SeattleGenetics

MATERIAL SAFETY DATA SHEET

21823 – 30th Drive SE
Bothell, WA 98021
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Section I – IDENTITY

Common Name: Brentuximab vedotin
Chemical Names: Chimeric IgG1 cAC10 covalently linked to vcMMAE
Synonyms/Trade Name: ADCETRIS™; SGN-35; cAC10-vcMMAE; cAC10-1006(4)
Manufacturer's Name: SEATTLE GENETICS, INC.
Address: 21823 30TH DRIVE SE
BOTHELL, WA 98021
Telephone number for information: 1-855-4SEAGEN
Date Prepared (or Revised): 03/01/2013
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
SGN-35	914088-09-8	NONE	NONE	N/A

Product is typically a solution formulated at 1-10 mg/mL in aqueous buffer. Product may also be present as lyophilized solid.

Section III - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: aqueous solution or powder
Boiling Point: ca. 100 °C
Vapor Pressure (mm Hg.): N/A
Vapor Density (Air=1): N/A
Solubility in Water: N/A
Appearance and Odor: Colorless liquid
Specific Gravity (H_2O =1): ca. 1.0
Melting Point: N/A
Evaporation Rate: N/A

Section IV - FIRST AID MEASURES

Eye Exposure: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical attention immediately.
Skin Exposure: Remove contaminated clothing and shoes. In case of skin contact, flush with copious amounts of water for at least 15 minutes. Seek medical attention immediately.
Ingestion: If swallowed, wash out mouth with water provided person is conscious. Seek medical attention immediately.
Inhalation: Remove the exposed person to fresh air and keep him/her calm. Loosen clothing as necessary. In the event of symptoms seek medical attention immediately.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Unknown
Flammable Limits: LEL: NA **UEL**: NA
Extinguishing Media: Use water or a multi-purpose ABC extinguisher.
Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters must use a (SCBA) self-contained breathing apparatus.
Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wearing latex or nitrile gloves wipe up and dispose of wastes properly (in accordance with local, state, and federal regulations). Absorb using appropriate materials. Wash areas exposed to SGN-35 with water, and absorb wash solutions. Dispose of sorbent in sealed containers.
Release to Air: If aerosol is in air, reduce exposures by ventilating area; clean up spills immediately and wear proper protective equipment.
Release to Water: Refer to local water authority. Drain disposal must not occur.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above; wear latex or nitrile gloves and safety glasses. If aerosol occurs, wear a half mask respirator with HEPA cartridges (P 100). For larger spills, additional protective clothing such as chemical protective coveralls, boots, double gloves, and self-contained breathing apparatus (SCBA) may be needed.
Waste Disposal Method: Incineration at an approved/permitted facility according to federal, state, and local guidelines.
Precautions to be taken in handling and storing: Lyophilized powder should be stored refrigerated (2-8 °C). Liquid formulations should be stored refrigerated, or for long periods, stored frozen. Protect from light.
Other Precautions: Follow OSHA guidelines for safe handling of cytotoxic products.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Effective engineering controls should be utilized to minimize worker exposure. Respiratory protection should not be used as a substitute. If a ventilated biological safety cabinet or chemical fume hood is unavailable, a half mask respirator equipped with HEPA cartridges (P-100) should be worn. Under normal use, respirators may not be required. If droplets of product are generated, a half-mask respirator with HEPA cartridges (P 100) may be worn. Personnel wearing respirators must be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.
Ventilation: Handle in a biological safety hood or in a well-ventilated area. Avoid creation of aerosols.
Protective Gloves: Latex or nitrile.
Eye Protection: Safety glasses or goggles.
Other Protective Clothing or Equipment: Necessary clothing to prevent skin contact such as a lab coat with a closed front, long sleeves, and elastic cuffs.
Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.
OEL: Unknown

Section IX - HEALTH HAZARD DATA

Routes of Entry: Primary routes of entry are Eye/Skin Exposure, Ingestion, Inhalation
Health Hazard (Acute & Chronic): SGN-35 is an anti-neoplastic agent. The acute and chronic health hazards are not known at this time.
Target Organs:
Carcinogenicity: **NTP?** NO **IARC Monographs?** NO **OSHA Regulated?** NO
Signs & Symptoms of Exposure: Unknown
Medical Conditions Generally Aggravated by Exposure: Unknown

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable under recommended storage conditions
Incompatibility (Materials to Avoid): Strong oxidizers
Hazardous Decomposition or Byproducts: Products of combustion may include potentially hazardous byproducts of nitrogen oxides, hydrogen chloride, carbon monoxide, and carbon dioxide.
Hazardous Polymerization: Will not occur.
Conditions to Avoid: Storage with strong oxidizers.

Section XI - TOXICOLOGICAL INFORMATION

Acute Toxicity (humans):
All studies were conducted by intravenous infusion. The single dose maximum tolerated dose was determined to be 1.8 mg/kg. Adverse events that occurred at doses greater than 1.8 mg/kg include febrile neutropenia and septic shock that resulted in death, severe hyperglycemia, severe renal failure, and severe febrile neutropenia.

Acute Toxicity (animals):
All studies were conducted by intravenous infusion. Single intravenous doses were tolerated in rats up to 15mg/kg and in monkeys up to 6mg/kg.

Rat NOAEL = 0.5mg/kg, intravenous, q1wx4
Rat HNSTD = 5mg/kg, intravenous, q1wx4
Monkey NOAEL = 1mg/kg, intravenous q3wx9
Monkey HNSTD = 3mg/kg, intravenous, q3wx9

Repeated Dose Studies (animals): Target organs include bone marrow, thymus, spleen, liver intestine, lung and testes

Irritation / Sensitization:
No data available for Brentuximab vedotin.

Chronic Toxicity
Severe adverse events that occurred in >2 patient treated with 1.8 mg/kg every 3 weeks included: neutropenia, thrombocytopenia, peripheral sensory neuropathy, anemia, and hyperglycemia.

Developmental Toxicity:
Brentuximab vedotin administered at doses > 1 mg/kg given twice one week apart to time-mated female rats resulted in embryo-fetal lethality and teratogenicity.

Reproductive Toxicity:
Brentuximab vedotin has not been evaluated for reproductive toxicity (effects on fertility). Repeated dose studies in laboratory animals have caused degenerative changes in the testes.

Mutagenicity:
No data available for brentuximab vedotin.

Carcinogenicity:
No data available for brentuximab vedotin.

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Brentuximab vedotin. Handle in a manner that prevents spills or releases to the environment. Do not dispose down the drain.

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state, and local guidelines.

Section XIV - TRANSPORTATION INFORMATION

Brentuximab vedotin is not listed as a DOT Hazardous Material. SGN-35 is not listed as a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed:	This product is not listed
CERCLA Reportable Quantity:	Unknown
RCRA listed:	This product is not listed
TSCA (Toxic Substance Control Act):	Not regulated

Section XVI - OTHER DATA

1. This MSDS does not address the therapeutic use of this material.

2. Persons preparing or administering parenteral antineoplastic agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all antineoplastic agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted the material should be segregated for incineration.

3. Persons using the material must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to in accordance with your standard company policy.

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