



# SAFETY DATA SHEET

Revision date: 25-Jan-2019

Version: 2.0

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

### Product Identifier

**Material Name:** Busulfan Injection (Hospira, Inc)

**Trade Name:** Not established

**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as Antineoplastic

### Details of the Supplier of the Safety Data Sheet

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Germ Cell Mutagenicity: Category 1B  
Reproductive Toxicity: Category 1B  
Carcinogenicity: Category 1B

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H319 - Causes serious eye irritation  
H350 - May cause cancer  
H360FD - May damage fertility. May damage the unborn child.  
H340 - May cause genetic defects

**Precautionary Statements:** 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  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P405 - Store locked up

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### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Busulfan	55-98-1	200-250-2	Repr. 1B (H360FD) Carc. 1B (H350) Muta. 1B (H340)	< 1
N,N-DIMETHYLACETAMIDE	127-19-5	204-826-4	Repr. 1B (H360D) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Eye Irrit. 2A (H319)	30 - 35

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

## 4. FIRST AID MEASURES

### Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

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Symptoms and Effects of Exposure:  
Medical Conditions Aggravated by Exposure:  
No data available  
None known

Indication of the Immediate Medical Attention and Special Treatment Needed  
Notes to Physician: None

### 5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. 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.

#### Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as Antineoplastic

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### N,N-DIMETHYLACETAMIDE

ACGIH Threshold Limit Value (TWA) 10 ppm

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH - Biological Exposure Limit:	30 mg/g creatinine
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	10 ppm
	36 mg/m <sup>3</sup>
Austria OEL - MAKs	10 ppm
	36 mg/m <sup>3</sup>
Belgium OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Cyprus OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Czech Republic OEL - TWA	30 mg/m <sup>3</sup>
Denmark OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Estonia OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Finland OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
France OEL - TWA	2 ppm
	7.2 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 ppm
	36 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 ppm
	36 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	30 mg/g
Greece OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Hungary OEL - TWA	36 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 ppm
	36 mg/m <sup>3</sup>
Italy OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Latvia OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Luxembourg OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Malta OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Netherlands OEL - TWA	36 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 ppm
	35 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	35 mg/m <sup>3</sup>
Portugal OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Romania OEL - TWA	10 ppm
	36 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	30 µg/g Creatinine
Russia OEL - TWA	1 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	10 ppm 36 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 ppm 36 mg/m <sup>3</sup>
Spain OEL - TWA	10 ppm 36 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	30 mg/g Creatinine
Sweden OEL - TWAs	10 ppm 35 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 ppm 35 mg/m <sup>3</sup>
UK - Biological Exposure Limit:	100 mmol/mol creatinine

#### Polyethylene glycol

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	1000 mg/m <sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

##### Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

##### Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

##### Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**N,N-DIMETHYLACETAMIDE**  
No data available  
**Polyethylene glycol**  
No data available  
**Busulfan**  
No data available  
**Decomposition Temperature (°C):** No data available.  
**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** No data available  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Viscosity:** No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**Known Clinical Effects:** Common adverse effects include seizure myelosuppression, cardiac tamponade, pulmonary dysfunction, fever, headache, loss of strength/exhaustion (prostration), increased heart rate (tachycardia), increase in blood pressure (hypertension), nausea, inflammation of the mouth (stomatitis), vomiting, loss of appetite (anorexia), insomnia, diarrhea, and anxiety. May cause adverse effects on the developing fetus.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### N,N-DIMETHYLACETAMIDE

Rabbit Dermal LD 50 2240 mg/kg  
Rat Inhalation LC50 1H 8.81 mg/L

##### Busulfan

Mouse Oral LD 50 120 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Busulfan**

Embryo / Fetal Development	Rat	Oral	48 mg/kg/day	LOAEL	Teratogenic, Early embryonic development
Reproductive & Fertility	Rat	Oral	49 mg/kg/day	LOAEL	Fertility
Embryo / Fetal Development	Rabbit	Oral	32 mg/kg/day	LOAEL	Teratogenic, Fetotoxicity, Early embryonic development
Embryo / Fetal Development	Mouse	Oral	40 mg/kg/day	LOAEL	Teratogenic, Fetotoxicity, Early embryonic development

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Busulfan**

<i>In Vivo</i> Chromosome Aberration	Rat	Positive
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vivo</i> Direct DNA Damage	Rat Hepatocyte	Positive
Sister Chromatid Exchange	Human Lymphocytes	Positive
Unscheduled DNA Synthesis	Mouse	Positive

**Carcinogen Status:** See below

##### **Busulfan**

**IARC:** Group 1 (Carcinogenic to Humans)  
**NTP:** Known Human Carcinogen

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

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### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of 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 wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Busulfan

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed carcinogen 2/27/1987 developmental toxicity 1/1/1989
Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 4
EU EINECS/ELINCS List	200-250-2

#### N,N-DIMETHYLACETAMIDE

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed developmental toxicity 5/21/2010 male reproductive toxicity 5/21/10
Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Present Schedule 5 Schedule 6
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 30.
REACH - Toxic to Reproduction Category 2: EU EINECS/ELINCS List	Present 204-826-4

#### Polyethylene glycol

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed Not Listed
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### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
	Schedule 3
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Carcinogenicity-Cat.1B; H350 - May cause cancer  
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects  
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.  
Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage.

**Revision date:** 25-Jan-2019  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**