



MATERIAL SAFETY DATA SHEET

Revision date: 15-Jun-2006

Version: 1.2

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

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Benadryl Allergy Kapseal Capsules

Trade Name: Benadryl®
Chemical Family: Mixture
Intended Use: antihistamine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Diphenhydramine hydrochloride	147-24-0	205-687-2	14
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
D&C red #28	18472-87-21	Not listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	*
FD & C Red No. 3 (E 127)	16423-68-0	240-474-8	*
FD&C Red No. 40	Not assigned	Not listed	*
Gelatin	9000-70-8	232-554-6	*
Glyceryl oleate	25496-72-4	247-038-6	*
Lactose NF, monohydrate	64044-51-5	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Capsules
Signal Word: CAUTION

Statement of Hazard: May cause eye irritation
May cause nervous system effects
May cause irritation based on components.
Eye Contact: Negligible skin irritant (based on components).
Skin Contact: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Inhalation: See 'Known clinical effects', below.
Ingestion:

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Known Clinical Effects: Diphenhydramine is a widely used over-the-counter medication. The most common adverse effects seen with the therapeutic use of diphenhydramine HCl include drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.

EU Indication of danger: Not classified

Additional Information: 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.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not determined

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal. Clean spill area thoroughly.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Protect from light. Protect from moisture.

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Storage Temperature: 59-77°F

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA
Australia TWA	= 2.5 mg/m ³ TWA containing no asbestos fibers

Titanium dioxide

OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA

Diphenhydramine hydrochloride

Pfizer OEL TWA-8 Hr: 0.15 mg/m³, (as free base)

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls:

Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands:	Wear protective gloves when working with large quantities.
Eyes:	Glasses or goggles are recommended if eye contact is possible.
Skin:	Wear protective clothing when working with large quantities.
Respiratory protection:	None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Capsule	Color:	No data available
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials:	None known
Hazardous Decomposition Products:	None known
Polymerization:	No data available

11. TOXICOLOGICAL INFORMATION

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General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

FD & C Red No. 3 (E 127)

Rat Oral LD50 1840 mg/kg
Mouse Oral LD50 1264 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Diphenhydramine hydrochloride

Rat Oral LD50 500 mg/kg
Mouse Oral LD50 114 mg/kg
Guinea Pig Oral LD50 284 mg/kg
Human Oral LDmin. 10.1 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Diphenhydramine hydrochloride

Eye Irritation Rabbit Non-irritating
Skin Sensitization - Beuhler Guinea Pig Negative
Skin Sensitization - LLNA Mouse Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Diphenhydramine hydrochloride

13 Week(s)	Rat	Oral	310 mg/kg/day	LOAEL	Liver
2 Year(s)	Rat	Oral	15 mg/kg/day	NOAEL	Liver
2 Year(s)	Mouse	Oral	21 mg/kg/day	NOAEL	Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Diphenhydramine hydrochloride

Embryo / Fetal Development	Rat	Oral	100 mg/kg/day	NOAEL	Not teratogenic, Maternal toxicity, Fetotoxicity
Embryo / Fetal Development	Mouse	Oral	80 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity, Fetotoxicity

Diphenhydramine hydrochloride

Bacterial Mutagenicity (Ames)	Salmonella	Negative
In Vitro Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive without activation Negative with activation
In Vitro Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Unscheduled DNA Synthesis	Rat Hepatocyte	Negative

Diphenhydramine hydrochloride

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2 Year(s) Rat Oral 15 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Mouse Oral 46 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

FD & C Blue No. 1

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

Talc (non-asbestiform)

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

CAUTION

May cause eye irritation

May cause nervous system effects

Canada - WHMIS: Classifications

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WHMIS hazard class:

None required

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.

FD & C Blue No. 1

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	223-339-8

FD & C Red No. 3 (E 127)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	240-474-8

Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

Glyceryl oleate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	247-038-6

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Lactose NF, monohydrate

Australia (AICS):	Present
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Diphenhydramine hydrochloride

Australia (AICS):	Present
EU EINECS List	205-687-2

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet