

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION		
<i>Product Information</i>		
Product name	Platinol-AQ	
Version	2.0, 07/03/2007	
Jurisdiction	This Material Safety Data Sheet was prepared for the jurisdiction USA.	
Chemical Name	Cis-Diamminedichloroplatinum	
Active substance	Cisplatin	
Synonyms	Cisplatin; BMY 25936	
Product Uses	Used to treat certain neoplastic diseases.	
<i>Company/Undertaking Identification</i>		
Address	Bristol-Myers Squibb Company P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-732-227-7380	
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergencies call CHEMTREC at 1-703-527-3887. Collect calls accepted.	
2. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Concentration	CAS-No.
<i>Hazardous components</i>		
Cisplatin	0.1 %	15663-27-1
<i>Other ingredients</i>		
Water	> 1 %	7732-18-5
Sodium Chloride	<1 %	7647-14-5
Other information: Hydrochloric acid is used for pH adjustment Sodium hydroxide is used for pH adjustment		
3. HAZARDS IDENTIFICATION		
<i>Emergency Overview</i>		
Appearance	liquid : clear colourless or blue	
Signal Word	Danger	
Hazard Statements	May cause cancer. May cause heritable genetic damage. May impair fertility. May cause harm to the unborn child. May cause harm to breastfed babies. Target Organs: kidney, bone marrow, gastrointestinal tract, ears, embryo/fetus, peripheral nervous system.	
Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure. Pregnant or nursing women should avoid exposure.	
<i>Potential Health Effects</i>		
Eyes	Possible mild eye irritant	

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3. HAZARDS IDENTIFICATION

Skin	May cause sensitization by skin contact.
Ingestion	Danger of serious damage to health by prolonged exposure.
Inhalation	May cause sensitization by inhalation.
Target Organs	kidney, bone marrow, gastrointestinal tract, ears, embryo/fetus, peripheral nervous system
Signs and Symptoms	Acute: allergic reactions, sneezing, cough, asthma, congestion, rash, redness and swelling of eyes, breathing difficulties, chest pain, gastrointestinal discomfort, hearing loss, ringing in ears, numbness, uncontrolled muscle movements, seizure disorders, confusion, vision changes, blurred vision, kidney toxicity, electrolyte disturbance, bone marrow suppression, decreased red blood cell count, anaphylaxis, increased liver enzymes, increase in blood pressure, heart attack, diabetes, changes in clinical chemistry parameters, sperm abnormalities, hair loss, decreased white blood cell count. Chronic: kidney failure, lowered blood pressure.
Medical conditions aggravated include:	kidney disorders, hearing loss, bone marrow suppression
<i>Environmental Effects</i>	Not available

4. FIRST AID MEASURES

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Wash contaminated clothing before re-use.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.
Notes to physician	Used to treat certain neoplastic diseases. This product may cause: allergic reactions, sneezing, cough, asthma, congestion, rash, redness and swelling of eyes, breathing difficulties, chest pain, gastrointestinal discomfort, hearing loss, ringing in ears, numbness, uncontrolled muscle movements, seizure disorders, confusion, vision changes, blurred vision, kidney toxicity, electrolyte disturbance, bone marrow suppression, decreased red blood cell count, anaphylaxis, increased liver enzymes, increase in blood pressure, heart attack, diabetes, changes in clinical chemistry parameters, sperm abnormalities, hair loss, decreased white blood cell count, kidney failure, lowered blood pressure, Organs effected may include: kidney, bone marrow, gastrointestinal tract, ears, embryo/fetus, peripheral nervous system. Medical conditions aggravated include: kidney disorders, hearing loss, bone marrow suppression. This product has been reported to interact with the following medications: aminoglycosides, other nephrotoxic medications, antineoplastic agents. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.

