1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Cisplatin Injection

| Trade Name: | Not applicable |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical product used as Antineoplastic |

2. HAZARDS IDENTIFICATION

Appearance: Aqueous sterile solution
Signal Word: DANGER

Statement of Hazard: May cause cancer. May cause genetic defects.

Additional Hazard Information:
- **Short Term:** May cause eye and skin irritation (based on components) May be fatal if swallowed
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys and blood and blood forming organs Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Mutagenic: Category 2 Carcinogenic: Category 2

EU Hazard Symbols: T

EU Risk Phrases: R45 - May cause cancer. R46 - May cause heritable genetic damage.

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisplatin</td>
<td>15663-27-1</td>
<td>239-733-8</td>
<td>Repr.Cat.2;R61</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mut.Cat.2;R46</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc.Cat.2;R45</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T;R25</td>
<td></td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35</td>
<td>**</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>**</td>
</tr>
</tbody>
</table>

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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

7. HANDLING AND STORAGE

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Cisplatin
- **Pfizer OEL TWA-8 Hr:** 2µg/m³
- **ACGIH Threshold Limit Value (TWA):** 0.002 mg/m³ TWA
- **Australia TWA:** 0.002 mg/m³
- **Austria OEL - MAKs:** Listed
- **Belgium OEL - TWA:** Listed
- **Czech Republic OEL - TWA:** Listed
- **Denmark OEL - TWA:** Listed
- **Finland OEL - TWA:** Listed
- **Ireland OEL - TWAs:** Listed
- **Netherlands OEL - TWA:** Listed
- **OSHA - Final PELS - TWAs:** 0.002 mg/m³
- **Portugal OEL - TWA:** Listed
- **Romania OEL - TWA:** Listed
- **Slovenia OEL - TWA:** Listed

Sodium chloride
- **Latvia OEL - TWA:** Listed
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Material Name:** Cisplatin Injection  
**Revision date:** 30-Mar-2011  
**Version:** 1.0

<table>
<thead>
<tr>
<th><strong>Engineering Controls:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Analytical Method:</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Analytical method available for cisplatin. Contact Pfizer Inc for further information.</td>
<td></td>
</tr>
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</table>

#### Hydrochloric Acid

<table>
<thead>
<tr>
<th><strong>ACGIH Ceiling Threshold Limit:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Austria OEL - MAKs</strong></th>
<th>Listed</th>
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</thead>
<tbody>
<tr>
<td><strong>Belgium OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Bulgaria OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Cyprus OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Czech Republic OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Estonia OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Germany - TRGS 900 - TWAs</strong></td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Germany (DFG) - MAK</strong></th>
<th>2 ppm MAK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.0 mg/m³ MAK</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Greece OEL - TWA</strong></th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hungary OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Ireland OEL - TWAs</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Italy OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Japan - OELs - Ceilings</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Latvia OEL - TWA</strong></th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lithuania OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Luxembourg OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Malta OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Netherlands OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Poland OEL - TWA</strong></td>
<td>Listed</td>
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<tr>
<td><strong>Romania OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Slovenia OEL - TWA</strong></td>
<td>Listed</td>
</tr>
<tr>
<td><strong>Spain OEL - TWA</strong></td>
<td>Listed</td>
</tr>
</tbody>
</table>

#### Sodium hydroxide

<table>
<thead>
<tr>
<th><strong>ACGIH Ceiling Threshold Limit:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>Listed</td>
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<tr>
<td>Bulgaria OEL - TWA</td>
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<td>Czech Republic OEL - TWA</td>
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<td>Estonia OEL - TWA</td>
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<td>France OEL - TWA</td>
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<tr>
<td>Greece OEL - TWA</td>
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<tr>
<td>Hungary OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>Listed</td>
</tr>
</tbody>
</table>

**Version:** 1.0

**Page 4 of 9**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Sterile solution
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

**Cisplatin**
- Rat Oral LD50 25.8 mg/kg
- Rat Para-periosteal LD50 8.0 mg/kg
- Mouse Oral LD50 32.7 mg/kg
- Mouse Intravenous LD50 11 mg/kg

