



# US - OSHA SAFETY DATA SHEET

11/24/14

Revision Date

Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** BENADRYL Allergy Dye-Free LIQUI-GELS

### Other means of identification

**Product Code** MCHC-BDRALLG  
C-1261

**Synonyms** Benadryl dye-free liquid gels  
Benadryl liquid gels

### Recommended use of the chemical and restrictions on use

**Recommended Use** Temporarily relieves these symptoms due to hay fever or other respiratory allergies: runny nose; sneezing; itchy, watery eyes; itching of the nose or throat.

**Recommended Restrictions** Temporarily relieves these symptoms due to the common cold: runny nose, sneezing.  
None Known.

### Details of the supplier of the safety data sheet

#### **Supplier Address**

McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.  
7050 Camp Hill Rd.  
Fort Washington, PA  
10934-2299

### Emergency telephone number

**Company Phone Number** (215) 273-7000

**24 Hour Emergency Phone Number** For 24-hour emergency assistance, call the 3E Company at 1 (877)-236-9871  
Provide the technician with the following product tracking code: 2277

## 2. HAZARDS IDENTIFICATION

### Classification

#### **Health Hazards**

Not classified

#### **Physical hazards**

Not Classified.

#### **OSHA Regulatory Status**

Over the counter drugs in their solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

**Label elements**

**Emergency Overview**

**Hazard statements**

This material does not meet the criteria for classification.

**Hazard Symbol**

None

**Signal Word**

None

**Appearance** Clear, oblong, soft, gelatin capsule printed "BENADRYL" on one side with white ink

**Physical state** Soft Gelatin Capsule

**Odor** Not available.

**Precautionary Statements - Prevention**

Not available

**Precautionary Statements - Response**

No specific first aid measures noted.

**Precautionary Statements - Storage**

Store at 20 -25 °C (68 - 77 °F). Avoid high humidity and excessive heat. Protect from light.

**Precautionary Statements - Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazards not otherwise classified (HNOC)**

Not classified.

**Other Information**

Not available.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Synonyms**

Benadryl dye-free liquid gels  
Benadryl liquid gels.

Chemical Name	CAS No.	Weight-%
Diphenhydramine Hydrochloride USP	147-24-0	1-5
Glycerin	56-81-5	1-15
Polyethylene Glycol	25322-68-3	20-40

**4. FIRST AID MEASURES**

**First aid measures**

**Eye contact**

In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

**Skin Contact**

Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.

**Inhalation**

If symptomatic, move to fresh air. Get medical attention if symptoms persist.

**Ingestion** If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Diphenhydramine is a potent anticholinergic agent. This activity is responsible for the side-effects of dry mouth and throat, increased heart rate, pupil dilation, urinary retention, constipation, and, at high doses, hallucinations or delirium.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical**

Not applicable.

**Explosion data**

**Sensitivity to Mechanical Impact** None known.

**Sensitivity to Static Discharge** None known.

**Protective equipment and precautions for firefighters**

Wear self-contained breathing apparatus and protective clothing.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Wear appropriate personal protective equipment (see Section 8).

**Environmental precautions**

**Environmental precautions** See Section 12 for additional ecological information.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**

If dry, vacuum and place into proper container for disposal. If wet, collect or scrape up and ensure area is thoroughly cleaned.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Advice on safe handling** Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep only in the original container. Store at 20 - 25 °C (68 - 77 °F). Avoid high humidity and excessive heat. Protect from light. Keep away from food, drink, and animal feedingstuffs. Keep out of reach of children.

**Incompatible materials**

None known based on information supplied. Strong oxidizing agents.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters****Biological limit values**

No biological limits noted for this ingredient.

**Exposure Guidelines**

Based on a review of animal and clinical literature, an Occupational Exposure Limit (OEL) of 139 µg/m<sup>3</sup> is recommended as an 8-hour TWA for Diphenhydramine Hydrochloride.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	-	TWA: 15 mg/m <sup>3</sup> mist, total particulate TWA: 5 mg/m <sup>3</sup> mist, respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate (vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction	-

**Appropriate engineering controls****Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and body protection**

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Hand protection**

Use protective gloves. None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection**

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards**

Not applicable.

