

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Busulfan Injection**
Manufacturer Name: Shilpa Medicare Limited
Address: Formulation Unit
 Plot No: S20 to S24A, Green Industrial Park, Polepally (V), Jadcherla (M),
 Mahaboobnagar Dist., Telangana, 509301
 India
General Phone Number: +91-08532 - 238704
General Fax Number: +91-08532 - 238876
Emergency Phone Number: +91-8532-235876
Distributor Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: October 14, 2019

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER!

GHS Class:

Acute toxicity - Oral, Category 3
 Eye irritation, Category 2A
 Germ cell mutagenicity, Category 2
 Reproductive toxicity, Category 2
 Carcinogenicity, Category 1B

Hazard Statements:

Toxic if swallowed.
 Causes serious eye irritation.
 Suspected of causing genetic defects.
 Suspected of damaging fertility or the unborn child.
 May cause cancer.

Precautionary Statements:

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wash hands thoroughly after handling.
 IF exposed or concerned: Get medical advice/attention.
 Store locked up.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 If eye irritation persists: Get medical advice/attention.
 Store in a well-ventilated place. Keep container tightly closed.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
 Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Use personal protective equipment as required.

Emergency Overview:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:

Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.
Skin: May cause skin irritation.
Inhalation: May cause irritation of respiratory tract.
Ingestion: May cause irritation.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
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N,N-dimethylacetamide (DMA)	127-19-5	33 %	204-826-4
Polyethylene glycol 400 (PEG 400)	25322-68-3	67 %	500-038-2
Busulfan	55-98-1	0.6 %	200-250-2

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition generates: Carbon oxides (CO, CO ₂). Nitrogen and sulfur oxides.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mist. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. When handling pharmaceutical products, avoid all contact and inhalation vapors/mist. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 2°C - 8°C (35.6 - 46.4°F) in a well ventilated area. Keep in container when not using.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapors.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

N,N-dimethylacetamide (DMA) :

Guideline ACGIH:	TWA - TLV: 10 ppm
Guideline NIOSH:	TWA - TLV: 10 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Clear
Odor:	Slight ammonia odor.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	No data available.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not determined.
Molecular Formula:	Mixture
Molecular Weight:	Variable.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Reactivity:	Exothermic reactions occur with carbon tetrachloride and hexachlorocyclohexane. It can react violently in the presence of iron. (DMA)
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	High temperatures
Incompatible Materials:	Strong bases, strong oxidizers, and halogenated compounds in the presence of iron.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, and respiratory irritation may occur.
Acute Effects:	Eye, skin, and respiratory irritation may occur.
Carcinogenicity:	May cause cancer
Mutagenicity:	May cause genetic effects.
Reproductive Toxicity:	May damage fertility or the unborn child.

N,N-dimethylacetamide (DMA) :

RTECS Number:	AB7700000
Skin:	LD50 Dermal - Rabbit - 2240 mg/kg
Inhalation:	LC50 Inhalation - Rat - 8.81 mg/l (1 hr)
Ingestion:	LD50 Oral - Rat - 4263 mg/kg

Polyethylene glycol 400 (PEG 400) :

RTECS Number:	TQ3500000
Skin:	LD50 Dermal - Rabbit - >20ml/kg

Ingestion: LD50 Oral - Rat - 22g/kg

Busulfan :

RTECS Number: EK1750000

Ingestion: LD50-Oral-Rat 19 mg/kg

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

IATA Shipping Name: Non regulated.

IATA UN Number: Non regulated.

IMDG UN Number : Non regulated.

IMDG Shipping Name : Non regulated.

SECTION 15 : REGULATORY INFORMATION

N,N-dimethylacetamide (DMA) :

EC Number: 204-826-4

Polyethylene glycol 400 (PEG 400) :

EC Number: 500-038-2

Busulfan :

EC Number: 200-250-2

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3*

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: X

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