4. FIRST AID MEASURES

Medical Surveillance	<p>A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: lung function test, a blood test for kidney function, a blood test for liver function, a blood test for thyroid function, EKG. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered.</p> <p>Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.</p>
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5. FIRE-FIGHTING MEASURES

Flammable Properties	Not available
Extinguishing Media	<p>Suitable extinguishing media: Dry chemical, Water spray, Foam</p> <p>Unsuitable extinguishing media: Do NOT use water jet.</p>
Protection of Firefighters	<p>Specific hazards: Carcinogen Teratogen</p> <p>Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.</p> <p>Hazardous Combustion Products: Gaseous hydrogen chloride (HCl), nitrogen oxides (NOx), platinum containing compounds</p>
Other information:	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE

Handling Precautions	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Store at room temperature. (15 - 25°C) Protect against light. Keep away from heat, sparks and flames. Avoid freezing and refrigeration.
Container Requirements	Store in glass vials. Store in non- aluminum container. Store in spill containment pallet or other device to confine spills.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Cisplatin	0.02 µg/m3 Sensitizer			
Exposure Control Band	<u>Cisplatin</u> <i>5sc</i> -- The established company exposure guideline falls within Exposure Control Band 5, Special Case (range < 0.1 µg/m3).			
Bristol-Myers Squibb Exposure Guidelines Summary	<u>Cisplatin</u> Materials require particular care and handling. Adherence to this guideline should protect employees from experiencing the therapeutic and/or adverse effects of this drug.			
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-7368. See Section 4 "Notes to Physician" for information on medical surveillance.			
Engineering Controls and Ventilation	Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.			
Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. If the occupational exposure limit(OEL) is exceeded, wear appropriate respiratory protection with a protection factor sufficient to control exposures to below the OEL. Note: May cause sensitization by inhalation.			
Eye protection	Chemical splash resistant goggles should be worn when potential for splash exists.			
Hand protection	Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. Disposable chemotherapy gloves made from nitrile, neoprene, polyurethane and natural latex have been shown to have low permeability to many chemotherapy agents. Persons who are allergic to natural rubber latex should select gloves made from one of the other materials. Check gloves frequently to ensure that there are no small cuts or holes. Change gloves frequently, and remove immediately after overt contamination. Use care when removing and disposing of gloves in order to minimize exposure. If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Wear double gloves and disposable wrist gauntlets unless working in a glove box. Skin should be washed after contact.			
Skin and body protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place.			
Hygiene	Wash hands and face before breaks and immediately after handling the product.			

9. PHYSICAL AND CHEMICAL PROPERTIES*Appearance*

Physical State	liquid
Color	clear colourless or blue
Form	Not available

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9. PHYSICAL AND CHEMICAL PROPERTIES*Descriptive properties*

Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Chemical Name	Cis-Diamminedichloroplatinum
Evaporation rate	(similar to water)
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	Not available
Odor Threshold	Not available
pH	3.7 - 6
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	Not available
Viscosity	similar to water

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available

Vapor Properties

Vapor Density	Water vapor has a vapor density less than 1. The water portion of this material is less dense than air. The other constituents should have a vapor density greater than 1 (heavier than air).
Vapor Pressure	similar to water
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY*Stability*

Chemical Stability	Stable under normal conditions. Aluminum reacts with material, causing precipitate formation and a loss of potency.
Conditions to avoid	Not available
Incompatible products	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: Gaseous hydrogen chloride (HCl)., nitrogen oxides (NOx), platinum containing compounds
Hazardous reactions	None known.

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11. TOXICOLOGICAL INFORMATION				
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact			
Eye irritation	<u>Cisplatin</u> Severely irritating to eyes.			
Skin irritation	<u>Cisplatin</u> Mildly and/or transiently irritating to skin.			
Respiratory Irritation	<u>Cisplatin</u> Respiratory sensitizer			
Sensitisation	<u>Cisplatin</u> See "Human Experience". Dermal sensitizer.			
Acute Toxicity Study	Acute Oral <u>Cisplatin</u> LD50(rat): 25.8 mg/kg			
Repeated dose toxicity	<u>Cisplatin</u> Assessment Repeat Dose Toxicity Several studies were conducted. See Section 11 Target Organs and Symptoms for a description of effects. See "Human Experience".			
Genetic Toxicity	<u>Cisplatin</u> Mutagenicity Assessment This material was positive in a battery of in vivo and in vitro genotoxicity assays.			
Carcinogenicity	<u>Cisplatin</u> Carcinogenicity Assessment This material was a carcinogen in animal studies. This material is considered to be a possible human carcinogen. Some secondary cancers developed in persons with other cancers who were treated with this drug, either alone or in combination with other anticancer drugs. It is not known whether these were a result of the treatment with this drug, with one of the other drugs, or a result of progression of the underlying disease. See Human Experience.			
Carcinogenicity	ACGIH	OSHA	NTP	IARC
Cisplatin	--	Listed	Listed	2A
Reproductive Toxicity	<u>Cisplatin</u> Assessment Reproductive Toxicity Animal studies indicate that reproductive effects can occur. May impair fertility. (male) Paternal exposure has been reported to cause adverse effects on the embryo/fetus. See "Human Experience".			

