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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

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
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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Busulfan</td>
<td>55-98-1</td>
<td>200-250-2</td>
<td>Repr. 1B (H360FD)</td>
<td>&lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc. 1B (H350)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Muta. 1B (H340)</td>
<td></td>
</tr>
<tr>
<td>N,N-DIMETHYLACETAMIDE</td>
<td>127-19-5</td>
<td>204-826-4</td>
<td>Repr. 1B (H360D)</td>
<td>30 - 35</td>
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<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4 (H312)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4 (H332)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2A (H319)</td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET

Material Name: Busulfan Injection (Hospira, Inc)
Revision date: 25-Jan-2019

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion: 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Organization</th>
<th>Limit Type</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH - Biological Exposure Limit</td>
<td></td>
<td>30 mg/g creatinine</td>
</tr>
<tr>
<td>ACGIH - Skin Absorption Designation</td>
<td></td>
<td>Skin - potential significant contribution to overall exposure by the cutaneous route</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
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<td></td>
<td></td>
<td>36 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>TWA</td>
<td>2 ppm</td>
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<td></td>
<td></td>
<td>7.2 mg/m³</td>
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<td>Germany - TRGS 900 - TWAs</td>
<td>TWA</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td></td>
<td>10 ppm</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Germany - Biological Exposure Limit</td>
<td></td>
<td>30 mg/g</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>TWA</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
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<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
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<td>10 ppm</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>TWA</td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>35 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Skin Notations</td>
<td></td>
<td>prevent or reduce skin absorption</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>TWA</td>
<td>35 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
<tr>
<td>Romania - Biological Exposure Limit</td>
<td></td>
<td>30 µg/g Creatinine</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 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

Material Name: Busulfan Injection (Hospira, Inc)

Solvent Solubility: No data available.
Water Solubility: No data available.
pH: No data available.

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

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL - TWAs 1000 mg/m³

Slovakia OEL - TWA 10 ppm
36 mg/m³
Slovenia OEL - TWA 10 ppm
36 mg/m³
Spain OEL - TWA 10 ppm
36 mg/m³
Spain - Biological Exposure Limit: 30 mg/g Creatinine
Sweden OEL - TWAs 10 ppm
35 mg/m³
Switzerland OEL - TWAs 10 ppm
35 mg/m³
UK - Biological Exposure Limit: 100 mmol/mol creatinine

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL - TWAs 1000 mg/m³

Exposure Controls

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.
SAFETY DATA SHEET

Material Name: Busulfan Injection (Hospira, Inc)
Revision date: 25-Jan-2019
Page 6 of 9
Version: 2.0

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:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): 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
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
In Vivo Chromosome Aberration Rat Positive
Bacterial Mutagenicity (Ames) Salmonella Positive
In Vivo 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
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: Not Listed
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 200-250-2

N,N-DIMETHYLACETAMIDE
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Developmental toxicity 5/21/2010, male reproductive toxicity 5/21/10
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- REACH - Toxic to Reproduction Category 2: Present
- EU EINECS/ELINCS List: 204-826-4

Polyethylene glycol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
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 |
| 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

Prepared by: Product Stewardship Hazard Communication

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