



US - OSHA SAFETY DATA SHEET

10/16/14

11/24/14

Version 1

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

Product identifier

Product Name BENADRYL Allergy ULTRATAB Tablets

Other means of identification

Product Code MCHC-BDRALUT
C-1183

Synonyms Benadryl Ultratabs

Recommended use of the chemical and restrictions on use

Recommended Use Temporarily relieves these symptoms due to hay fever or other upper 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

Physical hazards

Not Classified.

Health 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 Pink or mottled pink film-coated tablet with embossed "B" on one side and debossed with "WL 25" on the opposite side.	Physical state Solid	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). 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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Benadryl Ultratabs.

Chemical Name	CAS No.	Weight-%
Diphenhydramine Hydrochloride USP	147-24-0	10-15
Microcrystalline Cellulose NF	9004-34-6	50-60

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 Vacuum and place into proper container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Observe good industrial hygiene practices. Minimize dust generation and accumulation.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep only in the original container. Store at 20 - 25 °C (68 - 77 °F). 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/m³ is recommended as an 8-hour TWA for Diphenhydramine Hydrochloride.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline Cellulose NF 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 5 mg/m ³ (vacated) STEL: 10 mg/m ³	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³

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

Solid

Appearance

Pink or mottled pink film-coated tablet with embossed "B" on one side and debossed with "WL 25" on the opposite side.

Odor

Not available.

Color	Pink	Odor threshold	Not available.
Property	Values	Remarks • Method	
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. Minimize dust generation and accumulation.

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

Product Information	No data available
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Eye contact	Product dust or powder may cause mechanical eye irritation.
Skin Contact	This product is not expected to be a skin hazard.

Ingestion Unknown.

Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
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)
Microcrystalline Cellulose NF 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h	

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

Information on toxicological effects

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.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization Not available.
Germ cell mutagenicity Not available.
Carcinogenicity Not available.
Reproductive toxicity Not available.
STOT - single exposure Not classified.
STOT - repeated exposure Not classified.
Aspiration hazard 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

<u>DOT</u>	Not regulated as a hazardous material by DOT.
<u>IATA</u>	Not regulated as a dangerous good.
<u>IMDG</u>	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

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	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

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	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
Microcrystalline Cellulose NF 9004-34-6	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