11. TOXICOLOGICAL INFORMATION

Developmental Toxicity	<p><u>Cisplatin</u> Developmental Toxicity Assessment This material has been shown to cross the placenta. May be harmful to fetus. Fetal and postnatal exposure has been reported to cause pharmacological effects on the neonate. This compound and/or its metabolites may be excreted into the milk. See "Human Experience".</p>
Human experience	<p>Experiences with Human Exposure <u>Cisplatin</u> Incident report(s) worker exposure - Symptoms: allergic reactions, sneezing, cough, asthma, Irritating to respiratory system., congestion, rash, rash, redness and swelling of skin, breathing difficulties, chest pain. therapeutic use - Symptoms: gastrointestinal disturbance, nausea, vomiting, diarrhoea, decreased urine volume, thirst, taste disturbance, hearing loss, ringing in ears, numbness, tingling, uncontrolled muscle movements, seizure disorders, confusion, vision changes, Blurred vision, rash, redness and swelling of skin. Other effects include: kidney toxicity, kidney failure, electrolyte disturbance, bone marrow suppression, decreased red blood cell count, anaphylaxis, increased liver enzymes, increase in blood pressure, lowered blood pressure, heart attack, diabetes, changes in clinical chemistry parameters, sperm abnormalities. Incident report(s) therapeutic use - Pharmacological effects include: adverse effects on the newborn, hair loss, hearing loss, decreased white blood cell count. Fetal and postnatal exposure has been reported to cause pharmacological effects on the neonate.</p>
Target Organs	<p><u>Cisplatin</u> kidney, bone marrow, gastrointestinal tract, ears, embryo/fetus, peripheral nervous system</p>
Symptoms	Not available
Other Toxicity Information	Not available

12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic)	Not available
Ecotoxicological Information (Terrestrial)	Not available
Chemical fate information	Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation.

15. REGULATORY INFORMATION

United States of America

OSHA Hazard Classification	Carcinogen, Mutagen, Reproductive toxicant, Developmental toxicant, Target Organs.
313 Toxic Release Inventory. Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
TSCA Inventory	yes
California Prop. 65	Carcinogen

International

Canada

WHMIS	Final products in consumer packaging are exempt from this regulatory requirement. D2A Very Toxic Material Causing Other Toxic Effects
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DSL/NDSL	Not listed.
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Mexico

Mexico Classification	Health classification - Serious Hazard - 3 - Substances that can cause serious or permanent harm under emergency conditions
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Europe

EINECS/ELINCS Number	Cisplatin: 239-733-8 Water: 231-791-2 Sodium Chloride: 231-598-3
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R-phrases(s)	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.
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16. OTHER INFORMATION

MSDS preparation information

Prepared by	Corporate Quality, Environmental Health & Safety 1-732-227-7380
Prepared on	07/03/2007

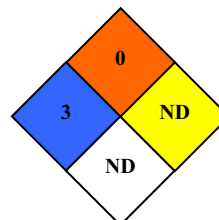
This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): 3, 5, 7, 8, 9, 10, 11, 12, 15, and 16.

Other information

HMIS	Health	3*
	Flammability	0
	Reactivity	Not Determined (ND)
	Personal protective equipment	See Section 8.

NFPA

Health	3
Fire	0
Reactivity	ND
Special	ND



The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.