

Herceptin Intravenous

Preparation Date 28-Mar-2008

Revision Date 28-Mar-2008

Revision Number 1

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

Product Name Herceptin Intravenous
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
Product Use Pharmaceutical product
Classification Antineoplastic Agent

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
Trastuzumab	180288-69-1	None assigned	440 mg/vial	None assigned

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 available

Inhalation

Not available

Ingestion

The most common effects may include fast or irregular heartbeat, cough increase, shortness of breath, swelling of feet or lower legs, unusual weakness, mild diarrhea, nausea, pain, vomiting, allergic reactions, angioedema, urticaria, Adult Respiratory Distress Syndrome (ARDS), bronchospasm, anemia, difficult or labored breathing, tightness of chest, hypotension, fever or chills, hoarseness, lower back pain, chest pain, difficult, fast, noisy breathing, pulmonary infiltrates, trouble in sleeping, loss of appetite, numbness or tingling of hands or feet, runny nose, and skin rash.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Systemic.

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 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 Trastuzumab	Exposure Guideline 100 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	Pharmaceutical powder	Physical State	Solid
Color	White to pale yellow	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not available	Melting Point	Not available
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

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**Trastuzumab**

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

Multiple Dose Toxicity**Trastuzumab**

No Toxicologic Effect Dose/Species/Study Length:	See Developmental Toxicity
---	----------------------------

Maximum Tolerated Dose (MTD), Oral**Trastuzumab**

Carcinogenicity	No carcinogenicity studies have been performed.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.
Reproductive Toxicity	See Developmental Toxicity.
Developmental Toxicity	Reproduction studies in monkeys at doses up to 25 times the weekly human maintenance dose found no effect on fertility, and no harm to the fetus.

Trastuzumab

Target Organ(s) of Toxicity	No data available
-----------------------------	-------------------

12. ECOLOGICAL INFORMATION

Chemical Fate Information	Not available
----------------------------------	---------------

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

Prepared By Format	Wyeth Department of Environment, Health & Safety This MSDS was prepared in accordance with Directive 2001/58/EC.
-------------------------------	---

16. OTHER INFORMATION**List of References**
Revision SummaryProduct Profiles
Changes to Section 8

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS