CYTOMX THERAPEUTICS

SAFETY DATA SHEET
CX-2009

1. BIOLOGICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:		CX-2009 Humanized Monoclonal Antibody conjugated to DM4 in solution
Synonyms:		Maytansinoid conjugated antibody
Chemical Family:		Maytansinoid armed antibody, mitotic inhibitor
C.A.S. No:		Not Applicable
Product Use:		Pharmaceutical Development for Oncology Indications
Company:	:	CytomX Therapeutics, Inc. 151 Oyster Point Blvd., Suite 400 South San Francisco, CA 94080 USA 650 515 3185
Manufacturer:		BSP Pharmaceuticals S.p.A. Via Appia Km. 65561 04013 Latina Sccalo (LT) Italy +39 0773 822 1
Emergency:		(650) 515-3185 (during office hours)
Last Updated:		14Sep2018

2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Classification or substance or mixture:

Germ cell mutagenicity:	Category 2; based on DM4 mechanism (DM4 CAS 796073-69-3)
Carcinogenicity:	Category 2
Reproductive toxicity:	Category 2

Specific target organ systemic toxicity – repeated exposure (intravenous):
Category 2; based on DM4 Mechanism

GHS label elements

Hazard pictograms: Pictogram

Health Hazard

Signal Word:	Danger
Hazard statements:	H341 Suspected of causing genetic defects. H351 Suspected of causing cancer. H361 Suspected of damaging fertility or the unborn child.
Precautionary Statements:	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood P280 Wear protective gloves/clothing/eye protection/face protection P273: Avoid release to the environment P501: Dispose of contents/container according to local, state, and federal requirements P305 + P351 + P338: If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Potential Health Effects / Principle Routes of Exposures:

Inhalation:	May cause respiratory irritation
Skin:	May cause skin irritation
Eyes:	May cause eye irritation
Ingestion:	Properties not thoroughly known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/ Mixture: Mixture

ctive Ingredients	**CAS#**	**% by wt**
Antibody conjugated to DM4	N/A	0.1 to 0.5
DM4 (as part of conjugate)	796073-69-3	0.0018 to 0.009
Inactive Ingredients	**CAS#**	**% by wt**
Water	7731-18-5	~92
Sucrose	57-50-1	7
L-Histidine	9005-65-6	23

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice

If inhaled:	Remove from exposure source; notify medical personnel and supervisor if breathing difficulties develop. Administer artificial respiration if necessary
In case of skin contact:	In case of contact, immediately flush skin with water for at least 15 minutes Remove contaminated clothing and shoes Get medical attention Wash clothing before reuse Thoroughly clean shoes before reuse
In case of eye contact:	Immediately flush eyes thoroughly with water for at least 15 minutes; Seek immediate medical assistance
If swallowed:	Seek immediate medical assistance. Do not induce vomiting, give liquids, or use any other method to remove poison unless advised by physician or Poison Control. (P301)(P321)
Protection of first-aiders:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists
Notes to physician:	Material is a solution of a humanized monoclonal antibody conjugated to a derivative of maytansine

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Water Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media:	None known
Specific hazards during fire fighting:	Exposure to combustion products may be a hazard to health
Hazardous combustion products:	Not applicable, mainly water
Specific extinguishing methods:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment Use water spray to cool unopened containers Remove undamaged containers from fire area if it is safe to do so Evacuate area
Special protective equipment for fire-fighters:	In the event of fire, wear self-contained breathing apparatus Use personal protective equipment Decontaminate all equipment after use

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Eye Protection:	Wear safety goggles or a face shield when cleaning up spills
Skin Protection:	Wear protective attire that prevents contamination of skin and personal clothing

Hand Protection:	Wear nitrile, thick latex, or vinyl gloves that cover exposed skin
Other Protections:	Avoid breathing mists, dusts, and aerosols
Environmental Controls:	Prevent spilled product from entering storm drains
SPILL CLEAN-UP MEASURES:	Contain the material to prevent it from becoming airborne
	Place absorbent materials on top of, and around, the perimeter of the spill
	Clean up the spilled material and decontaminate the area with soap and water or an equivalent cleaner or disinfectant
	Dispose of the material according to local and state regulations

7. HANDLING AND STORAGE

HANDLING:	Always wear recommended Personal Protective Equipment No special handling device required Use extreme caution when handling cytotoxic agents (i.e., use of engineering controls and/or other personal protective equipment if needed)
STORAGE:	Store at temperatures stated on product container or accompanying paperwork Keep in a tightly closed container and store as specified Protect against physical damage

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROL

Occupational exposure limits:	None established by OSHA, NIOSH or ACGIH
Engineering measures	If airborne dispersion of liquid aerosol is possible, handle material in a ventilated enclosure or other containment device with appropriate ventilation. engineering controls should be used as a primary means of controlling exposures.

PERSONAL PROTECTION

Eye Protection:	Wear safety glasses with appropriate side shields or chemical goggles at all times when handling this material.
Respiratory Protection:	Not required while the solutions of the material are being handled in a ventilated enclosure. If working with large quantities of material, a NIOSH approved respirator or other device that will protect from exposure should be worn to protect against airborne exposures exceeding the OEL.
Skin Protection:	Use double-layered latex or nitrile gloves at all times when handling this material. Use gloves which cover forearms or use arm shields if potential for exposure exists. Wear appropriate protective clothing to completely avoid contact with the skin.
Other:	Wash hands, face and other potentially exposed areas after working with this compound. Exercise extreme care when using sharps (e.g., needles, syringes) with maytansinoid drugs. Do not breathe mist/vapors/spray.(P260)

9. PHYSICAL AND BIOLOGICAL PROPERTIES

Appearance:	Powder
Color:	White to off-white

Odor:	No information available
Odor Threshold:	No data available
Melting point/freezing point:	No data available
Flash point:	No data available
Upper/lower flammability explosive limits:	No data available
Vapor pressure:	No data available
Relative vapor density:	No data available
Density:	No data available
Solubility(ies):	
Water solubility:	No data available
Partition coefficient:	
n-Octanol/water:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing
Molecular weight:	For conjugated DM4- approximately 147,000; DM4 is about 1.8% of total weight
Particle size:	No data available

10. STABILITY AND REACTIVITY

Reactivity:	Not reactive under ambient conditions and when stored properly
Chemical stability:	Stable chemical
Possibility of hazardous reactions:	N/A
Conditions to avoid:	Avoid freezing, heat, sunlight and strong bases, which may degrade the product
Incompatible materials:	Not known to be incompatible with other compounds
Hazardous decomposition products:	May decompose into hydrocarbons and steam

11. TOXICOLOGICAL INFORMATION

Acute Toxicity :	Single IV dose administration of 15 mg/kg CX-2009 to cynomolgus monkeys resulted in mortality. The maximum non-lethal dose was 10 mg/kg. The principal target organs for toxicity were skin, cornea, hematologic tissues and nerve
Repeat Dose Toxicity:	Repeat IV administration of CX-2009 to monkeys resulted in injury to nerves, hematologic tissues, and epithelial tissues (skin, tongue, cornea). With the exception of nerve damage, all findings were reversible. The maximum non-lethal dose was 10 mg/kg
Genotoxicity:	No data available
Carcinogenicity:	No data available
Reproductive and Developmental Toxicity:	No data available
Human Clinical Data:	The antibody – DM1 conjugate was studied in cancer patients in phase I clinical trials to determine the dose-limiting toxicities and the recommended phase two dose. Given intravenously, DLTs were observed at the following doses. 295 mg/m^2 given once every three weeks (2 of 3 patients) 235 mg/m^2 given once every three weeks (2 in 16 patients) 115 mg/m^2 given weekly (1 in 23 patients) Dose limiting toxicity consisted of liver toxicity (elevated hepatic transaminase levels) that was fully reversible. Although rarely severe, other toxicities include nausea, vomiting, fatigue, and diarrhea. On rare occasions hematopoietic toxicity was noted

12. ECOLOGICAL INFORMATION

Ecotoxicity:	No data available
Persistence and degradability:	No data available
Aquatic Toxicity:	No data available
Bioaccumulative potential	
Mobility in soil:	No data available
Other adverse effects:	No data available

13. DISPOSAL CONSIDERATION

Disposal methods

Waste from residues:	Dispose of in accordance with local regulations
Waste Treatment Options:	Follow federal, state and local waste disposal requirements
Sewage Disposition Options:	Check with local authorities before discharge to the sewer
Contaminated packaging:	Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified:	Dispose of as unused product\

14. TRANSPOTATION INFORMATION

International Regulations

UNRTDG:	Not regulated as a dangerous good
IATA-DGR:	Not regulated as a dangerous good
IMDG-Code:	Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not applicable for product as supplied

Domestic regulation 49 CFR: Not regulated as a dangerous good

15. REGULATORY INFORMATION

SARA 313:	This product is not regulated under SARA
US OSHA:	Not regulated as a hazardous material
US EPA:	Hazards to the environment have not been thoroughly investigated
EU REGULATIONS:	This safety data sheet conforms to Regulation (EC) No 1272/2008, 1907/2006, and other requirements established by the European Union

US State Regulations

Pennsylvania Right To Know:	Sucrose 57-50-1
Canadian WHMIS Hazard Class:	Class D, Division 1, Subdivision A. Class D, Division 2, Subdivision A.

US State Regulation:

California Proposition 65:	This product does not contain chemicals listed under Proposition 65
Chemical Safety Assessment:	A Chemical Safety Assessment has not been completed for this

product

16. OTHER INFORMATION

Further information

NFPA: HMIS® IV: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard

Sources of key data used to compile the Safety Data Sheet: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ Revision Date: 05/10/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable US / Z8

The information provided above is believed to be correct. As of the revision date all known information relevant to the foreseeable handling of the product is provided. This Safety Data Sheet is not intended to be a substitute for consultation with appropriately trained personnel.

This bulletin is for your guidance and is based upon information and tests believed to be reliable. CytomX makes no guarantee of the accuracy or completeness of the data and shall not be liable for any damages thereto. The data are offered solely for your consideration, investigation, and verification. These suggestions should not be confused with either state, municipal, or insurance requirements, or with national safety codes and constitute no warranty. Any use of these data and information must be determined by the user to be in accordance with applicable federal, state, and local regulations.