


ImClone Systems
*a wholly-owned subsidiary
of Eli Lilly and Company*
Material Safety Data Sheet

Section 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Information / Product Identification

Product Name: Erbitux® GCTS Formulation

Synonyms: C225; BMS 564717; Cetuximab; Anti-EGFr Chimeric Monoclonal Antibody in European Formulation

Product Uses: Drug used for the treatment of cancer

1.2 Company Information

Company Name / Address: ImClone Systems, A wholly-owned subsidiary of Eli Lilly and Company
33 ImClone Drive
Branchburg, NJ 08876
(908) 541-8140

Emergency Phone: (908) 218-9588

Section 2. COMPOSITION / INFORMATION ON INGREDIENTS

Name of Ingredients:	Conc.	CAS No.	EU Symbol	R Phase
1) Erbitux®	> 1%	205923-56-4	Not classified	Not classified
Sodium citrate	<1%	68-04-2	Not classified	Not classified
2) Sodium chloride	<1%	7647-14-5	Not classified	Not classified
3) Glycine	<1%	56-40-6	Not classified	Not classified
4) Mannitol	<1%	69-65-8	Not classified	Not classified
5) Tween 20	<1%	9005-64-5	Not classified	Not classified

Note: See section 8 for exposure limits, section 15 for regulatory information.

Section 3. HAZARDS IDENTIFICATION

3.1 Emergency Overview:

WARNING: CAUTION - SUBSTANCE NOT FULLY TESTED.

Acne-like rash was observed in the majority of clinical patients treated with Erbitux® by intravenous administration. Severe hypersensitivity reactions have been observed in <3% of clinical patients treated with Erbitux™ by intravenous administration. There is little or no data concerning the toxicity of the material under occupational exposures. Avoid inhalation, ingestion, skin and eye contact. Wash thoroughly after handling. Handle with appropriate care to minimize exposure.

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3.2 Major Health Hazards
Refer to Section 11

Section 4. FIRST AID MEASURES

Eye Contact:	Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used. Seek medical attention.
Skin Contact:	Wash with a non-abrasive soap and water. Get medical attention if irritation (redness, itching or swelling) develops or persists.
Inhalation:	Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. Oxygen may be administered if breathing is difficult. Seek medical attention.
Ingestion:	If ingested, seek medical advice immediately and show the container or the label. Induction of vomiting should be considered for significant ingestions if person is conscious and not experiencing convulsions. Never give anything by mouth to an unconscious person.
Notes to Physician:	This material is a drug used in the treatment of cancer. It has not been fully characterized. There are few or no data concerning the toxicity of the material under occupational exposures. It has been shown to cause acne-like rashes and hypersensitivity or acute allergic reactions by intravenous administration in clinical studies.
Medical Conditions aggravated:	None known

Section 5. FIRE FIGHTING MEASURES

Extinguishing Media/Instructions:	This material is a protein in an aqueous salt solution. Use extinguisher media appropriate for surrounding fire.
Hazardous Combustion Products:	Hazardous decomposition products may consist of CO _x and NO _x products.
Special Hazards:	CAUTION: Substance not fully evaluated


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Section 6. ACCIDENTAL RELEASE MEASURES
**Personal Precautions
and Methods of
Cleaning:**

Wear suitable protective clothing, gloves and eye/face protection. As a minimum this would include: splash goggles, disposable lab coat of low permeability with cuffs, double gloves, shoe covers, and an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges.

Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as self-contained breathing apparatus may be needed. Prevent entry into sewers, basements or confined areas. Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish by cleaning thoroughly with detergent and water and dispose of according to local and regional authority requirements.

**Environmental
Precautions:**

CAUTION: Substance not fully characterized. It is prudent to minimize release of this material to the environment.

Section 7. HANDLING & STORAGE
Handling Precautions:

Specific areas should be designated and restricted to persons who are trained and qualified to work with these materials wearing personal protective equipment. A designated area may encompass all or part of a laboratory, e.g. a hood.

Container Requirements:

Store in sturdy containers or use an unbreakable outer container.

Storage Conditions:

Store 2-8 degrees C. Store in a dry, cool and well ventilated area.

Section 8. EXPOSURE CONTROLS & PERSONAL PROTECTION
8.1 Exposure Limits:

Component:	REG. Limit	OSHA (PEL)	ACGIH (TLV®)
1) Cetuximab	Not established	Not established	Not established

8.2 Controls and PPE:
**Engineering Controls
And Ventilation:**

Material is not volatile. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limit.

Respiratory Protection:

Material is not volatile. Respiratory protection may be needed only if process creates a mist or spray. When engineering controls are not sufficient to control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges when handling

Eye Protection:

Wear safety glasses (ANSI Z87.1).

