



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 7

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

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CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Hydrocortisone Cypionate Oral Suspension, USP**

**Trade Name:** Cortef (R) Oral Suspension  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as anti-inflammatory.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydrocortisone Cypionate	508-99-6	208-091-0	<1
Glycerin, USP	56-81-5	200-289-5	*
Sucrose	57-50-1	200-334-9	*
Citric acid	77-92-9	201-069-1	*

Ingredient	CAS Number	EU EINECS List	%
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Xanthan gum	11138-66-2	234-394-2	*
Flavors	NOT ASSIGNED	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Propylparaben	94-13-3	202-307-7	*
Water	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:** Yellow Liquid

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

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, weakness muscle cramps, nervousness, restlessness, trouble sleeping. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Clinical use may cause an increase in blood pressure (hypertension). Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

**EU Indication of danger:** Not classified

## MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Revision date: 15-Dec-2006

Page 2 of 7

Version: 1.1

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get 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:** Carbon dioxide, carbon monoxide

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

**Fire / Explosion Hazards:** Not applicable

### 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:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

**Storage Conditions:** Store in a cool, dry place away from light. Keep out of reach of children.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glycerin, USP

## MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Page 3 of 7

Revision date: 15-Dec-2006

Version: 1.1

---

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

### Sucrose

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

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

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** 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>	Liquid	<b>Color:</b>	Yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 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)

#### 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/m <sup>3</sup>
Rat	Dermal	LD 50	>21.9 g/kg

## MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Page 4 of 7

Revision date: 15-Dec-2006

Version: 1.1

---

### Sucrose

Rat Oral LD50 29.7 g/kg

### Hydrocortisone

Rat Oral LD 50 5000 mg/kg

Mouse Oral LD 50 5000 mg/kg

Rat Subcutaneous LD 50 449 mg/kg

Rat Intraperitoneal LD 50 150 mg/kg

### Benzoic acid

Rat Oral LD 50 1700 mg/kg

Mouse Oral LD 50 1940 mg/kg

Rabbit Dermal LD50 > 5000 mg/kg

Rat Inhalation LC50 > 0.026 mg/L

### Citric acid

Rat Oral LD50 3000 mg/kg

### FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg

Mouse Oral LD50 > 6,000 mg/kg

### 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

### Xanthan gum

Rat Oral LD50 > 5000 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)

#### Glycerin, USP

Eye Irritation Rabbit Mild

#### Hydrocortisone

Eye Irritation Rabbit Minimal

#### Benzoic acid

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - Beuhler Guinea Pig Negative

Eye Irritation Rabbit Severe

#### Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

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

#### Hydrocortisone

## MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Page 5 of 7

Revision date: 15-Dec-2006

Version: 1.1

---

7 Day(s)	Mouse	Oral	140 mg/kg/day	LOAEL	Thymus
4 Day(s)	Mouse	Subcutaneous	100 mg/kg/day	LOAEL	Liver
2 Week(s)	Mouse	Subcutaneous	560 mg/kg/day	LOAEL	Liver, Bone Marrow
85 Day(s)	Rat	Subcutaneous	175 mg/kg/day	LOAEL	Adrenal gland

### Benzoic acid

250 Day(s)	Dog	Oral	1000 mg/kg/day	NOAEL	None identified
18 Month(s)	Mouse	Oral	80 mg/kg/day	NOAEL	None identified
18 Month(s)	Rat	Oral	80 mg/kg/day	NOAEL	

### 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

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Hydrocortisone

Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	LOAEL	Teratogenic
Reproductive & Fertility	Rat	Oral	210 mg/kg/day	LOAEL	Maternal Toxicity

#### Benzoic acid

Reproductive & Fertility	Rat	Oral	5 mg/kg/day	NOEL	Fertility, Not teratogenic
Fertility and Embryonic Development	Rat	Oral	500 mg/kg/day	NOAEL	No effects at maximum dose

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Hydrocortisone

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Unscheduled DNA Synthesis	Rat	Negative

#### Benzoic acid

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Sister Chromatid Exchange	Human Lymphocytes	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

#### FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3

## 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.

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

#### Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC-50	96 Hours	50 mg/L
<i>Daphnia Magna</i> (Water Flea)	EC-50	24 Hours	>500 mg/L

# MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Page 6 of 7

Revision date: 15-Dec-2006

Version: 1.1

## Benzoic acid

*Daphnia Magna* EC-50 24 Hours 500 mg/L

Fish LC50 96 Hours 180 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

## 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.

## 15. REGULATORY INFORMATION

**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.

#### Hydrocortisone Cypionate

EU EINECS List	208-091-0
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#### Glycerin, USP

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

#### Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

FD&C Yellow No. 6; (Sunset yellow)

# MATERIAL SAFETY DATA SHEET

Material Name: Hydrocortisone Cypionate Oral Suspension,  
USP

Page 7 of 7

Revision date: 15-Dec-2006

Version: 1.1

---

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	220-491-7
<b>Xanthan gum</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	234-394-2
<b>Citric acid</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	201-069-1
<b>Methylparaben</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	202-785-7
<b>Propylparaben</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	202-307-7
<b>Water</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	231-791-2

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations.

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

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**End of Safety Data Sheet**