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**SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

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<b>Additional Address</b>	<p>Sindan Pharma Ion Mihalache Blvd, 11 011171 Bucharest 1 Romania Tel: (+40) 21 318 17 67 Fax: (+40) 21 312 44 99</p>
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<b>Product identifier</b>	Carboplatin 10 mg/mL
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<b>Synonyms</b>	None identified
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<b>Trade names</b>	None identified
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<b>Chemical family</b>	Mixture - contains carboplatin, a cytotoxic agent
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<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical product/Formulated pharmaceutical product packaged in final form and intended for the final user
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<b>Note</b>	The toxicological and ecological properties of this mixture and/or its ingredients have not been fully characterized. This SDS will be revisited as more data become available.
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<b>Issue Date</b>	6 January 2011
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**SECTION 2 - HAZARDS IDENTIFICATION**

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<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.</b> Please consult the prescribing/packaging information. <b>The classification and labelling listed below is for bulk Carboplatin 10 mg/mL.</b>
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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**Regulation (EC) 1272/2008 [GHS]** Irritant (skin) - Category 2. Irritant (eye) - Category 2. Respiratory sensitizer - Category 1. Skin Sensitizer - Category 1. Germ Cell Mutagenicity - Category 1B. Carcinogenic - Category 2. Reproductive Toxicity - Category 1B. Specific Target Organ Toxicity (repeated exposure) - Category 1.

**Directive 67/548/EEC or 1999/45/EC** T - R48/25, R36/38, R42/43, R40 (Carc. Cat. 3), R46 (Muta. Cat. 2), R60 (Repr. Cat. 2), R61 (Repr. Cat. 2)

**Label elements****CLP/GHS hazard pictogram****CLP/GHS signal word**

Danger

**CLP/GHS hazard statements**

H315 - Causes skin irritation. H319 - Causes serious eye irritation. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317 - May cause allergic skin reaction. H340 - May cause genetic defects. H351 - Suspected of causing cancer. H360FD - May damage fertility. May damage the unborn child. H372 - Causes damage to bone marrow, hematological system, kidney, reproductive system, gastrointestinal tract and nervous system through prolonged or repeated exposure.

**CLP/GHS precautionary statements**

P201 - Obtain special instructions before use. P260 - Do not breathe mist/vapors/spray. P281 - Use personal protective equipment as required. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 - If exposed or concerned: get medical advice/attention. P337 + P313 - If eye irritation persists: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P362 - Take off contaminated clothing and wash before reuse. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**EU symbol/indication of danger**

T- Toxic.

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## SECTION 2 - HAZARDS IDENTIFICATION ...continued

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<b>Risk (R) Phrase(s)</b>	R36/38 - Irritating to eyes and skin. R48/25 - Toxic: Danger of serious damage to health by prolonged exposure if swallowed. R42/43 - May cause sensitization by inhalation and skin contact. R40 - Limited evidence of a carcinogenic effect. R46 - May cause heritable genetic damage. R60 - May impair fertility. R61 - May cause harm to the unborn child.
<b>Safety Advice</b>	S23 - Do not breathe spray. S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - Obtain special instructions before use.
<b>Other hazards</b>	<p>Contains carboplatin, a cytotoxic agent. The dose-limiting adverse effect seen with therapeutic use of carboplatin is myelosuppression. Other adverse effects may include hematological toxicity, gastrointestinal toxicity, nephrotoxicity, peripheral neurotoxicity, electrolyte disturbance, hearing loss and increased liver enzymes. Additionally, allergic reactions (including anaphylactic-type reactions) have been reported and may occur within minutes of therapeutic administration. Allergic reactions following occupational exposures to soluble platinum salts have also been reported. Carboplatin can also cause eye/skin/respiratory tract irritation. Secondary malignancies have been reported in association with multi-drug therapy.</p> <p>There are scientific studies that suggest personnel (<i>e.g.</i>, nurses, pharmacists) who prepare and administer parenteral antineoplastics may be at some risk due to potential mutagenicity, adverse effects on reproduction and/or carcinogenicity if these materials in the workplace if exposures are not properly controlled. The actual risk in the workplace is not known.</p>
<b>US Signal word</b>	Danger
<b>US Hazard overview</b>	Contains the cytotoxic drug, carboplatin. Causes eye/skin irritation. May cause respiratory tract irritation. May cause allergic skin/respiratory reaction. Harmful if swallowed. May cause myelosuppression, hematological toxicity, gastrointestinal toxicity, nephrotoxicity, nervous system toxicity and reproductive organ toxicity. Genotoxic. Possible cancer hazard - Contains material which may cause cancer.Reproductive/Developmental Hazard - May adversely affect the developing fetus or cause adverse reproductive effects. Birth Defect Hazard - May cause birth defects.
<b>Note</b>	This mixture is classified as dangerous/hazardous according to directive 1999/45/EC, Regulation (EC) No 1272/2008 (EU CLP) and applicable US regulations. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. See Section 16 for full text of EU and GHS classifications.

