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-BDRAUT
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: 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.
MCHC-BDRALUT BENADRYL Allergy ULTRATAB Tablets

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

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride USP</td>
<td>147-24-0</td>
<td>10-15</td>
</tr>
<tr>
<td>Microcrystalline Cellulose NF</td>
<td>9004-34-6</td>
<td>50-60</td>
</tr>
</tbody>
</table>

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**
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**
Observe good industrial hygiene practices. Minimize dust generation and accumulation.

**Advice on safe handling**
None provided.

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

**Storage Conditions**

**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.
### 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**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline Cellulose NF</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust</td>
<td>TWA: 10 mg/m³ total dust</td>
</tr>
<tr>
<td>9004-34-6</td>
<td>TWA: 5 mg/m³ respirable fraction</td>
<td>(vacated) TWA: 15 mg/m³ total dust</td>
<td>TWA: 1 mg/m³ respirable dust</td>
</tr>
<tr>
<td></td>
<td>(vacated) TWA: 5 mg/m³ respirable fraction (vacated)</td>
<td>TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

- **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.
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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
<th>Intravenous LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride USP</td>
<td>= 500 mg/kg (Rat)</td>
<td>= 280 mg/kg (Rat)</td>
<td>-</td>
<td>= 42 mg/kg (Rat)</td>
</tr>
<tr>
<td>147-24-0</td>
<td>= 160 mg/kg (Mouse)</td>
<td></td>
<td></td>
<td>= 29 mg/kg (Mouse)</td>
</tr>
<tr>
<td>Microcrystalline Cellulose NF 9004-34-6</td>
<td>&gt; 5 g/kg (Rat)</td>
<td>&gt; 2 g/kg (Rabbit)</td>
<td>&gt; 5800 mg/m³ (Rat) 4 h</td>
<td></td>
</tr>
</tbody>
</table>

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

14. TRANSPORT INFORMATION

DOT
IATA
IMDG
Transport in bulk according to
Annex II of MARPOL 73/78 and the
IBC Code

Not regulated as a hazardous material by DOT.
Not regulated as a dangerous good.
Not regulated as a dangerous good.
This substance/mixture is not intended to be transported in bulk

15. REGULATORY INFORMATION

International Inventories

TSCA
DSL/NDSL
EINECS/ELINCS
ENCS
IECS
KECL
PICCS
AICS

Does not comply
Does not comply
Does not comply
Does not comply
Does not comply
Does not comply
Does not comply
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
IECS - 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

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
Chronic Health Hazard
Fire hazard
Sudden release of pressure hazard
Reactive Hazard
No
No
No
No
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline Cellulose NF</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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