Safety Data Sheet

Section I. Identification of the substance

Product Name: DBCO-PEG4-Val-Cit-PAB-MMAE
Catalog number: BP-25659
Supplier: Broadpharm, 6625 Top Gun Street, Suite# 103, San Diego, CA 92121, USA.
Tel: +1-858-677-6760

Section II. Hazards identification

Classification Germ Cell Mutagenicity - Category 2
Toxic to Reproduction - Category 2
Specific Target Organ Toxicity (Repeat Exposure) - Category 1

Pictograms



Single word Danger
H341 Suspected of causing genetic defects
H361 Suspected of damaging the unborn child
H372 Causes damage to the lungs, liver, hematological system and peripheral nerves through prolonged or repeated exposure

Hazards Not Otherwise Classified
Cytotoxic
Tumor Lysis Syndrome
Serious infections and opportunistic infections
Anaphylaxis and infusion reactions

Precautionary Statement(s)
P201 Obtain special instructions before use
P202 Do not handle until all safety precautions have been read and understood
P260 Do not breathe dust
P264 Wash thoroughly after handling
P270 Do not eat, drink or smoke when using this product
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection
P308+P313 If exposed or concerned: Get medical advice/ attention
P405 Store locked up
P501 Dispose of contents/ container to approved disposal facility

Section III. Composition and information on ingredients.

Name: DBCO-PEG4-Val-Cit-PAB-MMAE
Formula: $C_{88}H_{128}N_{12}O_{19}$
MW: 1658.1
CAS: 2129164-91-4

Section IV. First aid measures

1.Skin contact: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

2.Eye contact: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

3.Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

4. Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

5. Note to Physicians This material is a potent cytotoxic antineoplastic material. Victims of chemical exposure must be taken for medical attention. Take a copy of the SDS to the physician or health professional with victim. Physicians should refer to Section XI (Toxicological Information) for additional treatment information.

Section V. Fire fighting measures

1. Extinguishing Media

Use extinguishing agent suitable for type of surrounding fire such as dry chemical, carbon dioxide, foam, water spray, sand or earth is recommended. Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces.

2. Specific Hazards Arising From the Chemical

Unusual Fire & Explosion Hazards:

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Hazardous Combustion Products

Combustion may yield smoke, carbon monoxide, and other products of incomplete combustion. Oxides of nitrogen may also be formed.

3. Special Protection Actions for Fire-Fighters

For fires beyond the initial stage, emergency responders in the immediate hazard area should wear protective clothing. When the potential chemical hazard is unknown, in enclosed or confined spaces, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section VIII).

Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done safely. Move undamaged containers from immediate hazard area if it can be done safely. Cool equipment exposed to fire with water, if it can be done safely.

Section VI. Accidental release measures

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid generating dust in enclosed spaces. Stay upwind and away from spill/release. Avoid direct contact with material. For large spillages, notify persons down-wind of spill/release, isolate immediate hazard area and keep unauthorized personnel out. Wear appropriate protective equipment, including respiratory protection, as conditions warrant (see Section VIII). See Sections II and VII for additional information on hazards and precautionary measures.

Environmental precautions:

Contain spill if it can be done safely. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways. Use

water sparingly to minimize environmental contamination and reduce disposal requirements.

Methods and Material for Containment and Cleaning Up:

Notify relevant authorities in accordance with all applicable regulations. Clean up spills in a manner that does not disperse dust into air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Carefully shovel or sweep up spilled material and place in a suitable container. Minimize dust generation.

Recommended measures are based on the most likely spillage scenarios for this material; however local conditions and regulations may influence or limit the choice of appropriate actions to be taken. See Section XIII for information on appropriate disposal.

Section VII. Handling and storage

Work and Hygiene Practices:

As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash thoroughly after handling.

Precautions for Safe Handling:

Under dusty conditions, avoid all sources of ignition, including sparks and static electricity. Minimize dust generation and accumulation in enclosed spaces. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Wash thoroughly after handling. Use good personal hygiene practices and wear appropriate personal protective equipment (see Section VIII). Do not wear contaminated clothing or shoes.

Conditions for Safe Storage:

Keep container(s) tightly closed and properly labeled. Use and store this material in cool, dry, well-ventilated areas away from heat, direct sunlight, hot metal surfaces, and all sources of ignition. Keep away from any incompatible material (see Section X). Protect container(s) against physical damage. Outdoor or detached storage is preferred. Indoor storage should meet OSHA requirements.

Protective Practices During Maintenance of Contaminated Equipment:

When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

Section VIII. Exposure Controls / PPE

Engineering Controls: Use with adequate ventilation. Follow standard medical handling procedures.

