



# BLINCYTO™

## Safety Data Sheet

Revision Number: 4

Date Issued 13-Nov-2015

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

#### 1.1 Product identifier

**Product Name:** BLINCYTO™  
**Common Name:** Blinatumomab  
**Chemical Name:** Proprietary Information  
**Synonyms:** Blinatumomab, AMG 103, MT103

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

#### Manufacturer:

Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799  
1-805-447-7233  
1-805-447-1000

#### Emergency Telephone Number:

Chemtrec  
NORTH AMERICA 1-800-424-9300,  
INTERNATIONAL 1-703-527-3887

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains blinatumomab, an active pharmaceutical ingredient for treatment of Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL). Dosage contents may pose a health hazard only if significant absorption occurs (e.g. inhalation after a major spill or leak). Avoid inhalation, skin contact, eye contact, and accidental ingestions. Does not meet GHS classification criteria and therefore is not classified.

#### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Does not meet GHS classification criteria and therefore is not classified.

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**  
*For the full text of the R phrases mentioned in this Section, see Section 16*

#### 2.2 Label elements

Does not meet GHS classification criteria and therefore is not classified.



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**2.3 Other Hazards** No information available

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Substances**

**Ingredients:** Each 4 mL single-use vial of BLINCYTO™ contains 38.5 mcg blinatumomab, citric acid monohydrate (3.68 mg), lysine hydrochloride (25.55 mg), polysorbate 80 (0.70 mg), trehalose dihydrate (105.5 mg), and sodium hydroxide to adjust pH to 7.0.

**CAS-No:** 853426-35-4

**4. FIRST AID MEASURES**

**4.1 Description of 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.



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**5. FIRE-FIGHTING MEASURES**

**5.1 Extinguishing media**

**Flammable Properties:** No information available.

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

**5.2 Special hazards arising from the substance or mixture**

**Hazardous Combustion Products:** No information available.

**5.3 Advice for firefighters**

**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**

**6.1 Personal precautions, protective equipment and emergency procedures**

**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. Avoid release to the environment.

**7. HANDLING AND STORAGE**

**7.1 Precautions for Safe Handling**

**Handling and Storage:** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 1 µg/m<sup>3</sup> 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. Blinatumomab has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 5 compound (0.1 µg/m<sup>3</sup> - 5 µg/m<sup>3</sup>).

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

#### 8.2 Exposure controls

##### 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. The choice of protection should be based on the job activity and the potential for exposure.

**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.

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White to off-white
<b>Physical State:</b>	Lyophilized powder
<b>Molecular Weight:</b>	55 kD
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	7 (as aqueous solution)
<b>Melting Point:</b>	No information available
<b>Boiling Point:</b>	No information available
<b>Flash Point:</b>	No information available
<b>Evaporation Rate:</b>	No information available
<b>Lower explosive limit:</b>	No information available
<b>Upper explosive limit:</b>	No information available
<b>Vapor Pressure:</b>	No information available
<b>Vapor Density (air = 1):</b>	No information available
<b>Relative density:</b>	No information available
<b>Water Solubility:</b>	No information available
<b>Partition Coefficient (log Kow):</b>	No information available
<b>Viscosity:</b>	No information available

### 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No information available
<b>10.2 Chemical stability</b>	No information available
<b>10.3 Possibility of hazardous reactions</b>	No information available
<b>10.4 Conditions to avoid</b>	No Information available
<b>10.5 Incompatible materials</b>	No information available
<b>10.6 Hazardous decomposition products</b>	No information available
<b>10.7 Other information</b>	None



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**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Serious eye damage/eye irritation:</b>	No information available
<b>Respiratory or skin sensitization:</b>	No information available
<b>Germ cell mutagenicity:</b>	No information available
<b>Carcinogenicity:</b>	No information available
<b>Reproductive toxicity:</b>	Even though this does not meet GHS classification, the following data is available: Blinatumomab was tested in an embryo-fetal study where mouse surrogates (muS103new) were dosed intravenously (0, 1, and 5 mg/kg/day) on post-coitum days 6-15. No adverse effects were observed on maternal clinical condition, pregnancy, or embryo-fetal development.
<b>STOT - single exposure:</b>	No information available
<b>STOT - repeated exposure:</b>	Even though this does not meet GHS classification, the following data is available: Blinatumomab adverse effects from clinical intravenous infusion at low doses can include neurotoxicity, cytokine release syndrome, elevated liver enzymes, infections, disseminated intravascular coagulation, venous thrombosis, thromboembolic events, fever, headache, fatigue, nausea, hypokalemia, tremor, diarrhea, and decreased lymphocytes.
<b>Aspiration Hazard:</b>	No information available

**12. ECOLOGICAL INFORMATION**

**12.1 Toxicity**

**Ecotoxicity effects:** No information available

**12.2 Persistence and degradability**

**Persistence/Degradability:** No information available

**12.3 Bioaccumulative potential**

**Bioaccumulation/ Accumulation:** No information available

**12.4 Mobility in soil**

**Mobility in Environmental Media:** No information available

**12.5 Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment:** No information available

**12.6 Other adverse effects**

**Other Adverse Effects:** No information available



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**13. DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods**

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

**14. TRANSPORT INFORMATION**

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



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**15. REGULATORY INFORMATION**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

**International Inventories**

TSCA: -  
EINECS/ELINCS -  
DSL/NDSL -  
PICCS: -  
ENCS: -  
CHINA: -  
AICS: -  
KECL: -

**Legend**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List  
PICCS - Philippines Inventory of Chemicals and Chemical Substances  
ENCS - Japan Existing and New Chemical Substances  
IECSC - China Inventory of Existing Chemical Substances  
AICS - Australian Inventory of Chemical Substances  
KECL - Korean Existing and Evaluated Chemical Substances

**State Regulations**

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

**15.2 Chemical safety assessment**

No CSA has been conducted.



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**16. OTHER INFORMATION**

**Text of R phrases mentioned in Section 2**

No information available

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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.