**Sodium hydroxide**
- Mouse IP LD50 40 mg/kg

**Sodium chloride**
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD50 4000 mg/kg

**Mannitol**
- Rat Oral LD50 13500 mg/kg
- Mouse Oral LD50 22 g/kg
11. TOXICOLOGICAL INFORMATION

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

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation Rabbit  Severe

Hydrochloric Acid
Skin Irritation  Severe
Eye Irritation  Severe

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Cisplatin
5 Day(s)  Dog  Intravenous  0.75 mg/kg/day  LOAEL  Kidney
5 Day(s)  Non-human Primate  Intravenous  2.5 mg/kg/day  LOAEL  Kidney
5 Day(s)  Non-human Primate  Intravenous  1.25 mg/kg/day  LOAEL  Kidney
5 Week(s) Non-human Primate  Intravenous  0.625 mg/kg/day  LOAEL  Kidney
11 Week(s) Rat  Intraperitoneal  1 mg/kg/day  LOAEL  Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cisplatin
Embryo / Fetal Development Mouse Intraperitoneal  3 mg/kg  LOAEL  Fetotoxicity, Teratogenic
Embryo / Fetal Development Rat Intraperitoneal  0.5 mg/kg  LOAEL  Fetotoxicity, Developmental toxicity
Embryo / Fetal Development Rabbit Intraperitoneal  0.125 mg/kg  LOAEL  Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal  0.25 mg/kg/day  LOAEL  Fetotoxicity, Developmental toxicity
Embryo / Fetal Development Rat Intravenous  0.375 mg/kg/day  LOAEL  Fetotoxicity

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

Cisplatin
In Vitro Chromosome Aberration  Human Lymphocytes  Positive
In Vivo Chromosome Aberration  Mouse Bone Marrow  Positive
Bacterial Mutagenicity (Ames)  Salmonella  Positive
Dominant Lethal Assay  Positive
In Vivo Sister Chromatid Exchange  Mouse Bone Marrow  Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cisplatin
8 Month(s)  Mouse  Intraperitoneal  1.62 mg/kg/week  LOAEL  Lungs, Tumors
52 Week(s) Mouse  Intraperitoneal  1.62 mg/kg/week  LOAEL  Skin, Tumors
15 Month(s) Rat  Intraperitoneal  1 mg/kg (3x/week)  LOAEL  Bone marrow, Kidneys, Malignant tumors

Carcinogen Status: See below

Cisplatin
IARC:  Group 2A - Probably Carcinogenic to Humans
11. TOXICOLOGICAL INFORMATION

- NTP: Listed
- OSHA: Present

Hydrochloric Acid

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

- EU Symbol: T
- EU Indication of danger:
  - Mutagenic: Category 2
  - Carcinogenic: Category 2
- EU Risk Phrases:
  - R45 - May cause cancer.
  - R46 - May cause heritable genetic damage.

- EU Safety Phrases:
  - S22 - Do not breathe dust.
  - S53 - Avoid exposure - obtain special instructions before use.
  - S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

DANGER
May cause cancer.
May cause genetic defects.
### 15. REGULATORY INFORMATION

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

#### Cisplatin

- **California Proposition 65**
  - Listed: Cancer
- **Inventory - United States TSCA - Sect. 8(b)**
  - Listed
- **Australia (AICS):**
  - Listed
- **Standard for the Uniform Scheduling for Drugs and Poisons:**
  - Schedule 4
- **EU EINECS/ELINCS List**
  - 239-733-8

#### Sodium chloride

- **Inventory - United States TSCA - Sect. 8(b)**
  - Listed
- **Australia (AICS):**
  - Listed
- **EU EINECS/ELINCS List**
  - 231-598-3

#### Hydrochloric Acid

- **CERCLA/SARA 313 Emission reporting**
  - 1.0% de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size

#### CERCLA/SARA Hazardous Substances and their Reportable Quantities:

- **CERCLA/SARA - Section 302 Extremely Hazardous TPQs**
  - 5000 lb final RQ
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**
  - 500 lb TPQ gas only

#### Water for Injection

- **Inventory - United States TSCA - Sect. 8(b)**
  - Listed
- **Australia (AICS):**
  - Listed
- **REACH - Annex IV - Exemptions from the obligations of Register:**
  - Present
- **EU EINECS/ELINCS List**
  - 231-791-2

#### Mannitol

- **Inventory - United States TSCA - Sect. 8(b)**
  - Listed
- **Australia (AICS):**
  - Listed
- **REACH - Annex IV - Exemptions from the obligations of Register:**
  - Present
15. REGULATORY INFORMATION

| Inventory - United States TSCA - Sect. 8(b) | Listed |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | 200-711-8 |

Sodium hydroxide

| CERCLA/SARA Hazardous Substances | 1000 lb final RQ |
| and their Reportable Quantities: | 454 kg final RQ |

Australia (AICS):

| Listed |
| Schedule 5 |
| Schedule 6 |

| EU EINECS/ELINCS List | 215-185-5 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.
R25 - Toxic if swallowed.
R35 - Causes severe burns.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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