skin irritation. Active ingredient is not a skin sensitizer (based on animal data).

Inhalation effects An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Ingestion effects May be harmful if swallowed. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Known clinical effects	The most common adverse effects seen with the therapeutic use of diphenhydramine HCl include drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.
Other potential health effects	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
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 until no evidence of product remains. If irritation occurs or persists, get medical attention.
Skin	Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
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.
Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Hazardous combustion products	None known or expected.
Flash point	>61°C (>141.8°F)

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Use non-combustible material to absorb spill; then place in a suitable, labeled recovery container. Clean spill area thoroughly.
Large spill	Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling	Use appropriate ventilation. Avoid breathing vapor or mist. Avoid contact with skin and clothing.
Storage conditions	Store at controlled room temperature. Protect from freezing and light.
Temperature range for storage	15-30°C (59-86°F)

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	0.15 mg/m ³ (as free base)	
Analytical method	Diphenhydramine: SAM# 190.0 (contact Pfizer for additional details)			
Ventilation	Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk. For laboratory use, handle in a lab hood.			
Eye protection	Safety glasses or goggles			
Skin protection	Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas.			
Hand protection	Wear protective gloves			
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	Sterile solution
Color	Colorless
Odor	Odorless

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ... continued

pH	5.0-6.0
Boiling point	100°C
Melting point	Not applicable
Density	1.05 g/cm ³
Vapor pressure	23 hPa at 20°C
Water solubility	Soluble
Solvent solubility	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable under normal conditions of use.
Conditions to avoid	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Hazardous decomposition products	None known
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Result</u>
Diphenhydramine hydrochloride	LD ₅₀	Oral	Rat	500 mg/kg
	Irritation	Ocular	Rabbit	Negative

Eye See Acute toxicity table.

Skin Skin irritation has been reported in clinical use.

Inhalation No data available

Ingestion See Acute toxicity table.

Mutagenicity No evidence of mutagenic activity in bacterial or mammalian cells *in vitro*, or clastogenic activity *in vitro*. Diphenhydramine hydrochloride was positive in the CHO assay in the absence of metabolic activation only.

Sensitization Negative in the Buehler test. Negative in the mouse Local Lymph Node Assay (LLNA).

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Subchronic effects	In a 13-week oral study, dose-related liver toxicity was seen in rats at doses of ≥ 13 mg/kg/day in males and ≥ 15 mg/kg/day in females. The NOAEL in this study was ~ 6.5 mg/kg/day (males) and 7 mg/kg/day (females). There were no compound-related histological effects observed in mice.
Chronic effects/ carcinogenicity	Liver toxicity 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. There was equivocal evidence of carcinogenic activity in male and female rats. No evidence of carcinogenic activity was observed in male or female mice.
Carcinogen status	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Reproductive effects	No evidence of impaired fertility was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.
Teratogenicity	No evidence of harm to the fetus was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
-------------------------------	--

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.
---------------------------	---

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
EU Labelling	None required

SECTION 15 - REGULATORY INFORMATION ... continued

WHMIS Classification 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.**