

This safety data sheet was created pursuant to the requirements of:  
US OSHA Hazard Communication Standard 1910.1200, Canada WHMIS 2015

**Issue Date** 16-Mar-2022**Revision Date** 16-Mar-2022**Version** 1

## 1. IDENTIFICATION

### Product identifier

**Product Name** Benadryl Allergy Ultratabs / Benadryl Allergy Diphenhydramine HCL 25 mg Antihistamine Ultratabs

### Other means of identification

**Safety Data Sheet Code** MCNEIL-NA-C-1183-3

**Reference document No.** C-1183-3

**Synonyms** None

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

**Recommended Use** This SDS is only intended for occupational use and not for consumer use (see packaging label and or insert). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished product. For health and safety information during manufacturing of this product, please refer to the appropriate SDS for each component.

**Uses advised against** None if used in accordance with product label.

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

United States of America Johnson & Johnson Consumer Companies Inc.  
199 Grandview Road,  
Skillman, New Jersey 08558  
USA: 1-800-361-8068

Canada Johnson & Johnson Inc.  
88 McNabb Street, Markham, Ontario, Canada  
L3R 5L2  
Canada 1-877-223-9807

### Emergency telephone number

**24 Hour Emergency Phone Number:** Call 3E company at 1-877-236-9871. Provide Technician with the following tracking code: 2277, Hours Open: 24 hours emergency assistance.

**Restrictions on emergency number:** None

## 2. HAZARDS IDENTIFICATION

### Classification

**Regulatory information** This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200), Canada WHMIS 2015

#### Label elements

**Signal word:**  
None

**Hazard statements**  
None

**Precautionary Statements - Prevention**  
None

**Precautionary Statements - Response**

**Eyes:** None  
**Skin:** None  
**Inhalation:** None  
**Ingestion:** None  
**Fire:** None.  
**Spill:** None

**Precautionary Statements - Storage**  
None

**Precautionary Statements - Disposal**  
None

**Other hazards**  
None known

**Numerical measures of toxicity** The acute toxicity of all ingredients has been evaluated for all applicable exposure routes associated with the product's intended use.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Mixture

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Microcrystalline Cellulose	9004-34-6	30 - 60	-	-
Diphenhydramine Hydrochloride	147-24-0	7- 13	-	-
Titanium Dioxide	13463-67-7	0.1 - 1	-	-

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST AID MEASURES

#### Description of first aid measures

**Inhalation** It is unlikely that emergency treatment will be required. Move victim to fresh air. If symptoms persist, call a physician.

**Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.

<b>Skin contact</b>	If skin irritation or rash occurs: Get medical advice/attention.
<b>Ingestion</b>	It is unlikely that emergency treatment will be required. See clinical drug insert information for treatment of overdose. Call a POISON CENTER or doctor if you feel unwell.

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

<b>Symptoms</b>	Ingestion above therapeutic dose: May cause Drowsiness.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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## 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	None known.
<b>Explosion data</b>	
<b>Sensitivity to Mechanical Impact</b>	None.
<b>Sensitivity to Static Discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

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

<b>Personal precautions</b>	In the event of an accidental release, the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
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**Environmental precautions**

<b>Environmental precautions</b>	Avoid release to the environment.
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**Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so. Clean contaminated surface thoroughly.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

<b>Advice on safe handling</b>	No special precautions are needed in handling this material.
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**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Protect from light. Store in accordance with: product packaging.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	
Titanium Dioxide 13463-67-7	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust (vacated) TWA: 10 mg/m³ total dust	IDLH: 5000 mg/m³ TWA: 2.4 mg/m³ CIB 63 fine TWA: 0.3 mg/m³ CIB 63 ultrafine, including engineered nanoscale	
Chemical name	Alberta	British Columbia	Ontario	Quebec
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³	TWA: 10 mg/m³
Titanium Dioxide 13463-67-7	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³	TWA: 10 mg/m³

**Other Information**

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. NIOSH IDLH: National Institute for Occupational Safety and Health - Immediately Dangerous to Life or Health. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. STEL (Short Term Exposure Limit). TWA (Time-Weighted Average). Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering controls** All personal protective equipment should be based on a risk assessment. Consult an Environmental Health and Safety Expert if necessary.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** None under normal use conditions. Avoid contact with eyes.

**Hand protection** None under normal use conditions.

**Skin and body protection** None under normal use conditions.

**Respiratory protection** None under normal use conditions.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

Physical state	Solid
Appearance	tablet
Color	pink
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	
Melting point / freezing point	No data available	
Boiling point / boiling range	No data available	
Flash point	No data available	
Evaporation rate	No data available	
Flammability (solid, gas)	No data available	
Flammability Limit in Air		
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	
Vapor density	No data available	
Relative density	No data available	
Water solubility	No data available	
Solubility in other solvents	No data available	
Partition coefficient	No data available	
Autoignition temperature	No data available	
Decomposition temperature	No data available	
Kinematic viscosity	No data available	
Dynamic viscosity	No data available	
Explosive properties	No information available	
Oxidizing properties	No information available	
<b>Other Information</b>		
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

## 10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

**Product Information**

Inhalation	No information available.
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**Eye contact** No information available.

**Skin contact** No information available.

**Ingestion** Ingestion above therapeutic dose: May cause Drowsiness.

**Information on toxicological effects**

**Symptoms** Ingestion above therapeutic dose: May cause Drowsiness.

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

**Skin corrosion/irritation** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) and a potential carcinogen by OSHA by inhalation in powder form. This is not applicable to this product.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Titanium Dioxide 13463-67-7	-	Group 2B	-	X

**Legend**

**IARC (International Agency for Research on Cancer)**

Group 2B - Possibly Carcinogenic to Humans

**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**

X - Present

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity** No information available.

**Persistence and degradability** No information available.

**Bioaccumulation** No information available.

**Other adverse effects** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**

**Waste from residues/unused products**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**

Do not reuse empty containers. Disposal should be in accordance with applicable regional, national and local laws and regulations.

**14. TRANSPORT INFORMATION**

**Note:**

The information provided in section 14 is intended to provide the user with guidance only on the proper shipping requirements for the finished product in the final packaging - NOT BULK. Transport classifications may vary by container volume and may be influenced by regional or country variations in regulations. It is the responsibility of the Shipper to ensure this product is shipped in accordance with all applicable regulations. Consult your company's Hazardous/Dangerous Goods Expert for information specific to your situation.

**DOT**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class / Division	Not applicable
Packing Group	Not applicable
Environmental Hazards	Not applicable
Special Provisions	Not applicable

**TDG**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class / Division	Not applicable
Packing Group	Not applicable
Environmental Hazards	Not applicable
Special Provisions	Not applicable

**IMDG**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class / Division	Not applicable
Packing Group	Not applicable
Marine pollutant	Not applicable
Special Provisions	Not applicable

**ICAO, TI, IATA**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class / Division	Not applicable
Packing Group	Not applicable
Environmental hazards	Not applicable
Special Provisions	Not applicable

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

**15. REGULATORY INFORMATION**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

### US Federal Regulations

#### **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**

See Section 2 for any applicable physical or health hazard categories.

#### **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).

#### **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

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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose 9004-34-6	X	X	X
Titanium Dioxide 13463-67-7	X	X	X

## 16. OTHER INFORMATION

Issue Date 16-Mar-2022

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Revision Note Not applicable

#### **Disclaimer**

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End of Safety Data Sheet