

# CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (COSHH) SHEET

## SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### PRODUCT NAME:

Cisplatin Injection BP 1 mg/mL, 10 mL, 25 mL, 50 mL and 100mL

### PRODUCT USE:

Medical Treatment: OTHER ANTINEOPLASTICS

### MANUFACTURER:

Intas Pharmaceuticals Ltd.

Plot No. 457, 458

Village-Matoda,

Bavla Road, Ta. Sanand,

Dist. Ahmedabad-382 210,

Gujarat, India

### MARKETING AUTHORISATION HOLDER:

Accord Healthcare Limited

Sage House

319, Pinner Road

North Harrow

Middlesex, HA1 4HF

United Kingdom

### RECOMMENDED INTERNATIONAL NONPROPRIETARY NAME:

Cisplatin INN

### CHEMICAL NAME:

Cis-diamminedi-chloroplatinum (II)

### CHEMICAL FORMULA:

$[\text{PtCl}_2(\text{NH}_3)_2]$

### CHEMICAL FAMILY:

Heavy metal complex

### HOW SUPPLIED:

Cisplatin Injection is supplied in 10 ml/ 25 ml/ 50 ml/ 100 ml type I amber glass vial containing 10 ml/ 30 ml/ 50 ml / 100 ml concentrate for solution respectively. Vials are closed using grey rubber stopper with an aluminium flip off seal.

- 1 glass vial in one monocarton
- 10 ml vial, containing 10 mg of Cisplatin, 1 mg/ml
- 25 ml vial, containing 25 mg of Cisplatin, 1 mg/ml
- 50 ml vial, containing 50 mg Cisplatin, 1 mg/ml
- 100 ml vial, containing 100 mg Cisplatin, 1 mg/ml

### DATE OF PREPARATION:

October 12, 2009

CISPLATIN INJECTION

## SECTION 2 – HAZARDS IDENTIFICATION

### EMERGENCY OVERVIEW:

Material is a clear, slight yellow liquid. It is a cytotoxic agent and a probable cancer hazard. Highly toxic if injected or swallowed. Eye and skin irritant. May cause damage to the reproductive system, kidneys, blood, hearing and nervous system. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling.



### SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:

This material is intended for injection under the supervision of physicians.

### INHALATION:

Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

### CONTACT WITH SKIN OR EYES:

Contact may cause irritation. Effects may include stinging, watering, redness swelling and damage to the eyes and redness, itching burning and damage to the skin. May cause allergic skin reactions.

### INGESTION:

Ingestion is not an anticipated route of occupational exposure. However, the active ingredient, Cisplatin, is highly toxic if swallowed. Symptoms similar to those identified under injection may occur.

### INJECTION:

Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including decreased blood platelets and white blood cells, nausea, vomiting, diarrhea, anemia, skin rash, tinnitus, hearing loss, electrolyte disturbances, irritation of the respiratory tract and hemolysis may occur. Severe injection overexposure may be fatal. See package insert for other adverse reactions associated with therapeutic doses of this product.

### HEALTH EFFECTS OR RISKS FROM EXPOSURE (AN EXPLANATION IN LAY TERMS):

#### Acute:

- The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as decreased blood platelets and white blood cells, nausea, vomiting, diarrhea, anemia, skin rash, tinnitus, hearing loss, electrolyte disturbances, irritation of the respiratory tract and hemolysis may occur.

#### Cancer:

- Cisplatin is considered probably carcinogenic (see Section 11).

#### Chronic:

- Cisplatin is considered a potential reproductive and developmental toxicant (see Section 11).

**Target Organs:**

- Potential hazard to the kidneys, blood, hearing and nervous system (see Section 11).

**SECTION 3 – COMPOSITION, INFORMATION ON INGREDIENTS**

Chemical Name	CAS #	mg/ml	EXPOSURE LIMIT IN AIR				
			ACGIH		OSHA		Other
			TLV	CEIL	PEL	CEIL	0.4µg/m <sup>3</sup> (*)
Cisplatin (exposure limit for Platinum, soluble salts as Platinum)	41575-94-4	1	0.002 mg/m <sup>3</sup>	NE	0.002 mg/m <sup>3</sup>	NE	0.002 mg/m <sup>3</sup> *
Sodium chloride	7647-14-5	9	NE	NE	NE	NE	NE
Sodium Hydroxide or Hydrochloric Acid 37 % pH adj.	--	-qs	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	Qs to 1 ml	NE	NE	NE	NE	NE

NE - Not Established

C - Ceiling Limit

\*NIOSH REL

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

**SECTION 4 – FIRST AID MEASURES****SKIN EXPOSURE:**

Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

**EYE EXPOSURE:**

Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention.

**INHALATION:**

If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

**INGESTION:**

If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

**NOTE TO PHYSICIANS:**

Cisplatin is a potent cytotoxic antineoplastic drug. It should only be administered under the supervision of physicians experienced in cancer chemotherapy.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians' Desk Reference for additional treatment information.

**SECTION 5 – FIRE FIGHTING MEASURES****FLASH POINT:**

Non-flammable

**AUTOIGNITION TEMPERATURE:**

Not applicable

**FLAMMABLE LIMITS (IN AIR BY VOLUME, %):**

- Lower: Not applicable
- Upper: Not applicable

**FIRE EXTINGUISHING EQUIPMENT:**

Use extinguishing agent suitable for type of surrounding fire.