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### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Carboplatin	41575-94-4	255-446-0	~1%	Toxic - T: R22, R36/38, R42/43, R40, R46, R60, R61, R48/25	ATO4: H302; SI2: H315; EI2: H319; RS1: H334; SS1: H317; GCM1B: H340; Carc2: H351; RT1B: H360FD; STOT- R1: H372

**Note** The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

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### SECTION 4 - FIRST AID MEASURES

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**Description of first aid measures**

**Immediate Medical Attention Needed**

Yes

**Eye Contact**

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

**Skin Contact**

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

**Inhalation**

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

**Ingestion**

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Protection of first aid responders**

See Section 8 for Exposure Controls/Personal Protection recommendations.

**Most important symptoms and effects, both acute and delayed**

See Sections 2 and 11.

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## SECTION 4 - FIRST AID MEASURES ...continued

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<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Contains the cytotoxic agent, carboplatin. Medical conditions aggravated by exposure: Myelosuppression. Renal impairment Hypersensitivity to carboplatin or platinum-containing compounds. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.
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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and platinum-containing compounds.
<b>Flammability/Explosivity</b>	No information identified. High concentrations of finely divided organic particles can explode if ignited.
<b>Advice for firefighters</b>	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/vapors/spray.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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<b>Precautions for safe handling</b>	If vials are crushed or broken, drug substance may be released into the air. Minimize generation and accumulation of airborne material. Follow recommendations for handling bulk formulated/packaged cytotoxic pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing vapor or mist. Do not permit eating/drinking/smoking near this material. Wash thoroughly after handling. All materials used for transferring or preparing this product must be considered contaminated and disposed of properly.
<b>Conditions for safe storage including any incompatibilities</b>	Store at controlled room temperature (15-30°C) away from incompatible materials. Avoid freezing and refrigeration. Protect against light. Keep away from heat and sources of ignition. Store locked up. Store in sealed containers that are appropriately labeled.
<b>Specific end use(s)</b>	No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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**Note** Dispose of broken vials/syringes in a sharps container.

**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Carboplatin	ACGIH, OSHA, NIOSH	OEL-TWA 8-Hr	0.002 mg/m <sup>3</sup> (soluble salts, as platinum)

**DNELs/PNECs** None identified.

**Exposure/Engineering controls** If handling bulk product or vials are opened/crushed/broken: Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

**Respiratory protection** If handling bulk product or vials are opened/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly worn powered air-purifying respirator equipped with appropriate HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Clear liquid
<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	5-7
<b>Melting point/ freezing point</b>	~0°C
<b>Initial boiling point and boiling range</b>	~100°C
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES** ...continued

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<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Completely miscible
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	Approximately the same as water
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	~371.2 (carboplatin)
<b>Molecular formula</b>	C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>4</sub> Pt (carboplatin)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Stable under recommended storage conditions. Aluminum reacts with material causing precipitate formation and loss of potency. Pharmacological stability not guaranteed beyond expiration date imprinted on package.
<b>Possibility of hazardous reactions</b>	No information identified.
<b>Conditions to avoid</b>	Avoid extreme temperatures. Avoid direct sunlight.
<b>Incompatible materials</b>	Aluminum
<b>Hazardous decomposition products</b>	No information identified. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides, nitrogen oxides and platinum-containing compounds.

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## SECTION 11 - TOXICOLOGICAL INFORMATION

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**Note** The following data describe the active ingredient, carboplatin.

