



# MATERIAL SAFETY DATA SHEET

Revision date: 10-Sep-2007

Version: 1.1

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

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

### Material Name: Betamethasone Benzoate Tablets

<b>Trade Name:</b>	Betacortril; Betacortril Forte
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product used as anti-inflammatory, immunosuppressive agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** White tablets  
**Signal Word:** WARNING

**Statement of Hazard:** Suspected of damaging the unborn child.  
May cause damage to adrenal gland through prolonged or repeated exposure.

### Additional Hazard Information:

**Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use.  
**Known Clinical Effects:** 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. Additionally, state of intense good feeling (euphoria), depression, adrenal suppression, gastrointestinal disturbances, lymphoid depletion, cataracts, increased intra-ocular pressure (glaucoma) may occur.

**EU Indication of danger:** Toxic to Reproduction: Category 2

### EU Hazard Symbols:



### EU Risk Phrases:

R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

**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.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Betamethasone Benzoate	22298-29-9	244-897-9	Repr.Cat2;R61	0.5 or 1.0 mg***
Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose	63-42-3	200-559-2	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*

### Additional Information:

\* Proprietary

\*\*\* per tablet/capsule/lozenge/suppository

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 eye(s) immediately with plenty of water. 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.

### 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:

Not determined

### 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.

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**Measures for Cleaning / Collecting:** 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.

**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:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

**Betamethasone Benzoate**  
Pfizer OEL TWA-8 Hr:

1 µg/m<sup>3</sup>, Skin (as free base)

**Starch**

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA
Australia TWA	= 10 mg/m <sup>3</sup> TWA
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Bulgaria OEL - TWA	= 10.0 mg/m <sup>3</sup> TWA
Czech Republic OEL - TWA	= 4.0 mg/m <sup>3</sup> TWA
Greece OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 5 mg/m <sup>3</sup> TWA
	= 10 mg/m <sup>3</sup> TWA
	= 4 mg/m <sup>3</sup> TWA
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA total
	= 5 mg/m <sup>3</sup> TWA
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED

**Magnesium Stearate**

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m <sup>3</sup> IPRV	
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

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

**Analytical Method:** Analytical method available for Betamethasone Benzoate. Contact Pfizer Inc for further information.

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**Engineering Controls:** 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.

**Personal Protective Equipment:**

**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable

**Conditions to Avoid:** Not determined

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

**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

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

**Betamethasone**

Mouse Oral LD 50 > 4500 mg/kg

**Starch**

Mouse IP LD50 6600 mg/kg

**Lactose**

Rat Oral LD50 > 10 g/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.

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

**Magnesium Stearate**

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

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

#### **Betamethasone**

Embryo / Fetal Development	Monkey	Intramuscular	600 ug/kg/day	LOAEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.2 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	0.15 mg/kg/day	LOAEL	Negative
Embryo / Fetal Development	Mouse	Subcutaneous	4.3 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	0.26 mg/kg/day	LOAEL	Teratogenic

#### **Betamethasone Benzoate**

Fertility and Embryonic Development	Rat	Subcutaneous	80 ug/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	1 mg/kg/day	LOAEL	Fetotoxicity
Fertility and Embryonic Development	Rat	Subcutaneous	10 mg/kg/day	LOAEL	Fetotoxicity
Fertility and Embryonic Development	Rabbit	Dermal	7500 ug/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Dermal	1500 ug/kg/day	LOAEL	Fetotoxicity

**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 have not been 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.

### **14. TRANSPORT INFORMATION**

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

### **15. REGULATORY INFORMATION**

**EU Symbol:** T  
**EU Indication of danger:** Toxic to Reproduction: Category 2

**EU Risk Phrases:**  
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**

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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.

May cause damage to adrenal gland through prolonged or repeated exposure.

## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Betamethasone Benzoate

EU EINECS/ELINCS List 244-897-9

### Lactose

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS/ELINCS List 200-559-2

### Starch

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present  
REACH - Annex IV - Exemptions from the obligations of Register: Present  
EU EINECS/ELINCS List 232-679-6

### Gelatin

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

### Magnesium Stearate

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

## 16. OTHER INFORMATION

### Full text of S3 R phrases

R61 - May cause harm to the unborn child.

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**Reasons for Revision:** Updated Section 2 - Hazard Identification. 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 15 - Regulatory Information.

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**