



# MATERIAL SAFETY DATA SHEET

Revision date: 30-Mar-2011

Version: 1.0

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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New York, New York 10017  
1-212-573-2222

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Pfizer Ltd**  
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**Sandwich, Kent**  
**CT13 9NJ**  
**United Kingdom**  
**+00 44 (0)1304 616161**  
**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

### Material Name: Cisplatin Injection

<b>Trade Name:</b>	Not applicable
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	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:

<b>Short Term:</b>	May cause eye and skin irritation (based on components) May be fatal if swallowed
<b>Long Term:</b>	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:



### EU Risk Phrases:

R45 - May cause cancer.  
R46 - May cause heritable genetic damage.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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## 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cisplatin	15663-27-1	239-733-8	Repr.Cat.2;R61 Mut.Cat.2;R46 Carc.Cat.2;R45 T;R25	0.1
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*

**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.

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**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/m <sup>3</sup>
ACGIH Threshold Limit Value (TWA)	0.002 mg/m <sup>3</sup> TWA
Australia TWA	0.002 mg/m <sup>3</sup>
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/m <sup>3</sup>
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed

#### Sodium chloride

Latvia OEL - TWA	Listed
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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA Listed

### Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm  
Australia PEAK 5 ppm  
7.5 mg/m<sup>3</sup>  
Austria OEL - MAKs Listed  
Belgium OEL - TWA Listed  
Bulgaria OEL - TWA Listed  
Cyprus OEL - TWA Listed  
Czech Republic OEL - TWA Listed  
Estonia OEL - TWA Listed  
Germany - TRGS 900 - TWAs 2 ppm  
3 mg/m<sup>3</sup>  
Germany (DFG) - MAK 2 ppm MAK  
3.0 mg/m<sup>3</sup> MAK  
Greece OEL - TWA Listed  
Hungary OEL - TWA Listed  
Ireland OEL - TWAs Listed  
Italy OEL - TWA Listed  
Japan - OELs - Ceilings 5 ppm  
7.5 mg/m<sup>3</sup>  
Latvia OEL - TWA Listed  
Lithuania OEL - TWA Listed  
Luxembourg OEL - TWA Listed  
Malta OEL - TWA Listed  
Netherlands OEL - TWA Listed  
Poland OEL - TWA Listed  
Romania OEL - TWA Listed  
Slovenia OEL - TWA Listed  
Spain OEL - TWA Listed

### Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m<sup>3</sup>  
Australia PEAK 2 mg/m<sup>3</sup>  
Austria OEL - MAKs Listed  
Bulgaria OEL - TWA Listed  
Czech Republic OEL - TWA Listed  
Estonia OEL - TWA Listed  
France OEL - TWA Listed  
Greece OEL - TWA Listed  
Hungary OEL - TWA Listed  
Japan - OELs - Ceilings 2 mg/m<sup>3</sup>  
Latvia OEL - TWA Listed  
OSHA - Final PELs - TWAs: 2 mg/m<sup>3</sup>  
Poland OEL - TWA Listed  
Slovenia OEL - TWA Listed  
Sweden OEL - TWAs Listed

### Analytical Method:

Analytical method available for cisplatin. Contact Pfizer Inc for further information.

### 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.



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### 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 LOEL Kidney  
5 Day(s) Non-human Primate Intravenous 2.5 mg/kg/day LOEL Kidney  
5 Day(s) Non-human Primate Intravenous 1.25 mg/kg/day LOEL Kidney  
5 Week(s) Non-human Primate Intravenous 0.625 mg/kg/day LOEL Kidney  
11 Week(s) Rat Intraperitoneal 1 mg/kg/day LOEL Kidney

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

##### **Cisplatin**

Embryo / Fetal Development Mouse Intraperitoneal 3 mg/kg LOEL Fetotoxicity, Teratogenic  
Embryo / Fetal Development Rat Intraperitoneal 0.5 mg/kg LOEL Fetotoxicity, Developmental toxicity  
Embryo / Fetal Development Rabbit Intraperitoneal 0.125 mg/kg LOEL Fetotoxicity  
Embryo / Fetal Development Rat Intraperitoneal 0.25 mg/kg/day LOEL Fetotoxicity, Developmental toxicity  
Embryo / Fetal Development Rat Intravenous 0.375 mg/kg/day LOEL 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 LOEL Lungs, Tumors  
52 Week(s) Mouse Intraperitoneal 1.62 mg/kg/week LOEL Skin, Tumors  
15 Month(s) Rat Intraperitoneal 1 mg/kg (3x/week) LOEL Bone marrow, Kidneys, Malignant tumors

**Carcinogen Status:** See below

##### **Cisplatin**

**IARC:** Group 2A - Probably Carcinogenic to Humans

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## 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.

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## 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:	2270 kg final RQ
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
Inventory - United States TSCA - Sect. 8(b)	5000 lb
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	231-595-7

### 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



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## 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 200-711-8

### Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	454 kg final RQ
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Listed
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	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**