### Information on toxicological effects

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

### Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Carboplatin	LD <sub>50</sub>	Oral	Rat	343 mg/kg
	LD <sub>50</sub>	Intravenous	Rat/Mouse	61/89 mg/kg

**Irritation/Corrosion** Carboplatin can cause eye, skin and/or respiratory tract irritation.

**Sensitization** Dermal and respiratory sensitization reactions have been observed with carboplatin.

**STOT-single exposure** No data available.

**STOT-repeated exposure/Repeat-dose toxicity** In repeat-dose animal toxicity studies, target organs included bone marrow, blood, kidney, liver, the nervous system, reproductive organs and the gastrointestinal tract.

**Reproductive toxicity** Reproductive organ toxicity and effects on sperm (impaired spermatogenesis) were noted in animal studies. Additionally, the addition of carboplatin to semen samples collected from healthy men has produced evidence of sperm membrane damage.

**Developmental toxicity** Carboplatin has been shown to be embryotoxic and teratogenic to the offspring of rats treated during organogenesis.

**Genotoxicity** Carboplatin was positive in a battery of *in vivo* and *in vitro* genotoxicity assays.

**Carcinogenicity** The carcinogenic potential of carboplatin has not been studied in animals, but compounds with similar mechanisms of action and mutagenicity profiles have been reported to be carcinogenic. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard** No data available.

**Human health data** See Section 2 - "Other hazards"

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## SECTION 12 - ECOLOGICAL INFORMATION

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### Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Carboplatin	--	--	--

**Persistence and Degradability** No data identified.

**Bioaccumulative potential** No data identified.

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**SECTION 12 - ECOLOGICAL INFORMATION** ...continued

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<b>Mobility in soil</b>	No data identified.
<b>Results of PBT and vPvB assessment</b>	Not performed.
<b>Other adverse effects</b>	No data identified.
<b>Note</b>	The environmental characteristics of the formulated product have not been fully investigated. Releases to the environment should be avoided.

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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<b>Waste treatment methods</b>	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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**SECTION 14 - TRANSPORT INFORMATION**

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<b>Transport</b>	Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	No special precautions needed.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

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## SECTION 15 - REGULATORY INFORMATION

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<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Yes. Danger. Contains the cytotoxic drug, carboplatin. Causes eye/skin irritation. May cause respiratory tract irritation. May cause allergic skin/respiratory reaction. Harmful if swallowed. May cause myelosuppression, hematological toxicity, gastrointestinal toxicity, nephrotoxicity, nervous system toxicity and reproductive organ toxicity. Genotoxic. Possible cancer hazard - Contains material which may cause cancer.Reproductive/Developmental Hazard - May adversely affect the developing fetus or cause adverse reproductive effects. Birth Defect Hazard - May cause birth defects.
<b>WHMIS classification</b>	Not required. Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
<b>TSCA status</b>	Drugs are exempt from TSCA.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Carboplatin is listed as a developmental toxicant.

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## SECTION 16 - OTHER INFORMATION

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<b>Full text of R phrases and EU Classifications</b>	T - Toxic. R22 - Harmful if swallowed. R36/38 - Irritating to eyes and skin. R42/43 - May cause sensitization by inhalation and skin contact. R40 - Limited evidence of a carcinogenic effect. R48/25 - Toxic: Danger of serious damage to health by prolonged exposure if swallowed. R60 - May impair fertility. R61 - May cause harm to the unborn child. R46 - May cause heritable genetic damage. Repr. Cat. 2 - Toxic for reproduction Category 2. Muta. Cat. 2 - Mutagenic Category 2. Carc. Cat. 3 - Carcinogenic Category 3.
<b>Full text of H phrases, P phrases and GHS classification</b>	ATO4 - Acute Toxicity (Oral) Category 4. EI2 - Eye irritant Category 2. SI2 - Skin irritant Category 2. RS1 - Respiratory Sensitizer Category 1. SS1 - Skin sensitizer Category 1. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. RT1B - Reproductive toxicity Category 1B. GCM1B - Germ Cell Mutagenicity Category 1B. Carc2 - Carcinogenicity Category 2. H302 - Harmful if swallowed. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. H340 - May cause genetic defects. H351 - Suspected of causing cancer. H360FD - May

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Full text of H phrases, P phrases and GHS classification** ...continued  
damage fertility. May damage the unborn child. H372 - Causes damage to bone marrow, hematological system, kidney, reproductive system, gastrointestinal tract and nervous system through prolonged or repeated exposure.

**Sources of data** Information from published literature, vendor SDSs, and internal company data.

**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**Revisions** This is the first version of this SDS.

**Disclaimer** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a potent pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.