



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Oct-2006

Version: 1.2

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

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

**Material Name: Caladryl® Lotion**

**Trade Name:** CALADRYL  
**Chemical Family:** Not determined  
**Intended Use:** topical analgesic, skin protectant.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Calamine(zinc oxide, ferric oxide)	8011-96-9	Not listed	8
SD Alcohol 38B	64-17-5	200-578-6	*
Pramoxine hydrochloride	637-58-1	211-293-1	1
Camphor	76-22-2	200-945-0	*
Diazolidinyl urea	78491-02-8	278-928-2	*
Fragrance	NOT ASSIGNED	Not listed	*

Ingredient	CAS Number	EU EINECS List	%
Polysorbate 80	9005-65-6	Not listed	*
Xanthan gum	11138-66-2	234-394-2	*
Hypromellose	9004-65-3	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Propylene glycol	57-55-6	200-338-0	*
Propylparaben	94-13-3	202-307-7	*
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:** Opaque, pink lotion with a characteristic odor

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**

**Short Term:** Topical anesthetic drug: may cause localized numbness. May cause skin irritation. May cause eye irritation (based on components) . An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). Ingestion should be avoided.

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**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:** 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:** As for primary cause of fire.

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

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 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:** 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:** Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Close 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:** Use adequate ventilation. Avoid contact with eyes. Wash thoroughly after handling.

**Storage Conditions:** Store in a cool, dry, well-ventilated area.

**Storage Temperature:** 15-25°C (59-77°F)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### SD Alcohol 38B

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

#### Camphor

OSHA - Final PELs - TWAs:	= 2 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (TWA)	= 2 ppm TWA
ACGIH Threshold Limit Value (STEL)	= 3 ppm STEL
Australia STEL	= 19 mg/m <sup>3</sup> STEL = 3 ppm STEL
Australia TWA	= 12 mg/m <sup>3</sup> TWA = 2 ppm TWA

#### Propylene glycol

Australia TWA	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 474 mg/m <sup>3</sup> TWA
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#### Engineering Controls:

Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

#### Personal Protective Equipment:

<b>Hands:</b>	Wear protective gloves when working with large quantities.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	Not required for the normal use of this product. 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:

<b>Physical State:</b>	Lotion	<b>Color:</b>	Pink
<b>Odor:</b>	Characteristic odor	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		
<b>Solubility:</b>	Insoluble: Water		
<b>pH:</b>	6.0-7.2		
<b>Specific Gravity:</b>	1.045-1.075		

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Conditions to Avoid:</b>	High temperatures
<b>Incompatible Materials:</b>	No data available

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**Hazardous Decomposition Products:** No data available

**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this product. The information included in this section describes the potential hazards of the individual ingredients.

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

##### **Methylparaben**

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 mg/kg

##### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg

Mouse Intraperitoneal LD 50 200 mg/kg

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Hypromellose**

Rat Oral LD50 > 10,000 mg/kg

##### **Xanthan gum**

Rat Oral LD50 > 5000 mg/kg

##### **Propylene glycol**

Mouse Oral LD50 22,000 mg/kg

Rat Oral LD50 20,000 mg/kg

Rabbit Dermal LD50 20,800 mg/kg

##### **Diazolidinyl urea**

Rat Oral LD50 2570 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

Rat Inhalation LC50 4.5h (50% aq. solution) 1.3 mg/kg

##### **Camphor**

Mouse Oral LD50 1310 mg/kg

##### **Pramoxine hydrochloride**

Mouse Oral LD50 1050 mg/kg

Mouse IV LD50 79.5 mg/kg

Rabbit IV LD50 39 mg/kg

##### **Calamine(zinc oxide, ferric oxide)**

Mouse Oral LD50 (ZnO) 7950 mg/kg

Mouse Inhalation LD50 (ZnO) 2500 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)**

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### Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

### Calamine(zinc oxide, ferric oxide)

Skin Irritation Rabbit Mild (ZnO)

Eye Irritation Rabbit Mild (ZnO)

### Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe

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

#### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

## 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)

#### Diazolidinyl urea

Rainbow Trout LC50 96 Hours > 100 mg/L

Daphnia magna LC50 48 Hours 34.9 mg/L

#### Ethyl alcohol (ethanol)

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

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

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

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## 15. REGULATORY INFORMATION

EU Symbol: None required  
EU Indication of danger: Not classified

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

#### 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.

#### Calamine(zinc oxide, ferric oxide)

Australia (AICS): Present

#### SD Alcohol 38B

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

#### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b) XU

Australia (AICS): Present

#### Xanthan gum

Inventory - United States TSCA - Sect. 8(b) XU

Australia (AICS): Present

EU EINECS List 234-394-2

#### Pramoxine hydrochloride

EU EINECS List 211-293-1

#### Camphor

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 200-945-0

#### Diazolidinyl urea

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 278-928-2

#### Hypromellose

Inventory - United States TSCA - Sect. 8(b) XU

Australia (AICS): Present

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### Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

### Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

### Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

### Water, purified

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

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients.

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

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**End of Safety Data Sheet**