MATERIAL SAFETY DATA SHEET

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

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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:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Cisplatin Solution for Injection - 0.5 and 1 mg/ml

Trade Name: Platamine; Cisplatino; Cisplatine; Platiblastin; Plastisil; Platiblastin S
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Cisplatin	15663-27-1	239-733-8	0.1
Hydrochloric Acid	7647-01-0	231-595-7	**
Sodium hydroxide	1310-73-2	215-185-5	**

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water for Injection	7732-18-5	231-791-2	*
Mannitol	69-65-8	200-711-8	*

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

3. HAZARDS IDENTIFICATION

Appearance: Clear to light yellow solution - 0.5 mg/ml
Clear solution - 1 mg/ml
Signal Word: WARNING

Statement of Hazard: Possible carcinogen and mutagen
Additional Hazard Information:
Short Term: May cause eye and skin irritation; May be fatal if swallowed (based on components)
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:

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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: Not applicable

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: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

Storage Conditions: Store at controlled room temperature. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Cisplatin

OSHA - Final PELS - TWAs:	= 0.002 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 0.002 mg/m^3 TWA = 1 mg/m^3 TWA
Australia TWA	= 0.002 mg/m^3 TWA = 1 mg/m^3 TWA

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak = 7.5 mg/m^3 Peak

Sodium hydroxide

OSHA - Final PELS - TWAs:	2 mg/m^3
ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak

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. Local exhaust ventilation is required unless used in a closed system.

Personal Protective Equipment:

Hands:	Rubber gloves
Eyes:	Safety glasses or goggles
Skin:	Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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	**Color:**	Clear to Light yellow (0.5 mg/ml); clear (1 mg/ml)
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known
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 LD 50 25.8 mg/kg
Rat Intravenous LD 50 8.0 mg/kg
Mouse Oral LD 50 32.7 mg/kg
Mouse Intravenous LD 50 11 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

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

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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
NTP: Reasonably Anticipated To Be A Carcinogen
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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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:
WARNING
Possible carcinogen and mutagen

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)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	239-733-8

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS 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 = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only

CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet