

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-001

Effective Date: 26th April 2021

Carmustine powder and solvent for injection, 100 mg/vial

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Carmustine powder and solvent for injection, 100 mg/vial

Intended Use:	Multiple Myeloma / Plasma Cell Disorders
Chemical formula:	C ₅ H ₉ Cl ₂ N ₃ O ₂
Details of the Supplier of the Safety Data Sheet	
Manufacturer: Intas Pharmaceuticals Ltd. Plot Numbers 457 and 458 Sarkhej-Bavla Highway Matoda, Sanand, Ahmedabad-382 210, India	Sponsor: Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Usual Chemical Name of the drug used in the Injection	-		
CAS Number for the drug used in the Vials	154-93-8		
Ingredient Contributing to Hazard			
Ingredients of the product	Range/Conc. of drug	Class	Risk Phrases
Bischloroethyl nitrosourea	100 mg	-	-
NFPA Rating of the drug used in the product	-		
Other ingredient of the product*	Bischloroethyl nitrosourea, Dehydrated alcohol (Ethanol anhydrous)		
Route of Entry	intravenous infusion after reconstitution		

SECTION 3 - HAZARDS IDENTIFICATION

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

Harmful Effect of the drug on Health : Fatal if swallowed.

Effects on the Environment : The environmental impact of this product has not been fully investigated.

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Physical & Chemical Hazards : Fatal if swallowed
May cause genetic defects
May cause cancer
May damage fertility or the unborn child

ROUTE OF EXPOSURE

Potential Acute Health Effects : -

Potential Chronic Health Effects : Investigated as a drug, mutagen, reproductive effector, and tumorigenic.

Carcinogenic Effects : Not available.

Mutagenic Effects : Not available.

Teratogenic Effects : Not available.

Developmental Toxicity : Not available.

Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation or skin absorption. May cause cancer. May cause eye, skin, or respiratory system irritation. May damage fertility or the unborn child.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

SECTION 4 - FIRST AID MEASURES

Contact With Skin : Remove all contaminated clothing and rinse area thoroughly with soap and water for 15 minutes; Seek immediate medical assistance and notify supervisor.
Seek medical attention.

Contact With Eyes : Immediately flush eyes thoroughly with water for at least 15 minutes; Seek immediate medical assistance and notify supervisor.

Ingestion : Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately

Inhalation :

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Instruction for the Physician	:	Remove from exposure source; notify medical personnel and supervisor if breathing Difficulties develop. Administer artificial respiration if necessary. Move to fresh air
Protection for first aiders	:	Treat symptomatically. Use personal protective equipment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves

SECTION 5 - FIRE FIGHTING MEASURES

Specific hazards	:	Not available
Fire extinguishing media	:	Use suitable extinguishing media (e.g., water, alcohol foam, dry chemical, CO ₂)
Protection equipment	:	
Eye Protection	:	Safety glasses
Protective Gloves	:	Compatible chemical-resistant gloves
Other Protective Clothing	:	Lab coat Respiratory Equipment NIOSH approved respirator, as conditions warrant.
Other advice	:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions	:	Personnel involved in clean-up should wear appropriate personal. Protective equipment (See Section 8). Minimize exposure
Precautions for environmental Protection	:	Take steps to avoid release into the environment, if safe to do so.
Cleaning methods	:	not available

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SECTION 7 - HANDLING AND STORAGE

- Handling Appropriate technical measures : Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Use only in area provided with appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use.
- Storage Recommended storage conditions : product in a refrigerator (2°- 8°C, 36° - 46°F). Protect from light Store.
- Recommended packaging materials : Glass vials
- Precautions : Not Applicable

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

- Technical measures : Engineering controls should be used as the primary means to control exposures. Use Process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted. Showers Eyewash station ventilation systems.
- Respiratory protection : If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
- Hand protection : Compatible chemical-resistant gloves recommended and refer the Gloves manufacturer permeability data
- Eye protection : Tightly fitting safety goggles
- Body and skin protection : Wear impervious disposable protective clothing when handling this compound

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Specific safety protection : Use Necessary PPE
Exposure limits : Not available

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Size/shape/colour description of the vials or Appearance : Lyophilized pale yellow flakes or congealed mass
Form : No data available
Odor : No data available
Water Solubility : It is highly soluble in alcohol and lipids, and poorly soluble in water
Boiling Point : No data available
Melting Point : No data available
Molecular Weight : 214.06
Vapor Pressure : No data available
Specific gravity : No data available
Percent Volite : No data available
Vapor density : No data available
Evaporation : No data available

SECTION 10 - STABILITY AND REACTIVITY

Stability : Stable under recommended storage conditions.
Conditions to avoid : Protect from light
Materials to avoid : No data available
Hazardous decomposition Products : Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen Oxides (NO_x). Hydrogen chloride

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Incompability : Not known
Hazardous Polymerization : No Data Available

SECTION 11 - TOXICOLOGY INFORMATION

Routes of Entry : Intravenous infusion after reconstitution.
Toxicity to Animals : No Data Available
Chronic Effects on Humans : Prolonged or repeated exposure increases the risk
Possible risks of irreversible effects
Other Toxic Effects on Humans : No Data Available

Special Remarks on Toxicity to Animals :

Species	Route	End Point	Dose
Rat	Oral	LD50	-
Rat	Intraperitoneal	LD50	17420 ug/kg
Rat	Subcutaneous	LD50	83200 ug/kg
Mouse	Oral	LD50	19 mg/kg
Mouse	Intraperitoneal	LD50	21260 ug/kg
Mouse	Subcutaneous	LD50	24 mg/kg

Special Remarks on Chronic Effects on Humans : Investigated as a drug, mutagen, reproductive effector, and tumorigenic.
Special Remarks on other Toxic Effects on Humans : No Data Available

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Persistence / degradation of the drug : No Data Available.
Bioaccumulation : No Data Available
Aquatic Toxicity : No data available

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SECTION 13 - DISPOSAL INFORMATION

Product disposal : This material, as supplied, is not a hazardous waste according to Federal regulations (40CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

SECTION 14 - TRANSPORTATION INFORMATION

Un number: 2811		Packing group: II	
Land	RTMD	Class	6.1 - POISON
Rail	RID/ADR	Class	6.1 - POISON
Sea	IMCO/IMDG	Class	No Data Available
Air	OACI/IATA	Class	6.1 - POISON
River	DON/AONR	Class	No Data Available
UN proper shipping name DOT / IATA		6.1 -POISON	

SECTION 15 - REGULATORY INFORMATION

Eec regulations : No Data Available

Federal and State Regulations : No Data Available

National Fire Protection Association (U.S.A.) : No Data Available

Protective Equipment : Self-contained Breathing apparatus

SECTION 16 - OTHER DATA

Notes:

ACGIH TLV : American Conference of Governmental Industrial Hygienists – Threshold Limit Value

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CAS	:	Chemical Abstracts Service Number
CERCLA	:	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	:	US Department of Transportation Regulations
EEL	:	Employee Exposure Limit
IATA	:	International Air Transport Association
LD50	:	Dosage producing 50% mortality
NIOSH	:	National Institute for Occupational Safety and Health
OSHA PEL	:	US Occupational Safety and Health Administration – Permissible Exposure Limit
TSCA	:	Toxic Substance Control Act
TWA	:	8-hour Time Weighted Average
EC50	:	concentration that causes an effect in 50% of test organisms
LC50	:	concentration that is lethal in 50% of test organisms
NOEC	:	No Observed Effect Concentration

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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