**General Hygiene Considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Physical state	Soft Gelatin Capsule	Odor	Not available.
Appearance	Clear, oblong, soft, gelatin capsule printed "BENADRYL" on one side with white ink		
Color	Clear	Odor threshold	Not available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Lower explosive limit:	Not available.	
Upper explosive limit:	Not available.	
Oxidizing properties	Not available.	

## 10. STABILITY AND REACTIVITY

### Reactivity

Stable at normal conditions.

### Chemical stability

Stable.

### Possibility of Hazardous Reactions

Hazardous polymerization does not occur.

### Conditions to avoid

Low and elevated temperatures. High humidity and light.

### Incompatible materials

None known based on information supplied. Strong oxidizing agents.

### Hazardous Decomposition Products

Carbon oxides. Silicon oxides. Nitrogen oxides. Sodium oxides.

**11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

<b>Product Information</b>	No data available
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Eye contact</b>	This product is not expected to be an eye hazard.
<b>Skin Contact</b>	This product is not expected to be a skin hazard.
<b>Ingestion</b>	Unknown.

**Acute Effects**

<b>Chemical Name</b>	<b>Oral LD50</b>	<b>Dermal LD50</b>	<b>Inhalation LC50</b>	<b>Intravenous LD50</b>
Diphenhydramine Hydrochloride USP 147-24-0	= 500 mg/kg ( Rat ) = 160 mg/kg (Mouse)	= 280 mg/kg (Rat)	-	= 42 mg/kg (Rat) = 29 mg/kg (Mouse)
Glycerin 56-81-5	= 12600 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 570 mg/m <sup>3</sup> ( Rat ) 1 h	-
Polyethylene Glycol 25322-68-3	= 28 g/kg ( Rat )	> 20 mL/kg ( Rabbit ) > 20 g/kg ( Rabbit )	-	

Acute intravenous lowest observed toxic dose (TDLo) was 5 mg/kg in rats and 1 mg/kg in mice.

**Information on toxicological effects**

<b>Symptoms</b>	Diphenhydramine is a potent anticholinergic agent. This activity is responsible for the side-effects of dry mouth and throat, increased heart rate, pupil dilation, urinary retention, constipation, and, at high doses, hallucinations or delirium.
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**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Sensitization</b>	Not available.
<b>Germ cell mutagenicity</b>	Not available.
<b>Carcinogenicity</b>	Not available.
<b>Reproductive toxicity</b>	Not available.
<b>STOT - single exposure</b>	Not classified.
<b>STOT - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Due to the physical form of the product it is not an aspiration hazard.

**Numerical measures of toxicity - Not available.****12. ECOLOGICAL INFORMATION****Ecotoxicity**

This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Mobility**

No information available.

**Other adverse effects**

No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Disposal of wastes** Dispose in accordance with applicable federal, state, and local regulations.

**Local disposal regulation** Dispose in accordance with local regulations.

**Hazardous waste code** Hazardous waste codes should be determined in accordance with hazardous waste regulatory authorities

**Waste from residue / unused packaging** Dispose in accordance with applicable regulations.

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. TRANSPORT INFORMATION

#### DOT

Not regulated as a hazardous material by DOT.

#### IATA

Not regulated as a dangerous good.

#### IMDG

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** This substance/mixture is not intended to be transported in bulk

### 15. REGULATORY INFORMATION

#### International Inventories

<b>TSCA</b>	Does not comply
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	Complies
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Complies

#### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

#### US Federal Regulations

#### US OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous listed.

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

#### SARA 311/312 Hazard Categories

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No

<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

**Drug Enforcement Administration (DEA) List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))**

Not regulated

**DEA Exempt Chemical Mixtures Code Number**

Not regulated

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPS) List**

Not regulated

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated

**CWA (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)

**Safe Drinking Water Act (SDWA)**

Not regulated

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**CA State Regulations**

This product does not contain a chemical known to the State of California to cause cancer, birth defects, or other reproductive harm

**California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Glycerin 56-81-5	X	X	X

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not available

**16. OTHER INFORMATION**

**Revision Date**

**Revision Note**

Not available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

**End of Safety Data Sheet**