Controls and PPE Continued:

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Hand/Arm Protection:	Wear impervious (nitrile or low protein; powder free latex) gloves whenever the potential exists for skin contact. Please note that individuals allergic to natural rubber latex should use nitrile gloves. Use particular care when removing gloves to minimize exposure.
Skin Protection:	Depending on the potential for dust or mist generation; wear protective laboratory coat or coverall when handling quantities greater than 1 kilogram.
Hygiene:	Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day

Section 9. PHYSICAL & CHEMICAL PROPERTIES

Description:	Clear, colorless liquid which may contain particulates
Physical State:	Liquid
Color:	Clear Colorless
Chemical Formula:	Trade Secret
Molecular Weight:	Trade Secret
Boiling Point:	Not available
Freezing/Melting Point:	Not available
Octanol/Water Partition Coefficient (Log <i>k</i>_{ow}):	Not available
Odor:	Not available
pH:	5.3-5.7
Solubility in Water:	Not available
Specific Gravity:	Not available
Vapor Density:	Not available
Vapor Pressure:	Not available
Viscosity:	Not available
Bulk Density:	Not available
Oxidizing Potential:	Not available
Flash Point (method):	Not available
Autoignition Temp:	Not available
Explosive Limits:	Not available
Combustibility:	Not available


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Section 10. STABILITY AND REACTIVITY
10.1 Stability and Incompatibilities

Stability:	The product is stable.
Incompatibilities:	Not available
Conditions to Avoid:	Not available
Hazardous Decomposition Products:	If involved in a fire, toxic gases including COx and NOx can be generated.
Hazardous Polymerization:	Not available

10.2 Sensitivity to Static Discharge/Dust Explosion Potential

Summary Statements:	Product is provided as a solution in water. It is not sensitive to static discharge or dust explosion.
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Section 11. TOXICOLOGICAL INFORMATION

Routes of Entry:	Dermal contact. Inhalation. Ingestion. Eye Contact
Eye Irritation:	No specific information
Skin Irritation:	No specific information
Sensitization:	Not available
Toxicity:	LD50: Not available LC50: Not available
Mutagenicity:	Not available
Target Organs:	Skin
Carcinogenicity:	Not available. Not listed as carcinogen by ACGIH, EPA, OSHA, EU, IARC, NTP, and NIOSH
Teratogenicity:	Erbitux® binds to the placenta and the potential for harm is unknown, therefore pregnant women should avoid exposure to Erbitux™.
Reproductive Toxicity:	Human IgG is excreted in human milk and the potential for absorption and harm to the infant is unknown, therefore nursing mothers should avoid exposure to Erbitux™.
Toxicological Synergistic Products:	Not available
Other:	CAUTION: Erbitux® has not been fully characterized. There are few or no data concerning the toxicity of the material under occupational exposures. Chronic health effects have not been evaluated. Handle with appropriate care to minimize exposure.

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Section 12. ECOLOGICAL INFORMATION

*12.1 Ecotoxicological Information***Toxicity to Daphnia,** Not available**Algae, Fish:****Sludge Respiration
Inhibition:** Not available**Microbial Inhibition:** Not available*12.2 Chemical Fate Information***Biodegradation:** Not available**Hydrolysis/Mobilization:** Not available**Accumulation:** Not available*12.3 Summary Statements:***CAUTION: Substance not fully characterized. It is prudent to minimize release of this material to the environment.**

Section 13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of according to all federal, state and local applicable regulations.**U.S. Regulations:** Erbitux® is not a listed hazardous waste.

Section 14. TRANSPORT INFORMATION

U.S.A. DOT: Not classified**ICAO/IATA:** Not classified

(Air Transport)

IMO/IMDG: (Maritime
Transport) Not classified

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Section 15. REGULATORY/STATUTORY INFORMATION

15.1 U.S.A.

- Hazard Communication:** Based on the criteria of the OSHA Hazard Communication Standard, specific hazards have not been identified. Very limited data is currently available for this drug candidate. Acne-like rash was observed in the majority of patients treated with Erbitux® by intravenous administration. Severe hypersensitivity reactions have been observed in clinical patients treated with Erbitux® by intravenous administration. Use of appropriate care to minimize exposure is recommended.
- DEA:** Not applicable
- Other (State, etc.):** No applications were found

15.2 International

- Canada:** Not listed by WHMIS. Covered by the Food & Drug regulation. See U.S.A. Section 15.1 above
- Europe/Other:** See EC labeling below.

15.3 EC Labeling

- EINECS/ELINCS Number:** Not available
- Symbol(s):** Not classified
- R Phrase(s):** This product is not classified according to the EU regulations as data is limited and substance is not fully characterized. See U.S.A. Section 15.1 above.
- S Phrase(s):** S23- Do not breathe gas/fumes/ vapor/spray.
S24/25- Avoid contact with skin and eyes.
S36/37/39- Wear suitable protective clothing, gloves and eye/face protection.
S38- In case of insufficient ventilation, wear suitable respiratory equipment.
S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible).
CAUTION - SUBSTANCE NOT FULLY TESTED.



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Section 16. OTHER INFORMATION

16.1 MSDS Preparation Information

MSDS Date: December 21, 2010

Prepared by: Beverly Hiles

Phone Number: (908) 218-9588

Revision Information: Revision 2 - 2010

16.2 Other Information

The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. And we assume no liability from its use.