



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Nov-2009

Version: 1.3

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

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### Material Name: Hydrocortisone Sodium Succinate for Injection

Trade Name:	Solu-Cortef®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as anti-inflammatory

## 2. HAZARDS IDENTIFICATION

Appearance: White to off-white powder  
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.

### Additional Hazard Information:

**Short Term:** May cause slight irritation ; May cause skin irritation. (based on components) . May be absorbed through the skin in harmful amounts. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. May cause stomach irritation, diarrhea, nausea, or vomiting.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus. However, occupational handling of this product is not expected to result in relevant exposures.

**Known Clinical Effects:** Effects on vision have been seen during clinical use. 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. Clinical use may cause an increase in blood pressure (hypertension). Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

**EU Indication of danger:** Toxic to Reproduction: Category 3

### EU Hazard Symbols:

Xn



### EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hydrocortisone Sodium Succinate	125-04-2	204-725-5	Repr.Cat.3;R63	91.3

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*

**Additional Information:** \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

## 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.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrocortisone Sodium Succinate  
Pfizer OEL TWA-8 Hr:

100µg/m<sup>3</sup>, Skin

<b>Analytical Method:</b>	Analytical method available for hydrocortisone. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Powder	<b>Color:</b>	White to off-white
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water		

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under recommended storage conditions. Solutions are unstable after 4 hours.
<b>Conditions to Avoid:</b>	Exposure to light
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
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### Acute Toxicity: (Species, Route, End Point, Dose)

#### **Hydrocortisone Sodium Succinate**

Rat	Oral	LD 50	5000 mg/kg
Mouse	Oral	LD 50	5000 mg/kg
Rat	Subcutaneous	LD 50	449 mg/kg
Mouse	Subcutaneous	LD 50	>500 mg/kg
Rat	Intraperitoneal	LD 50	150 mg/kg

#### **Sodium phosphate, dibasic**

Rat	Oral	LD 50	17 g/kg
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#### **Sodium phosphate, monobasic**

Rat	Oral	LD 50	8290 mg/kg
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#### **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)

#### **Hydrocortisone Sodium Succinate**

Eye Irritation	Rabbit	Minimal
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#### **Sodium phosphate, dibasic**

Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

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

#### **Hydrocortisone Sodium Succinate**

7 Day(s)	Mouse	Oral	140 mg/kg/day	LOAEL	Thymus
4 Day(s)	Mouse	Subcutaneous	100 mg/kg/day	LOAEL	Liver

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### 11. TOXICOLOGICAL INFORMATION

11 Day(s)	Mouse	Subcutaneous	62 mg/kg/day	LOAEL	Endocrine system
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

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

##### Hydrocortisone Sodium Succinate

Reproductive & Fertility-Females	Rat	Oral	210 mg/kg/day	LOAEL	Maternal toxicity
Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	LOAEL	Developmental toxicity

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

##### Hydrocortisone Sodium Succinate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo In Vitro</i> Direct DNA Damage	Rat , Mouse	Positive
<i>In Vivo In Vitro</i> Chromosome Aberration	Rat , Mouse	Positive
Cytogenetics	Mouse	Negative

#### Carcinogen Status:

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

**EU Symbol:** Xn  
**EU Indication of danger:** Toxic to Reproduction: Category 3

**EU Risk Phrases:** R63 - Possible risk of harm to the unborn child.

#### EU Safety Phrases:

100 MG PLAIN

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## 15. REGULATORY INFORMATION

S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

### OSHA Label:

WARNING

Suspected of damaging the unborn child.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Hydrocortisone Sodium Succinate

Australia (AICS):	Listed
EU EINECS/ELINCS List	204-725-5

### Sodium phosphate, monobasic

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-449-2

### Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-448-7

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R63 - Possible risk of harm to the unborn child.

#### Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

#### Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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**Prepared by:**

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

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**End of Safety Data Sheet**