



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET		
Product Name	CARMUSTINE FOR INJECTION USP 100 mg/Vial	Page No. 1 of 5

1. Product Information

Product Name: Carmustine for injection USP 100 mg/Vial

2. Composition/Information on Ingredients

C.A.S. No : : 154-93-8
Molecular Formula : $C_5H_9Cl^2N_3O_2$
Molecular Weight : 214.05
Chemical Name : N,N' -bis(2-chloroethyl)-N-nitroso-urea; BCNU; bis-Chloroethylnitrosourea

3. Hazards Identification

Acute Toxicity: Oral, Category 2
Carcinogenicity, Category 1B
Toxic To Reproduction, Category 1B
GHS Hazard Phrases:

H300: Fatal if swallowed.
H350: May cause cancer.
H360: May damage fertility or the unborn child.

GHS Hazard Phrases:

Label Elements:

Danger GHS Signal Word:

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P264: Wash {hands} thoroughly after handling.
P280: Wear {protective gloves/protective clothing/eye protection/face protection}.P281: Use personal protective equipment as required.

GHS Precaution Phrases:

P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P308+313: IF exposed or concerned: Get medical attention/advice.
P330: Rinse mouth.

4. First Aid Measures

After Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

After skin contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

After eye contact: check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

After swallowing: if swallowed, wash out mouth with copious amounts of water; call a physician.



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SAFETY DATA SHEET		
Product Name	CARMUSTINE FOR INJECTION USP 100 mg/Vial	Page No. 2 of 5

Notes to Physician: Treat symptomatically.

5. Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains Carmustine, an active pharmaceutical ingredient, for treatment of multiple myeloma. Dosage contents may pose a health hazard only if significant absorption occurs (e.g. inhalation after a major spill). Avoid inhalation, skin contact, eye contact, and accidental ingestions. Based on available data, the GHS classification criteria are not met.

6. Fire Fighting Measures

Suitable extinguishing agents: water spray, carbon dioxide, dry chemical powder or foam

Protective equipment: wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Unusual fire hazard: emits toxic fumes such as carbon monoxide, etc.

7. Accidental Release Measures

Person-related safety precautions: cordon off area of spill; wear self-contained breathing apparatus, protective clothing and heavy rubber gloves

Measures for cleaning/collecting: absorb solutions with finely- powdered liquid-binding material (diatomite, universal binders); decontaminate surfaces and equipment by scrubbing with alcohol; dispose of contaminated material according to Section 13.

8. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store at 2°C to 8°C (36° to 46°F). Do not freeze:

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MSN Laboratories Private Limited
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SAFETY DATA SHEET		
Product Name	CARMUSTINE FOR INJECTION USP 100 mg/Vial	Page No. 3 of 5

9. Exposure Controls/Personal Protection

Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 6 $\mu\text{g}/\text{m}^3$ 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. Carmustine has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 4 compound (5 $\mu\text{g}/\text{m}^3$ - 20 $\mu\text{g}/\text{m}^3$).
Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

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.

Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment.

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MSN Laboratories Private Limited
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SAFETY DATA SHEET		
Product Name	CARMUSTINE FOR INJECTION USP 100 mg/Vial	Page No. 4 of 5

10. Physical and Chemical Properties

Appearance: Pale yellow flakes or congealed mass

11. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: No data available.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

12. Toxicological Information

Toxicological Effects : The toxicological effects of this product have not been thoroughly studied.

Carmustine - Toxicity Data: Oral LD50 (rat): ntraperitoneal LD50 (rat): 17420 ug/kg; Subcutaneous LD50 (rat): 83200 ug/kg; Oral LD50 (mouse): 19 mg/kg; ntraperitoneal LD50 (mouse): 21260 ug/kg; Subcutaneous LD50 (mouse): 24 mg/kg;

Chronic Toxicological Effects : Carmustine - Investigated as a drug, mutagen, reproductive effector, and tumorigen.

Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here.

See actual entry in RTECS for complete information.

Carmustine RTECS Number: YS2625000

13. Disposal Considerations

Dispose off waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

14. Transport Information

DOT Not regulated by U.S. DOT or IATA

15. Regulatory Information

- 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

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MSN Laboratories Private Limited
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SAFETY DATA SHEET		
Product Name	CARMUSTINE FOR INJECTION USP 100 mg/Vial	Page No. 5 of 5

- 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.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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