Personal Protective Equipment:

Eye/Face Protection: The use of eye protection that meets or exceed ANSI Z.87.1 is recommended to protect against potential eye contact, irritation, or injury. Depending on conditions of use, a face shield may be necessary.

Skin/Hand Protection: The use of skin protection is not normally required; however, good industrial hygiene practice suggests the use of gloves or other appropriate skin protection whenever working with chemicals.

Respiratory Protection: The use of a chemical hood and respirator is required when working with the solid. A NIOSH certified air-purifying respirator with a type 100 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known or any other circumstances where air-purifying respirators may not provide adequate protection.

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Section IX. Physical and Chemical properties

Appearance: Solid
Odor: No data
Boiling point: No data
Melting point: No data
Flash point: No data
Density: No data
Molecular formula: $C_{88}H_{128}N_{12}O_{19}$
Molecular weight: 1658.1

Section X. Stability and reactivity

Reactivity: Stable under normal ambient and anticipated conditions of use.
Chemical Stability: Stable under normal ambient and anticipated conditions of use.
Possibility of hazardous Reactions: Hazardous reactions not anticipated.
Conditions to avoid: Avoid all possible sources of ignition.
Materials to avoid: None known.
Hazardous Decomposition Products: Not anticipated under normal conditions of use.
Hazardous Polymerization: Not known to occur.

Section XI. Toxicological information

Information on toxicological effects of substance/Mixture:

Acute Toxicity	Hazard	Additional Information	LC50/LD50 Data
Inhalation	Unknown		No data
Skin Absorption	Unknown		No data
Ingestion (Swallowing)	Unknown		No data
Intravenous	Not determined	No lethality	0.05, 0.25mg/kg

This material is cytotoxic. Common side-effects of cytotoxic materials include fatigue, reversible alopecia, nausea and vomiting, oral ulceration, diarrhea, skin rashes, bone marrow suppression and effects on fertility.

Irritancy of Product: The dust of this product may cause mechanical irritation to eyes and skin.

Sensitization to the Product: Infusion-related reactions, including anaphylaxis, have occurred with this material.

Mutagenicity: Positive in an in vivo rat chromosomal aberration in bone marrow micronucleus assay.

Carcinogenicity: Carcinogenicity studies have not been conducted.

Specific Target Organ Toxicity (Repeated Exposure): This material has demonstrated numerous effects on various target organs. Effects seen include peripheral neuropathy (predominantly sensory), hematological toxicities (severe neutropenia, thrombocytopenia or anemia), immunological effects (serious infections and

opportunistic infections such as pneumonia, bacteremia and sepsis or septic shock), liver toxicity (elevation or transaminases and/or bilirubin and death) and pulmonary toxicity (pneumonitis, interstitial lung disease and acute respiratory distress syndrome.

Reproductive Toxicity Information: Listed below is information concerning the effects of this product on human and animal reproductive systems. This material is classified as a Pregnancy Category D (Positive evidence of risk).

Embryotoxicity/Teratogenicity/Reproductive Toxicity: No adequate and well-controlled human data on reproductive and developmental toxicity. However, based on the mechanism of action and findings in animals, this material can cause fetal harm when administered to pregnant women. In addition, repeat-dose toxicity studies in rats indicate the potential to impair male reproductive function and fertility. Effects seen were seminiferous tubule degeneration, Sertoli cell vacuolation, reduced spermatogenesis and spermia were observed.

Other effects: Stevens-Johnson Syndrome and toxic epidermal necrolysis, including fatal outcomes, have been reported with this material. In addition, Tumor Lysis Syndrome has also been reported.

Section XII. Ecological information

All work practices must be aimed at eliminating environmental contamination. No specific information is available on the effect of this material on plants or animals in the aquatic environment.

Section XIII. Disposal consideration

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

Section XIV. Transportation information

This material is not hazardous as defined by 49 CFR 172.101 by the U.S. Department of Transportation.

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Parking Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B

Transport Canada Transportation of Dangerous Goods Regulation: Not applicable

Section XV. Regulatory information

U.S. Regulations:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This material is not found on the TSCA inventory list.

California State Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain chemicals known to the State of California to cause cancer or reproductive effects.

Canadian Regulations:

Canadian DSL/NDSL Status: This material is not found on the DSL/NDSL inventory lists.

Section XVI. Other information

The information presented in this Safety Data Sheet is based on data believed to be accurate as of the date this Safety Data Sheet was prepared. HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THE INFORMATION PROVIDED ABOVE, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE. No responsibilities is assumed for any damage or injury resulting from abnormal use or form any failure to adhere to recommended practices. The information provided above, and the product, are furnished on the condition that the person receiving them shall make their own determination as to the suitability of the product for their particular purpose and on the condition that they assume the risk of their use. In addition, no authorization is given nor implied to practice any patented invention without a license.