

Enbrel

Preparation Date 26-Jul-2007

Revision Date 09-Sep-2008

Revision Number 3

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

**Product Name** Enbrel  
**Common Name** Not available  
**Chemical Name** Not applicable  
**Synonyms** Etanercept  
**Product Use** Pharmaceutical product  
**Classification** Disease Modifying Antiarthritic Drug

**Supplier** Wyeth  
 P.O. Box 8299  
 Philadelphia, PA 19101 USA.  
 Telephone: 1-610-688-4400

**Emergency Telephone Number** Chemtrec USA, Puerto Rico, Canada 1-800-424-9300  
 Chemtrec International 1-703-527-3887

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Etanercept	185243-69-0	None assigned	25 mg/vial	R36, S13/36/37/39

### 3. HAZARDS IDENTIFICATION

#### Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

**Appearance** Pharmaceutical powder      **Physical State** Solid      **Odor** Not available

**Potential Physical Hazards** Powders and solids are presumed to be combustible.

#### Potential Health Effects

**Eyes** May cause mechanical eye irritation.  
**Skin** Not applicable  
**Inhalation** See Ingestion and/or Other  
**Ingestion** Not applicable  
**Other** The most common effects may include immune system suppression which can cause an increase in infections and lymphoma, antibody formation, allergic reactions, rash, itching, blood disorders, heart disorders, nervous system effects, headache, nausea, rhinitis, dizziness, pharyngitis, cough, abdominal pain, peripheral edema, dyspepsia, sinusitis, vomiting, mouth ulceration, sepsis, Lupus-like syndrome, and loss of hair.

Please see Patient Package Insert for further information.

**Therapeutic Target Organ(s)** Immune system.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects**

There is no known ecological information for this product.

**4. FIRST AID MEASURES****Eye Contact**

In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

**Skin Contact**

Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**Inhalation**

Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

**Ingestion**

If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**5. FIRE-FIGHTING MEASURES****Flammable Properties**

Not flammable

**Extinguishing Media****Suitable Extinguishing Media  
Unsuitable Extinguishing  
Media**

Use water spray, foam, dry chemical or carbon dioxide.  
Do NOT use water jet.

**Fire Fighting**

Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

**Hazardous Combustion Products**

Carbon oxides, nitrogen oxides.

**Protective Equipment and  
Precautions for Firefighters**

In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

**6. ACCIDENTAL RELEASE MEASURES****Personal Precautions**

Refer to protective measures listed in Sections 7 and 8.

**Environmental Precautions**

Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

**Methods for Containment**

Not available

**Methods for Cleaning up**

Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

**7. HANDLING AND STORAGE****Handling**

For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

**Storage**

No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Common Name</b> Etanercept	<b>Exposure Guideline</b> 350 mcg/m <sup>3</sup>
<b>Engineering Controls</b>	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Provide eye protection based on risk assessment.
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pharmaceutical powder	<b>Physical State</b>	Solid
<b>Color</b>	White	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not available		
<b>Specific Gravity</b>	Not applicable	<b>Water Solubility</b>	Not available
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Pressure</b>	Not applicable
<b>Boiling Point</b>	Not available	<b>Autoignition Temperature</b>	Not available
<b>Flash Point</b>	Not available	<b>Melting Point</b>	Not available
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Explosion Limits</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	No data available
<b>Materials to Avoid</b>	No materials to be especially mentioned.
<b>Hazardous Decomposition Products</b>	None under normal use.
<b>Possibility of Hazardous Reactions</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

**Acute Toxicity****Etanercept**

<b>LD50 Oral</b>	Not applicable
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable

**Multiple Dose Toxicity****Etanercept**

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	Not applicable
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**Maximum Tolerated Dose (MTD), Oral****Etanercept**

<b>Carcinogenicity</b>	Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
<b>Genetic Toxicity</b>	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
<b>Reproductive Toxicity</b>	Animal studies to evaluate effects on fertility have not been conducted.
<b>Developmental Toxicity</b>	Developmental toxicity studies in rats and rabbits have revealed no evidence of harm to fetus.

**Etanercept**

<b>Target Organ(s) of Toxicity</b>	No data available
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**12. ECOLOGICAL INFORMATION**

The following effects are based on the Active Pharmaceutical Ingredient.

**Chemical Fate Information**

This product is protein based and will rapidly degrade in the environment.

**Ecotoxicity**

Not available

**13. DISPOSAL CONSIDERATIONS****Waste Disposal Method**

Dispose of in accordance with local and national regulations.

**14. TRANSPORT INFORMATION****Transport Information**

This material is not classified as hazardous for transport.

**U.S. Department of Transport (DOT)**

Enbrel in bulk drug substance is transported in dry ice and this is classified as hazardous for transport by sea and air, it is non hazardous by road: UN Number: 1845. Proper Shipping Name: Carbon dioxide, solid. Class or Division: 9. Packing Group: III.

**15. REGULATORY INFORMATION**

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

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**16. OTHER INFORMATION**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with Directive 2001/58/EC.
<b>List of References</b>	See Patient Package Insert for more information.
<b>Revision Summary</b>	Addition to Section 12.

## Disclaimer:

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**End of MSDS**