Vectibix®
Material Safety Data Sheet

Revision Number: 2 **Date Issued** 08-May-2008

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Vectibix®
Common Name: Panitumumab
Chemical Name: rhuMAb-EGFr
Synonyms: ABX-EGF, AMG 954, Panitumumab

Manufacturer:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

Emergency Telephone Number:
Chemtrec NORTH AMERICA 1-800-424-9300, INTERNATIONAL 1-703-527-3887
Amgen 1-805-447-7233 or 1-800-447-1000

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains Vectibix®, a recombinant human IgG2 monoclonal antibody directed against the EGF receptor, an active pharmaceutical ingredient for treatment of cancer. Dosage from contents may pose a health hazard only if significant absorption occurs (e.g., inhalation after major spill or leak). Avoid inhalation, skin contact, eye contact and accidental ingestion.

Potential Health Effects

Principle Routes of Exposure: Inhalation, Skin and Eye Contact, Accidental Ingestion.

Inhalation: No data with inhalation exposure available.
Skin: No data with dermal exposure available. Based on its molecular weight, this product should not be readily absorbed through the skin.
Eyes: No data with ocular exposure available.
Ingestion: No data with oral exposure available.

See Section 11 for additional Toxicological information.

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 60 µg/m^3 as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Vectibix® has been classified per Amgen's Health Hazard Classification System as an Occupational Exposure Band 3 R compound (20 µg/m^3- 100 µg/m^3) based on the potential for reproductive and/or developmental effects.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients: See below

CAS-No: 339177-26-3
Formula: Proprietary Information

Each single-use 5 mL vial contains 100 mg of panitumumab with:

	CAS-No	Amount
Sodium chloride (NaCl)	7647-14-5	29 mg
Sodium acetate	127-09-3	34 mg
Water for Injection, USP	7732-18-5	---

Each single-use 10 mL vial contains 200 mg of panitumumab with:

	CAS-No	Amount
Sodium chloride (NaCl)	7647-14-5	58 mg
Sodium acetate	127-09-3	68 mg
Water for Injection, USP	7732-18-5	---

Each single-use 20 mL vial contains 400 mg of panitumumab with:

	CAS-No	Amount
Sodium chloride (NaCl)	7647-14-5	117 mg
Sodium acetate	127-09-3	136 mg
Water for Injection, USP	7732-18-5	---

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: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. 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.

Notes to Physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties: Not applicable/aqueous solution

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous Combustion Products: No information available.

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Spill Procedures: If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations.

7. HANDLING AND STORAGE

Handling and Storage: Avoid contact with skin, eyes or clothing. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Clean protective equiment thoroughly after each use. Store in a well ventilated area.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed.

Other: Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear colorless liquid (May contain white to translucent proteinaceous Vectibix® particles)
Physical State:	Liquid
Molecular Weight:	Approx. 147kD
pH:	5.8
Flash Point:	Not applicable /aqueous solution
Boiling Point:	No information available
Melting Point:	Liquid
Explosion Limits	Not applicable/aqueous solution
Vapor Pressure:	No information available
Vapor Density (air = 1):	No information available
Specific Gravity:	1.0 gm/mL
Water Solubility:	Not applicable
Partition Coefficient (log Kow):	No information available

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to Avoid: None

Incompatible Materials: None

Hazardous Decomposition Products: None

Chemical Reactivity: Not applicable

11. TOXICOLOGICAL INFORMATION

Single Dose Studies: A single dose safety pharmacology study evaluated the potential effects of Vectibix® on cardiovascular, respiratory, and central nervous system function in cynomolgus monkeys. No evidence of treatment-related effects on these organs was observed.

LD50 Oral: No LD50 test was conducted.

Eye irritation: No specific studies were conducted to assess the potential to cause eye irritation.

Skin irritation: No specific studies were conducted to assess the potential to cause skin irritation.

Sensitization: No specific studies were conducted to assess the potential to cause skin sensitization.

Repeated Dose Studies Vectibix® was administered IV to cynomolgus monkeys once weekly at doses up to 30 mg/kg for 4, 13, or 26 consecutive weeks. The major and consistent treatment-related findings observed across all toxicity studies were dose-dependent skin rash and diarrhea, ranging from mild to severe which are attributable to the pharmacologic activities of Vectibix® . These effects were completely reversible.

Based on therapeutic administration via IV administration, Vectibix® may affect the gastrointestinal system. Diarrhea has been observed in monkeys injected with Vectibix® In addition to diarrhea, skin, hair and nail toxicity occurs in patients receiving Vectibix® administered via IV administration. Skin rashes have been observed in humans starting at a systemic dose of 0.75 mg/kg. Exposure by accidental injection may cause site reactions.

Reproductive and Developmental Toxicity: Administration of Vectibix® to female monkeys caused alterations in serum hormone concentrations and the timing of peaks, resulting in prolonged menstrual cycles and/or amenorrhea. No NOAEL was identified for these effects. Fetal abortions or fetal deaths were observed at all dose levels tested. However, no fetal malformations or other evidence of teratogenesis were noted in the monkeys. Although no formal reproductive toxicity study was conducted in male monkeys, no histopathologic differences were observed in the reproductive organs of males treated with Vectibix® for up to 6 months compared to control male monkeys. FDA Pregnancy Category C

Mutagenicity/Genotoxicity Studies: Per ICH S6, no genotoxicity tests were performed.

Carcinogenicity Studies: Not listed by NTP, IARC, or OSHA as a carcinogen Per ICH S6, no carcinogenicity tests were performed.

Target Organ Effects: Skin, mucosa, eyes, and lungs.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects: No information available

Persistence/Degradability: No information available

Bioaccumulation/ Accumulation: No information available

Mobility in Environmental Media: No information available

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of any waste according to prescribed federal, state and local guidelines.

14. TRANSPORT INFORMATION

DOT: Not regulated by U.S. DOT or IATA

15. REGULATORY INFORMATION

International Inventories

Components are Exempt from Regulatory Requirements

USA - State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

16. OTHER INFORMATION

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The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it may be biologically active.