- Water Spray: OK
- Carbon Dioxide: OK
- Halon: OK
- Foam: OK
- Dry Chemical: OK
- Other: Any "ABC" Class

**UNUSUAL FIRE AND EXPLOSION HAZARDS:**

No unusual fire or explosion hazards are expected.

**EXPLOSION SENSITIVITY TO MECHANICAL IMPACT:**

Not sensitive.

**EXPLOSION SENSITIVITY TO STATIC DISCHARGE:**

Not sensitive.

**SPECIAL FIRE FIGHTING PROCEDURES:**

For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

**NFPA HAZARD CLASS:**

- Health: 2 (Moderate)
- Reactivity: 0 (Least)
- Flammability: 0 (Least)

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

### SPILL AND LEAK RESPONSE:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

## SECTION 7 – HANDLING AND STORAGE

**CISPLATIN IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.**

### WORK AND HYGIENE PRACTICES:

As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes

### STORAGE AND HANDLING PRACTICES:

Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10). Store at room temperature 15-25°C (59-77°F). Protect from light. Do not use discolored solutions.

### PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT:

When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

## SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

### VENTILATION AND ENGINEERING CONTROLS:

Use with adequate ventilation. Follow standard medical product handling procedures.

### EYE PROTECTION:

Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

**HAND PROTECTION:**

Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

**BODY PROTECTION:**

A full body gown which is closed at the front and has long sleeves is recommended.

**PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL:**

Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

Relative Vapor Density (air = 1):	ND
Specific Gravity (water = 1):	ND
Solubility in Water:	Sparingly
Vapor Pressure, mm Hg @ 25°C.	ND
Odor Threshold:	ND
Evaporation Rate (n-BuAc=1):	ND
Melting/Freezing Point:	0°C (32°F)
Boiling Point:	100°C (212°F)
pH	5 - 7

ND = No data

**SECTION 10 – STABILITY AND REACTIVITY**

<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Materials with which Substance is Incompatible</b>	This product is generally compatible with other common materials in a medical facility. Contact with aluminum may lead to the formation of a platinum precipitate.
<b>Hazardous Combustion Products</b>	Oxides of carbon and nitrogen and platinum-containing compounds with possible carcinogenic potential.
<b>Hazardous Polymerization</b>	Will not occur.

**SECTION 11 – TOXICOLOGY INFORMATION****ACGIH BIOLOGICAL EXPOSURE INDICES:**

Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

**SECTION 12 – ECOLOGICAL INFORMATION**

All work practices must be aimed at eliminating environmental contamination.

**ENVIRONMENTAL STABILITY:**

It is anticipated that this compound will decompose into a variety of organic compounds.

**EFFECT OF MATERIALS ON PLANTS OR ANIMALS:**

This product may be harmful to contaminated plant and animal life. See Section 11 (Toxicological Information) for additional information.

**EFFECT OF CHEMICALS ON AQUATIC LIFE:**

This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities.

**SECTION 13 – DISPOSAL CONSIDERATIONS****PREPARING WASTES FOR DISPOSAL:**

This material, if discarded as produced, is not a RCRA “listed” or “characteristic” hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

**U.S. EPA WASTE NUMBER:**

None

**SECTION 14 – TRANSPORTATION INFORMATION**

This material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation.

**PROPER SHIPPING NAME:**

→ Not applicable

**HAZARD CLASS NUMBER AND DESCRIPTION:**

→ Not applicable

**UN IDENTIFICATION NUMBER:**

→ Not applicable

**PACKING GROUP:**

→ Not applicable

**DOT LABEL(S) REQUIRED:**

→ Not applicable

**NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (1996):**

→ Not applicable

**GMARINE POLLUTANT:**

→ No component of

this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

**TRANSPORT CANADA TRANS. OF DANGEROUS GOODS REGULATIONS:**

→ Not applicable

**SECTION 15 – REGULATORY INFORMATION****U.S. REGULATIONS****U.S. SARA REPORTING REQUIREMENTS:**

The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

**U.S. SARA THRESHOLD PLANNING QUANTITY:**

Not applicable

**U.S. TSCA INVENTORY STATUS:**

Cisplatin is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

**CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):**

This product contains a chemical known to the State of California to cause cancer - Cisplatin.

**OTHER U.S. FEDERAL REGULATIONS:**

Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

**CANADIAN DSL/NDL STATUS:**

Cisplatin is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

**ANSI LABELING (BASED ON 129.1, PROVIDED TO SUMMARIZE OCCUPATIONAL EXPOSURE HAZARDS):**

**DANGER!** Cytotoxic Agent. Accidental Injection or Ingestion Can Be Fatal. Highly toxic if injected or swallowed. Eye and skin irritant. May cause damage to the reproductive system, kidneys, blood, hearing and nervous system. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling. Cisplatin should be administered under the supervision of a qualified physician. Avoid accidental injection. Do not eat, drink or smoke when handling Cisplatin. Clean up spills promptly.

**SECTION 16 – OTHER INFORMATION****ISSUE DATE:**

October 12, 2009

**DISCLAIMER:**

The information in this document is believed to be correct as of the date issued. HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE. This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assumes the risk of his use thereof.