



MATERIAL SAFETY DATA SHEET

Revision date: 15-Jun-2006

Version: 2.2

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

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Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

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

Material Name: Benadryl® Itch Stopping Spray, Original Strength and Extra Strength

Trade Name: Benadryl®
Chemical Family: Not determined
Intended Use: anti-itch treatment (antipruritus)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	*
Diphenhydramine hydrochloride	147-24-0	205-687-2	2
Zinc acetate dihydrate	5970-45-6	Not listed	0.1
Glycerin, USP	56-81-5	200-289-5	*

Ingredient	CAS Number	EU EINECS List	%
Tromethamine	77-86-1	201-064-4	*
Povidone	9003-39-8	Not listed	*
Water, purified	7732-18-5	231-791-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, pale, yellow liquid with an alcohol odor
Signal Word: DANGER

Statement of Hazard: Flammable liquid. May cause eye and respiratory tract irritation. May cause liver, cardiovascular and central nervous system effects.

Eye Contact: May cause eye irritation.
Skin Contact: Not a skin irritant
Inhalation: Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: Ingestion of large quantities may cause headache, dizziness, nausea, vomiting, diarrhea, dehydration, and symptoms of alcohol intoxication. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

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Known Clinical Effects: Diphenhydramine is a widely used over-the-counter medication. Ingestion of this material may cause effects similar to those seen in clinical use including drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

Potential Health Effects: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

EU Indication of danger: Flammable
Irritant

EU Hazard Symbols:

Xi



EU Risk Phrases:

R10 - Flammable.
R36 - Irritating to eyes.

**Additional Information:
Note:**

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If discomfort persists, get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Carbon dioxide, dry chemical, or foam. Do not use water.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turnout gear.

Fire / Explosion Hazards: Flammable liquid.

6. ACCIDENTAL RELEASE MEASURES

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Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Use non-combustible absorbent material to wipe up spill and place in a sealed 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. Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled container and move it to a secure holding area.
Additional Information:	Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling:	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing.
Storage Conditions:	Store in a cool, dry, well-ventilated area. Keep away from heat, sparks, flame, and other sources of ignition. Keep container tightly closed when not in use.
Storage Temperature:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ethyl alcohol (ethanol)

OSHA - Final PELs - TWAs:	= 1000 ppm TWA = 1900 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m ³ TWA

Diphenhydramine hydrochloride

Pfizer OEL TWA-8 Hr:	0.15 mg/m ³ , (as free base)
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Glycerin, USP

OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA

Engineering Controls: Keep airborne contamination levels below the exposure limits listed above in this section. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands:	Wear protective gloves when working with large quantities.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	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.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid	Color:	Pale yellow
Odor:	Alcohol like	Molecular Formula:	Mixture
Molecular Weight:	Mixture		
Solvent Solubility:	Soluble: Alcohol		
Solubility:	Soluble: Water		
pH:	7.0 - 7.5		
Boiling Point (°C):	78 based on major component: Ethanol		
Vapor Pressure (kPa):	5.90 (20 °C) based on major component (Ethanol)		
Specific Gravity:	0.88 (approximately)		
Autoignition Temperature (Solid) (°C):	425 based on major component (Ethanol)		
Flash Point (Liquid) (°C):	<21 based on major component (Ethanol)		

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge).
Incompatible Materials:	None known
Hazardous Decomposition Products:	None known
Polymerization:	Will not occur

11. TOXICOLOGICAL INFORMATION

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

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

Tromethamine

Rat Oral LD50 5900 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Glycerin, USP

Mouse Oral LD50 4090 mg/kg

Rat Oral LD50 12.6 g/kg

Rabbit Dermal LD50 > 10 g/kg

Rat Inhalation LC50 1hr > 570 mg/m³

Rat Dermal LD 50 >21.9 g/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

Zinc acetate dihydrate

Rat Oral LD50 794 mg/kg

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Mouse Oral LD50 287 mg/kg

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg

Rat Oral LD50 7060 mg/kg

Rat Inhalation LC50 10h 20,000 ppm

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)

Glycerin, USP

Eye Irritation Rabbit Mild

Diphenhydramine hydrochloride

Eye Irritation Rabbit Non-irritating

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe

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

Diphenhydramine hydrochloride

13 Week(s) Rat Oral 310 mg/kg/day LOEL 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

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. See below

Povidone

IARC: Group 3

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12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC-50 96 Hours 50 mg/L

Daphnia Magna (Water Flea) EC-50 24 Hours >500 mg/L

Ethyl alcohol (ethanol)

Rainbow Trout LC50/96h 12,900-15,300 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Waste materials may be classified as hazardous due to the low flash point. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good.

Proper shipping name: Ethanol solution
UN / ID No: UN 1170
Hazard class: 3
Packing group: II

If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a consumer commodity and exempted from additional requirements as applicable. For small quantities packed in combination packaging [limited to inner packaging < 1.0L (0.3 gal) and outer packaging < 30 kg (66 lb.) gross weight], the following will apply:

IATA Proper shipping name: Consumer Commodity
IATA UN / ID No: ID 8000
IATA Hazard Class: 9

IMDG Technical Shipping Name: Ethanol solution Limited Quantity
IMDG UN / ID No: UN 1170
IMDG Hazard Class: 3
IMDG Packing Group: II

DOT Technical Shipping Name: Consumer Commodity
DOT UN / ID No: UN 1170
DOT Hazard Class: ORM-D

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Flammable
Irritant

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EU Risk Phrases:

R10 - Flammable.
R36 - Irritating to eyes.

EU Safety Phrases:

S2 - Keep out of reach of children.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36 - Wear suitable protective clothing.

OSHA Label:

DANGER

Flammable liquid. May cause eye and respiratory tract irritation. May cause liver, cardiovascular and central nervous system effects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A



Tromethamine

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-064-4

Ethyl alcohol (ethanol)

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-578-6

Diphenhydramine hydrochloride

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

Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Zinc acetate dihydrate

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ no reporting of releases of this hazardous substance is required if the diameter of the pieces of the solid metal released is equal to or exceeds 0.004 inches
	= 454 kg final RQ no reporting of releases of this hazardous substance is required if the diameter of the solid metal released is equal to or exceeds 0.004 inches
Australia (AICS):	Present

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Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet