

Enbrel Prefilled Syringe

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 Prefilled Syringe
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	50 mg/ml	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 Biopharmaceutical liquid **Physical State** Liquid **Odor** Not available

Potential Physical Hazards None known

Potential Health Effects

Eyes May cause eye irritation.
Skin None known
Inhalation See Ingestion and/or Other
Ingestion Not available
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

Common Name Etanercept	Exposure Guideline 350 mcg/m ³
Engineering Controls	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.
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	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

Appearance	Biopharmaceutical liquid	Physical State	Liquid
Color	Clear colorless	Odor	Not available
Odor Threshold	Not available		
pH	6.3		
Specific Gravity	Not available	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not available
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not available	Melting Point	Not available
Flammability Limits in Air	Upper Not available	Lower Not available	
Explosion Limits	Upper Not available	Lower Not available	

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity**Etanercept**

LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity**Etanercept**

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

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

Etanercept

Target Organ(s) of Toxicity	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.

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

16. OTHER INFORMATION

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

Disclaimer:

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End of MSDS