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

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

*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.
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 COx and NOx products.

- **Special Hazards:** CAUTION: Substance not fully evaluated
Material Safety Data Sheet

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 any 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:

<table>
<thead>
<tr>
<th>Component:</th>
<th>REG. Limit</th>
<th>OSHA (PEL)</th>
<th>ACGIH (TLV®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Cetuximab</td>
<td>Not established</td>
<td>Not established</td>
<td>Not established</td>
</tr>
</tbody>
</table>

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:
**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>Clear, colorless liquid which may contain particulates</td>
</tr>
<tr>
<td><strong>Physical State:</strong></td>
<td>Liquid</td>
</tr>
<tr>
<td><strong>Color:</strong></td>
<td>Clear Colorless</td>
</tr>
<tr>
<td><strong>Chemical Formula:</strong></td>
<td>Trade Secret</td>
</tr>
<tr>
<td><strong>Molecular Weight:</strong></td>
<td>Trade Secret</td>
</tr>
<tr>
<td><strong>Boiling Point:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Freezing/Melting Point:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Octanol/Water Partition Coefficient (Log kow):</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Odor:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH:</strong></td>
<td>5.3-5.7</td>
</tr>
<tr>
<td><strong>Solubility in Water:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Specific Gravity:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Density:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Pressure:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Bulk Density:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Oxidizing Potential:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flash Point (method):</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Autoignition Temp:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Explosive Limits:</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Combustibility:</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>
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.

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.
Section 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicological Information
- Toxicity to Daphnia, Algae, Fish: Not available
- 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
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.
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.